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Making Access to a Population of Bodies in the Name of Autonomy

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Abstract

Developments within biotechnology are of a pace and complexity that challenge the predictability at the foundation of legislation, i.e. the possibility for politicians to foresee pitfalls and hazards, and design legislation accordingly. The lack of predictability is not only a challenge for the legislature, but also for the citizen, who is to consent to the new biotech services offered by the health authorities. How can one give informed consent to a measure, the consequences of which is hard to predict? Does the uncertainty and lack of predictability mean that paternalism slipped back in as a 'self-selected' responsiveness to the rhetoric of the health regime? Recently, Denmark has taken another step in the direction of voiding autonomy of actual value by rendering genetic analysis contingent on agreeing that the resulting data may be stored in the recently established National Genome Centre, and reused for research unless the patient opts out.

Keywords

genetics, DNA, informed consent, biotechnology, welfare state, Rose, Foucault, WGS, health law

1 Introduction¹

Interest in genetics and biotechnology has intensified over the last decades. As Nikolas Rose points out, in this century we are preoccupied with controlling, managing, shaping and reshaping the very ability of human life and DNA.² Artificial insemination and the procurement of blood from the umbilical cord are services offered, along with organ transplantation, personal DNA-mapping and physical restructuring, from a new face to gender. The range of techniques, practices and scientific discoveries is challenging our understanding of human life. Meanwhile, legal institutions must contend with understanding rapidly developing biomedical research, materials and possibilities, as well as implementing adequate, timely legislation.³

We will use one of the latest biotechnological advances, Whole Genome Sequencing (hereafter WGS) as a case study.⁴ WGS is the mapping of a person's entire genome in order to,

¹This article is based on an article previously published in Danish, I.H. Asmussen, 'Vil du h re din DNA-sk bnefort lling?: Det informerede samtykke kommer til kort i moderne bioteknologi', *Retf erd* 40(1) (2017) 15-23. The authors are grateful to Professor Mette Hartlev for her helpful comments.

² N. Rose, *The Politics of Life Itself: Biomedicine, Power, and Subjectivity in the Twenty-First Century* (Princeton: Princeton University Press, 2007).

³ S. Jasanoff, *Reframing Rights: Bioconstitutionalism in the Genetic Age* (Cambridge: Massachusetts Institute of Technology, 2011).

⁴ The article is also relevant to other survey methods which belong under the term 'comprehensive mapping of individual genomes', such as Whole Exom Sequencing (WES), complete RNA sequencing, Next Generation Sequencing (NGS) as well as the NGS for the sequencing of DNA/RNA from human tumours.

among other things, uncover the disease susceptibility of that person. WGS is used in hospitals in connection with the treatment of diseases suspected to be genetically related and in research projects, such as the 100.000 Genomes Project in the United Kingdom, which investigates rare diseases.⁵ Yet, many have expressed concern that WGS may create unnecessary uncertainty and concern about the diseases for which one is predisposed. In this context, the requirement to obtain informed consent from the patient has been used as a kind of ethical warrant, namely: 'The patients have agreed to it'. As Hoeyer puts it 'In informed consent procedures, authorities have found a way to document that no abuse has taken place'.⁶

Informed consent implies that the patient must be informed and give consent before a medical treatment or investigation begins, including a WGS. However, as we will elaborate further, the results of a WGS are difficult to comprehend and often very uncertain, just as it is difficult to predict how the results of a WGS will be used in the future. For example, while international bodies have called on states to prohibit genetic discrimination, few jurisdictions have introduced legislation prohibiting employers and insurance companies from accessing genetic data.⁷ Even in jurisdictions that have legislated, this position may change, should WGS become a mainstream form of preventive medicine. The uncertainty and unpredictability of the consequences of a WGS also include the constantly evolving knowledge about what answers a WGS can provide. In other words, how doctors interpret the output of the technology. Ultimately, how can patients consent to something, the scope and importance of which doctors struggle to explain?

At the same time, consent has the consequence that the citizen may be held accountable for accepting these risks. The individualisation of responsibility for health attached to informed consent is here viewed in light of the modern, neoliberal welfare state, where responsibilities that previously belonged to the state are transferred to the citizen.⁸ We will first elaborate on what WGS entails and the specific challenges associated with its increased use. The recent establishment of the Danish National Genome Centre is drawn upon as an example of how WGS is increasingly endorsed as routine prevention by the welfare state.

2 Whole Genome Sequencing (WGS)

WGS means mapping the entire genome of a person for the purpose of analysing risks of developing certain diseases. If, for example, research shows that a proportionally higher number of people with a particular gene mutation will develop breast cancer, the person whose cells contain this gene mutation will be estimated to have a relatively higher risk than others of developing breast cancer. WGS thereby represents a basis for probability calculations. Later research may show that

⁵ Genomics England, 'Introduction to the 100.000 Genomes Project' (2015).

⁶ K. Hoeyer, 'Informed Consent: The Making of a Ubiquitous Rule in Medical Practice', *Organization* 16(2) (2006) 267-288.

⁷ The Convention on Human Rights and Biomedicine prohibits all forms of discrimination on grounds of genetic heritage (Article 11), but is not self-executing. In the US, the Genetic Information Nondiscrimination Act of 2008 (Pub.L. 110-233, 122 Stat. 881, enacted May 21, 2008, GINA), prohibits the use of genetic information in health insurance and employment, but not life or disability insurance. In Denmark, insurance companies and employers are not permitted to receive or request predictive genetic information unless it relates to an existing illness. Insurance Contracts Act, LBK no 1237, 09/11/2015, § 3a and the Health Information Act § 1, paragraph 1 and paragraph 3.

⁸ More in-depth study is possible, for example by following Sharon, who uses Michel de Certeau's theory of creative tactics and strategies in everyday life, thereby opening up a more symbiotic approach to the relationship between autonomy and heteronomy. However, this falls outside the purpose of this article. See, T. Sharon, 'Healthy citizenship beyond autonomy and discipline: Tactical engagements with genetic testing', *Biosocieties* 10(3) (2015) 295-316.

the gene mutation only causes this increased risk in combination with, for example, a second gene mutation or a specific diet. Genes are thus only one factor among several determining that diseases one develops. Other factors may be exercise, education, pollution, food and environment. While there is still only limited knowledge about what these other factors signify for the development of diseases, we know that genes generally play a small role. A genetic study will thus, in most cases, only provide an uncertain picture of whether the person investigated has an elevated risk.⁹ In addition, the dissemination of the results opens a gateway of possibilities for misunderstanding and misinterpretation.¹⁰

Over the years, genetic tests have been utilised in clinical practice,¹¹ and it is becoming more and more common to supplement these tests with a WGS. Increasingly, WGS is used in large-scale research projects. Meanwhile, commercial testing, such as analyses of heritage and disease risk, has exploded.¹² On the internet, anyone can buy an elementary mapping for less than 100 euro.

Personalised medicine - the possibility that treatment and prevention can be tailored to suit the specific DNA composition of the individual - is a major driving force within the mapping of genomes. In recent years, several governments, including welfare states, such as the United Kingdom, Denmark, France and Norway, have embarked on national strategies for personalised medicine.¹³ These initiatives are dependent on the analysis of the population's genetic and health information, meaning more and more individuals will be invited to have their genome sequenced. For instance, in 2015, then United States President Obama introduced his 'Precision Medicine' initiative, declaring:

We're going to ... create a research group of one million volunteers. And just like analyzing our DNA teaches us more about who we are than ever before, analyzing data from one of the largest research populations ever assembled will teach us more about the connections between us than ever before. And this new information will help doctors discover the causes, and one day the cures, of some of the most deadly diseases that we face.¹⁴

The Danish government's vision for personalised medicine is arguably more ambitious (and controversial). In 2017, the government launched its strategy for personalised medicine, including draft legislation establishing a National Genome Centre that will store sequenced genetic and health data from the entire Danish population. To start, 100,000 Danes will be offered sequencing, although the intention is that, in the future, *all* Danes will have their genomes sequenced – a more

⁹*Explanatory Report to the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* (Oviedo, 4.IV.1997), (Explanatory Report), paras. 79 and 80.

¹⁰ In particular, it has created concern and given rise to discussion, when genetic information has been communicated by personnel who are not health professionals, A. Harris, S.E. Kelly and S. Wyatt, 'Counseling Customers: Emerging Roles for Genetic Counselors in the Direct-to-Consumer Genetic Testing Market', *Journal of Genetic Counseling* 22(2) (2013) 277-288.

¹¹ G. De Vries, 'The 'unknown' practice of genetic testing' in: G. De Vries and K. Horstman (eds.), *Genetics from Laboratory to Society* (London: Palgrave Macmillan, 2007).

¹² Harris et al., *supra* note 10.

¹³ See further, Ministry for Health and Elderly, *National Strategy for Personalised Medicine 2017-2020* (Ministry for Health and Elderly: Denmark, 2016), p. 9.

¹⁴ B. Obama, 'Remarks by the President on Precision Medicine', Obama White House Archives, 30 January 2015, <https://obamawhitehouse.archives.gov/the-press-office/2015/01/30/remarks-president-precision-medicine>, retrieved 19 July 2018.

ambitious target than that of President Obama.¹⁵ The proposal provoked controversy in Denmark, with critics arguing that the amendment to the Health Act breaches the right to privacy, while supporters maintain that the Centre is vital for ensuring innovative treatment in the future.¹⁶ Informed consent manifested as a particular point of contention, as discussed further in section 8. Next, the genesis of informed consent as a requirement in treatment and research is introduced.

3 Informed Consent in Clinical and Research Settings

During the second half of the 20th century, informed consent emerged as a fundamental principle of national and international law, transforming the relationship between the medical profession and the individual from one grounded in paternalism to one of patient autonomy.¹⁷ Today, numerous international treaties and declarations contain provisions enshrining informed consent. While informed consent in treatment and research developed in parallel and encompass different legal requirements, they share commonalities.¹⁸ Notably, in both cases, outside forces, specifically judges and legislators – not clinicians – were the drivers.

The philosophical justification for informed consent is the recognition of the individual's right to self-determination. Judges, adjudicating battery claims, played a critical role in clarifying physicians' legal obligations.¹⁹ Informed consent to treatment protects the patient's right to control what is done to her body, even when this goes against medical opinion. The doctrine thereby rejects a paternalistic model of care, where the physician makes clinical decisions based on her assessment of the patient's interests and 'protects' the patient through withholding potentially distressing information.²⁰ Instead, the doctor must provide the patient with adequate information, owing to her fiduciary duties, and with a view to correcting the information imbalance between the doctor and patient.²¹ Treatment is thereby no longer driven by beneficence (i.e. doctor knows best), but by the patient's decisions regarding her own health. At the same time, this can prove demanding, requiring the patient to understand and weigh complex (and sometimes unclear) health information, as in the case of WGS.

Separately, the international community, horrified by systematic violations of research subjects' rights during World War II, drafted hard and soft law protecting informed consent in clinical research,²² starting with the Nuremberg Code.²³ Consent in research settings seeks to ensure

¹⁵ Danske Regioner, *Handlingsplan for Personlig Medicin* (Danske Regioner, 2015) p. 6 (emphasis added).

¹⁶ H. Ullum and A. Beich, 'Genomecenter – ja eller nej', *Ugeskrift for læger* 10/9 (2018) 822-825.

¹⁷ Instances of consent in ancient times have been recorded, see, for example, S. Selek, 'A written consent five centuries ago', *Journal of Medical Ethics* 36(10) (2010) 635-638. However, these lack the elements of informed consent: namely, the obligation of the physician to inform and obtain the patient's consent.

¹⁸ See, for example, P. Nelson-Marten and B.A. Rich, 'A historical perspective of informed consent in clinical practice and research', *Seminars in Oncology Nursing* 15(2) (1999) 81-88. For a detailed discussion of the history of informed consent see, R.R. Faden, T.L. Beauchamp, *A History and Theory of Informed Consent* (Oxford University Press, 1986) pp. 26, 56-58.

¹⁹ Particularly, common law countries, like the USA and UK. See, *Schloendorff v. Society of New York Hospital*. Vol. 211 N.Y. 125, 105 N.E. 921914.

²⁰ P.M. Murray, 'The History of Informed Consent', *The Iowa Orthopaedic Journal* 10 (1990) 104-109, p. 104; M.D. Ginsberg, 'Beyond Canterbury: Can Medicine and Law Agree about Informed Consent? And Does It Matter?' *The Journal of Law, Medicine & Ethics* 45(1) (2017) 106-111.

²¹ Faden and Beauchamp, *supra* note 18, p. 26.

²² UNESCO, *Report of the International Bioethics Committee of UNESCO (IBC) on Consent* (UNESCO, 2008) p. 15.

²³ *The Nuremberg Code 1947* (Trials of War Criminals before the Nuremberg Military Tribunals) under Control Council Law No. 10", Vol. 2, pp. 181-182. (Washington, D.C.: U.S. Government Printing Office, 1949). Subsequent non-

that the individual is not at the mercy of science and society – but adequately informed and thereby willingly agrees to the potential risks associated with taking part in research.

Binding post-World War II human rights treaties also enshrine informed consent in treatment and research, namely, the International Covenant on Civil and Political Rights²⁴ and the European Convention on Human Rights.²⁵ These treaties aim to protect human dignity and human rights, and to avoid future violations of individual rights by nation states. Notably, in 1997, the first convention dedicated to providing minimum standards in biomedical law entered into force: the Council of Europe Convention on Human Rights and Biomedicine.²⁶ The Biomedicine Convention's origin lies in a desire on the part of the Council of Europe to protect human dignity in light of biotechnological advances.

Several non-binding declarations apply informed consent to the field of genetics, notably the Universal Declaration on the Human Genome and Human Rights, The International Declaration on Human Genetic Data, and the Universal Declaration on Bioethics and Human Rights.²⁷ The Council of Europe has adopted an Additional Protocol to the Biomedicine Convention on Genetic Testing for Health Purposes (it does not apply to research settings).²⁸ However, while the Biomedicine Convention has been widely ratified, the Additional Protocol does not enjoy the same widespread support or influence, with a mere five states parties.²⁹

The Biomedicine Convention, which applies to both clinical medicine and research, reiterates the rule that medical interventions can only be carried out with 'free and informed consent', following 'appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks'.³⁰ While a weakness of the Biomedicine Convention is that no Court is tasked with monitoring compliance, the European Court on Human Rights draws on the Biomedicine Convention in determining whether a state party has breached the European Convention on Human Rights. For instance, the Court has found that sterilisation without full, free and informed consent runs contrary to the principles of autonomy and dignity, and thereby violates rights to family life and freedom from inhuman and degrading treatment under the European

binding declarations include: World Medical Association, 'Declaration Of Helsinki – Ethical Principles For Medical Research Involving Human Subjects', adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 (last amended 2013). The Council for International Organizations of Medical Sciences (CIOMS) and World Health Organisation 'International Ethical Guidelines for Biomedical Research Involving Human Subjects' (CIOMS, 2002).

²⁴ Article 7 ICCPR prohibits medical or scientific experimentation without 'free consent', while protecting rights to privacy and family life, and freedom from inhuman treatment. UN General Assembly, International Covenant on Civil and Political Rights, 16 December 1966, United Nations, Treaty Series, vol. 999, p. 171. See, for example, Human Rights Committee, *Alyne da Silva Pimentel v. Brazil* (Communication No. 17/2008).

²⁵ Council of Europe, 'European Convention for the Protection of Human Rights and Fundamental Freedoms', as amended by Protocols Nos. 11 and 14, 4 November 1950, ETS 5 (see, Article 8). Further, Article 3 of the European Charter on Fundamental Rights (ECFR) guarantees the right to respect bodily integrity, including the right to the free and informed consent of the person (Charter of Fundamental Rights of the European Union 2012/C 326/02).

²⁶ Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (1997) ETS No. 164

²⁷ UNESCO, Universal Declaration on the Human Genome and Human Rights, 11 November 1997; International Declaration on Human Genetic Data, 16 October 2003; Universal Declaration on Bioethics and Human Rights, 19 October 2005.

²⁸ Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes (2008) CETS No.203.

²⁹ Council of Europe, *Details of Treaty No. 203* <https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/203>.

³⁰ The explanatory report notes that consent is 'an already well-established rule'. Explanatory report, *supra* note 9.

Convention on Human Rights.³¹ The Court has also held that the desire to conceive a child unaffected by a genetic disease of which the applicants are carriers and to use technology to achieve this desire, is protected under Article 8 ECHR.³²

The above declarations and treaties attest to sustained international endorsement of informed consent as a fundamental principle of international bio law and human rights. Fundamentally, informed consent is underpinned by respect for the individual's dignity and self-determination. Furthermore, the principle has been included in newer declarations relating to the human genome, thus underscoring its continued application to genetic analysis, including WGS. However, as discussed in the next section, informed consent has not fully transformed the power dynamics of the patient-doctor relationship. Perhaps part of the answer lies in the genesis of informed consent: a doctrine imposed on doctors by lawyers and politicians.

4 Self-determination and Power

Informed choice is seen as the basis for the patient's autonomous choice, and most research in genetics and genetic counselling assumes that 'true non-directiveness is a realistic and desirable goal'.³³ This is fully in line with the legal assumption that underlies informed consent: giving the citizen the opportunity for self-determination.

Based on their observational study of genetic counselling, Koch and Svendsen question the assumption of autonomous choice.³⁴ They take as their starting point a Foucault-inspired concept of power. Foucault describes power as productive, i.e. that power not only oppresses and confines subjectivity and autonomy, but also that power is exercised through certain contextual rationales that govern autonomous choice in a particular direction.³⁵ Koch and Svendsen thereby describe how genetic counsellors have specific normative rationales that they, in various ways, express and support in the person being advised.

For instance, the information that a patient gains through sequencing may be relevant to family members. If the genetic knowledge is disseminated to relations, the latter will also have the ability to prevent the increased risk that they as family members may bear.³⁶ But when the genetic counsellor only has access to the patient, the possibility of briefing family members goes through the patient. The patient's willingness to involve the family is supported by a moral norm of

³¹ See, *V.C. v. Slovakia* App. No. 18968/07, European Court of Human Rights, 16 June 2009; *IG & Others v. Slovakia* App. no. 15966/04, European Court of Human Rights, 13 November 2012. See further: W. Buelens, C. Herijgers and S. Illegems, 'The View of the European Court of Human Rights on Competent Patients' Right of Informed Consent. Research in the Light of Articles 3 and 8 of the European Convention on Human Rights', *European Journal of Health Law* 23 (2016) 481-509.

³² *Costa and Pavan v. Italy* App. No. 54270/10, European Court of Human Rights, 28 August 2012, para 57.

³³ L. Koch and M.N. Svendsen, 'Providing solutions – defining problems: the imperative of disease prevention in genetic counselling', *Social Science & Medicine* 60(4) (2005) 823-32, p. 824 (referencing a series of studies).

³⁴ *Ibid.*

³⁵ M. Foucault, 'Technologies of the Self', in: L.H. Martin, H. Gutman and P.H. Hutton(eds.), *Technologies of the Self: A Seminar with Michel Foucault* (University of Massachusetts Press, 1988).

³⁶ This generates renewed attention for biological relatedness, when disease becomes a part of family culture: 'This thing in our family' (S.M. Cox, W. McKellin, 'There is this thing in our family: predictive testing and the construction of risk of Huntington Disease', *Sociology of Health & Illness* 21(5) (1999) 622-646. Leeming describes a historical change in the conceptualization of recurrent disease in the family from being 'biological relatedness' to 'related to chromosomes and genes' (W. Leeming, 'Tracing the shifting sands of 'medical genetics': What's in a name?', *Studies in History and Philosophy of Science Part C* 41(1) (2010) 50-60, p. 51).

‘familial responsibility’.³⁷ This is, for example, expressed in the way that when the patient is willing to follow up with family members, this is accepted without any further comment, whereas a lack of willingness is challenged, referencing a rationale of accountability. This means that the counsellor introduces a premise that the patient qua her knowledge about the increased risk holds a familial and social responsibility. Thus, a ‘yes’ and a ‘no’ answer to the question of informing family do not hold the same moral status. The patient-doctor relationship, in other words, contains an imperative of ‘yes’ to mapping of genes for disease prevention. The point is not that the governance is in opposition to autonomous choice, but rather that specific rationales are prevalent and become powerful *through* voluntary consent.³⁸ The responsibility of dealing with and preventing the possible effects of the genetic risk information is thus changed from being an individual question to assuming the form of a family obligation.³⁹

In this manner, relations’ fates become intertwined, yet, under law, they primarily remain separate beings with individual rights to autonomy and privacy. Interestingly, Danish law includes an exception to the norm of patient consent. Under the Health Act, information about a patient’s health can be shared without their consent, where necessary to protect the interests of others, such as a family member.⁴⁰ Indeed, the preparatory works of the law mention the situation where a patient or family member has a serious hereditary disease, as a basis for bypassing patient consent.⁴¹ Therefore, the law reinforces the decision to inform as an ethical ‘choice’ for the patient. If the doctor views the patient’s decision not to inform her family as immoral, she may even bypass patient consent.

The issue of relatives is also an example of how the neoliberal technology of governance works. Specific rationales and truth logics are reproduced and created not only through formalised practices, like the doctor’s conversation with the patient, but also from family member to family member. If we simplistically assume that a patient consents to a WGS on the basis of biological self-image, which in combination with an accountability rationale leads to the patient contacting another family member, the patient will in one form or another reproduce these forms of logics to the family member she contacts. In that way, specific rationales and understandings are ‘democratised’ and disseminated directly from citizen to citizen too:⁴² A motion that continuously takes place in an infinite and complex bricolage of reproduction and translation through relations, networks, symbols and stories.⁴³ This complex negotiation of normative narratives is also described in health policy.⁴⁴

³⁷ Koch and Svendsen, *supra* note 33; A. Petersen, ‘The new genetics and the politics of public health’, *Critical Public Health* 8(1) (1998) 59-71; D. Lupton, *The Imperative of Health: Public Health and the Regulated Body* (London: Sage, 1995); R. Kenen, ‘The human genome project: Creator of the potentially sick, potentially vulnerable and potentially stigmatized?’, in I. Robinson (ed.), *Life and Death under High Technology Medicine* (Manchester: Manchester University Press, 1994).

³⁸ *Ibid.*, p. 828.

³⁹ Kenen, *supra* note 37; Lupton, *supra* note 37; Petersen, *supra* note 37; M. Arribas-Ayllon, S. Sarangi and A. Clarke, ‘Managing self-responsibility through second-oriented blame: Family accounts of genetic testing’, *Social Science and Medicine* 66 (7) (2008) 1521-32.

⁴⁰ Sundhedsloven (Health Act), § 43(2)2.

⁴¹ Lovforslagets bemærkninger (Comments to Genome Centre Bill), section 4.2.4.

⁴² M. Valverde, *Diseases of the Will – Alcohol and the Dilemmas of Freedom* (Cambridge: Cambridge University Press, 1998); N. Mik-Meyer, *Dømt til personlig udvikling* (Københavns Universitet, Sociologisk Institut, PhD thesis, Copenhagen, 2004); I.H. Asmussen, *Fra Retsstat til Omsorgsstat – om syndsforladelse i konfliktråd* (Copenhagen: DJØFs forlag, 2014).

⁴³ Asmussen, *ibid.*

⁴⁴ See, for example, L. Koch and M.N. Svendsen, ‘Genetics and prevention: a policy in the making’, *New Genetics and Society* 25(1) (2006) 51-68.

The basic premise of the patient's 'free and informed consent' as defined under national and international law must thus be seen in light of the rationales that characterise the context in which the consent is given. This applies not only to the actual meeting between doctor and patient, but also the institutional context (typically a hospital), and the more general social discourse, the importance of which we elaborate on below.

5 The Genetic Human Being

Nikolas Rose describes how citizens in the Western world have increasingly begun to understand themselves as biological, medical and genetic beings. In the language of biomedicine, we are 'somatic' beings who experience, articulate, judge and act in relation to our own bodies, often expressed as 'genetic responsibility' or 'genetic prudence'.⁴⁵ For example, the body is used as an expression of the degree of life fitness. Today, a clean bill of health is no longer a sign that you have a fit and healthy body.⁴⁶ Because, are you eating healthily enough? Are you exercising adequately? Moreover, is your everyday life too stressful or is your sleeping pattern in disarray? Regardless of a lack of symptoms, the body is viewed as a ticking time bomb of disease risks, and a number of government screening programmes contribute to viewing it as such.⁴⁷ Thus, we see people as potentially ill or pre-ill rather than healthy people, even when they do not have active symptoms. However, you can maximize your vital capital, as Leeming puts it,⁴⁸ for example, by having your DNA mapped and following advice on eating and lifestyle habits.⁴⁹ In practice, this means that being diagnosed with a serious illness, previously considered 'bad luck', is today regarded as something for which you are individually responsible.⁵⁰ Through the mapping of genetic risk for various diseases, a moral responsibility is placed on the individual, for example, when a woman takes a position on whether she wants to have a breast removed as prevention against breast cancer.

The concept of biopower indicates that the world has not, 'itself' designated what constitutes a 'healthy' or a 'sick' body, but that specific descriptions and classifications mean that certain bodily expressions are defined as 'sick', for example by defining what constitutes a 'gene mutation'.⁵¹ WGS is an example of such a risk assessment. Hacking describes how estimates, like probability calculations and statistics, have in the course of the nineteenth century challenged a deterministic view on risk, as the possibility of 'taming' the risk by means of preventative measures was thus made accessible.⁵²

Further, the shift towards an individualisation of responsibility for risk through sophisticated genetic testing, DNA screening and WGS can be seen in the light of what is described as the neoliberal welfare state. It is the term used for a welfare state increasingly emphasising efficiency, responsibility, freedom, empowerment, self-help and similar values for

⁴⁵ Rose, *supra* note 2.

⁴⁶N. Mik-Meyer and K. Villadsen, *Power and Welfare – Understanding Citizens' Encounters with State Welfare* (New York: Routledge, 2013) p. 113.

⁴⁷S. Scott, L. Prior, F. Wood and J. Gray, 'Repositioning the patient: the implications of being "at risk"', *Social Science & Medicine* 60(8) (2005) 1869-1879.

⁴⁸ Leeming, *supra* note 36.

⁴⁹ A. Harvey, 'Genetic risks and healthy choices: creating citizen-consumers of genetic services through empowerment and facilitation', 32(3) *Sociology of Health & Illness* (2010) 365.

⁵⁰ A. Rouvroy, *Human Genes and Neoliberal Governance. A Foucauldian Critique* (Abingdon: Routledge-Cavendish, 2009) p. 9.

⁵¹For example, I. Hacking, 'Memory Science, Memory Politics', in P. Antze, D. Premack and J.A. Premack (eds.), *Tense Past. Cultural Essays in Trauma and memory* (New York: Routledge, 1996).

⁵²I. Hacking, *The Taming of Chance* (Cambridge: Cambridge University Press, 1990).

the citizen, thus helping to shape the citizen as someone who can and wants to solve their own problems.⁵³ For example, by highlighting 'citizens who take responsibility for their own lives and health', the state contributes to creating citizens who take care of their own lives and their own risks.⁵⁴ It is not a matter of well thought out manipulations arising from individuals, but rather that societal development contributes to shaping that perceptions of truth become dominant. As the welfare state came under financial pressure, we started talking about 'withdrawal of the welfare state' and 'privatisation'. These agendas, however, have been reworded into 'self-management', 'empowerment' and 'self-determination'. The difference is that the former terms relate to the wishes of the state, while the latter address citizens' interests, which by their very nature has won rhetorical ground in the political agenda.

WGS can thereby be seen as an example of this neoliberal form of governance where the citizen is held responsible for her own health. Through the results of the sequencing, the citizen is made aware of the specific risks her body holds, and in that way also given the opportunity to act responsibly by preventing these risks through medicine, physical intervention and modification of diet, exercise and sleep habits. However, this assumes that the individual is able to understand and accurately interpret the results of sequencing, as discussed in the next section.

6 Master of One's Own Body?

Free, informed consent requires that the patient can understand the consequences of giving consent.⁵⁵ The patient must have the capacity to consent, meaning the patient's ability to make decisions must not be impaired, due to, for example, illness, disability or age.⁵⁶ If the patient is to be able to foresee the consequences of giving consent, it follows that whoever is 'prepping' the patient to give consent, normally the health care professional, *can* in fact predict those consequences. The question thereby becomes whether the professionals can genuinely foresee the consequences of a WGS.

Previously, consent was given to carry out examinations to explain specific, present symptoms. The patient's consent has thus been given to uncover *current* diseases. In the case of a WGS, consent is given to uncover *potential* disease scenarios, which may, or may not, occur. This is even expressed with a stipulated percentage calculation. The uncertainty alone of being in a 'risk situation' will affect the self-image and life quality of most people. A study shows, for example, that citizens who are considered to be at risk of developing cancer were likely to see themselves as in a borderline position: as neither sick nor healthy. As a result, they consistently sought out health authorities for health checks.⁵⁷

Further, despite the expectation of self-determination, WGS may challenge the patient's autonomy. International bodies, including the UNESCO International Bioethics Committee, have pointed to several ethical dilemmas.⁵⁸ One central dilemma questions the breadth of the 'right not to know', where a WGS shows that the patient has a fatal disease unconnected with

⁵³Mik-Meyer and Villadsen, *supra* note 46.

⁵⁴K. Villadsen, 'Forord til den danske udgave', in M. Dean (ed.), *Governmentality – magt og styring i det moderne samfund* (Frederiksberg: Forlaget Sociologi, 2006), p. 10.

⁵⁵ Explanatory Report, *supra* note 9, paras 35-37.

⁵⁶ Convention on Human Rights and Biomedicine, *supra* note 26, Article 6.3.

⁵⁷ Scott et al., *supra* note 47.

⁵⁸ International Bioethics Committee, *Report of the IBC on the Principle of Non-discrimination and Non-stigmatization* SHS/EGC/IBC-20/13/2 REV.3 Paris, 6 March 2014, Section 5.1.2, online at: <http://unesdoc.unesco.org/images/0022/002211/221196E.pdf>.

the purpose of the sequencing. Generally, patients can opt out of receiving findings that go beyond the original purpose of the treatment or research – so-called incidental or secondary findings. Yet, informing the patient may be time-sensitive, for instance, if the potential for successful treatment will become more remote the more time that passes before the patient is treated. In this situation, two significant interests collide: respect for the patient’s right not to know and the doctor’s obligation to save lives. While Wolf and others argue that doctors hold a legal and ethical duty to inform patients of incidental findings,⁵⁹ informing the patient against her wishes undermines self-determination, which is supposed to be upheld by the informed consent paradigm.⁶⁰

Less comprehensive sequencing offered by private companies can also bring unforeseen consequences beyond the original purpose. A recent example is the identification of the ‘Golden Gate killer’, forty years after a string of unsolved murders and rapes in California. According to news media, police identified the suspect after uploading DNA gathered from a crime scene to an open-sourced genealogy website. The website then matched the suspect’s DNA with that of a relative who had uploaded his data for genealogy purposes.⁶¹

Were users aware that law enforcement could or would use genealogy websites to track murder suspects? The website used claims that it was neither contacted by police nor cooperated.⁶² While commercial websites enter into legal agreements with their users, which would require a warrant to assist police, not for profit, open access sites go unregulated. For example, under Danish law, DNA gathered under the DNA registration law must be deleted after ten years, whereas DNA voluntarily uploaded will remain online presumably until the owner deletes it (that may be much longer than ten years). Such online databases thereby potentially allow police to bypass laws regulating official DNA databases. Furthermore, the individual’s decision to upload her personal data can have unintended, unpredictable consequences for relations.

7 The Autonomous Self-determining Citizen

The shift - from the paternalistic professional as an omniscient expert opposite a passive citizen, to the 'coach' or 'facilitator' of an active citizen, whose knowledge and resources are at the heart of the citizens’ decisions - is sometimes described as a ‘paradigm shift’ and denotes the development that has taken place in the relationship between the state and citizen through recent decades. This applies, for example, to the relationship between teachers and students in schools, doctors and patients in hospitals, and caseworkers and clients in the probationary system and employment services.⁶³ In a legal context this development, as described above, signifies that consideration for the autonomy of the individual has become a priority. The paradigm shift is usually described as positive and welcome, that we do not contest. However, we believe that it is essential to recognise that the notion of an autonomous choice cannot stand alone, but must be read in light of the institutional and societal context. The ‘autonomous’ choice cannot be reduced to something that

⁵⁹ S.M. Wolf et al, ‘Managing incidental findings in human subjects research: analysis and recommendations’, *The Journal of law, medicine & ethics* 36(2) (2008) 219-248.

⁶⁰ G.J. Annas and S. Elias, ‘23andMe and the FDA’, *New England Journal of Medicine* 370(11) (2014) 985-988.

⁶¹ Sarah Zhang, ‘How a Genealogy Website Led to the Alleged Golden State Killer’, *The Atlantic*, 27 April 2018, online at: <https://www.theatlantic.com/science/archive/2018/04/golden-state-killer-east-area-rapist-dna-genealogy/559070>, retrieved 19 July 2018.

⁶² Lizzie Johnson and Trisha Thadani, Arrest of suspected Golden State Killer through genealogy opens ‘Pandora’s box’, *San Francisco Chronicle*, 29 April 2018, online at: <https://www.sfchronicle.com/crime/article/Arrest-of-suspected-Golden-State-Killer-through-12872258.php>, retrieved 19 July 2018..

⁶³ On the paradigm shift within the legal system, see, Asmussen, *supra* note 42.

comes ‘from the inside’, but is a choice made by a person whose statements are created by the relationships, contexts and discourses, she has been and continues to be surrounded by. So, who or what is it actually that gives consent to a WGS? It seems somewhat misleading to maintain a notion that the decision merely stems from one person, namely the one who is articulating the answer. This pattern is intensified where the welfare state actively promotes WGS through prioritising personalised medicine, as discussed in the coming section.

8 The Danish National Genome Centre

Seen in this light, how should we understand the latest controversial initiative in Denmark, where genetic analysis is only possible if the patient agrees to her data being stored in the National Genome Centre?

Despite the international norm of informed consent, the establishment of the Danish National Genome Centre requires that a patient who undergoes any form of genetic analysis, simultaneously agrees to her data to be stored in the Centre.⁶⁴ Further, this data can be reused for research, unless the patient opts out. Already under the Danish Health Act, biological samples gathered during treatment (through informed consent) can be stored and reused for research without the patients’ renewed consent.⁶⁵ The new legislation extends the opt-out to not only biological samples, but also to *any* information stored in the National Genome Centre derived from biological material.⁶⁶ The Health Act now stipulates that, when gathering informed consent for genetic analysis, the doctor must inform the patient of the right to opt-out.⁶⁷ However, even where the patient opts out, her samples will be stored in the National Genome Centre unless she specifically requests her samples be destroyed or returned to her.

While the Danish government describes the legislation as in line with the principle of informed consent,⁶⁸ it is problematic for two reasons. First, the patient does not have a choice whether her data is transferred to the National Genome Centre. An ill patient must therefore forego treatment if she does not want her data to be stored in the Centre. Second, the patient must take action to avoid her data being used for future research, otherwise her consent is presumed. The government has thereby created an expectation of both consent and involvement in the Genome Centre, meaning that consent is even more clearly normalised and moralised. The ‘morality’ of the Genome Centre is underscored by the surrounding policy documents that emphasise the necessity of widespread sequencing for the future of the (arguably already beleaguered) Danish welfare state

⁶⁴ Ministry of Health, Forslag til lov om ændring af sundhedsloven (L 146, 2018).

⁶⁵ Health Act (LBK nr 191 af 28/02/2018), § 29.

⁶⁶ Law amending the Health Act (L 146), § 29(1).

⁶⁷ Ibid, § 29a. This was not provided for in the first draft of the bill (Forslag til lov om ændring af sundhedsloven (organiseringen i Sundheds- og Ældreministeriet, oprettelse af Nationalt Genom Center m.v. (18 september 2017)). The adopted legislation now gives the Minister of Health the power to adopt rules on how the patient should be informed (§ 29a(2)). Further, the Minister plans to introduce rules that require consent to genome sequencing to be given in writing (SUU spørgsmål nr. 16 (L 146 – forslag til lov om ændring af sundhedsloven (Organiseringen i Sundheds- og Ældreministeriet, oprettelse af Nationalt Genom Center m.v.)).)

⁶⁸ For instance, when answering questions of members of parliament on the bill establishing the National Genome Centre, the Minister for Health replied: Det er min klare overbevisning, at der er med lovforslaget sikres et fyldestgørende samtykke. (it is my clear assessment that the bill secures a fullest consent). (Health and Elderly Committee 2017-18 L 146, answer to question no 16).

and the health of the Danish population.⁶⁹ Ultimately, neither the patient nor the state knows how the patient's data will be used in the future but it is the patient who must accept the risks: she cannot access treatment, unless she accepts that her data is kept in the Genome Centre.

By reusing the same term, 'consent', the actual gap between asking and not asking seems smaller. The term 'consent' draws from a reference to an enforcement that stems from peoples' wishes. In other words, though the initiative is a limitation on the room for 'no' to genetic analysis, the naming of the initiative puts focus on the remaining possibility of autonomy. Nevertheless, in reality it is a step back to paternalism as the state presumes, and thereby governs, the citizens in a much more direct way than described in regards to an *actual* informed consent alias: Are you going to do the opposite of the norm of the majority? It thereby calls for consistent, strong and well-informed attitudes to take another position than 'expected'.

The distribution of roles and power is certainly more evident and straight-forward here compared to our portrayal of the international norm of informed consent, but that is of course not to say that it to any extent legitimises the Danish construction.

9 Conclusion

Within pragmatic welfare policy and legal regulation, it is often overlooked that self-determination can only be exercised within a certain normative framework. Autonomy continues to be governed and controlled by a specific institutional practice, disseminated through the professional. The practice of self-determination is thus accompanied by instructing, motivating and follow-up conversations that guide and regulate the conversation in a certain direction. At the same time, the citizen is articulated as the ultimate drafter of agreements and decisions, and as a result, the citizen feels to a greater extent bound by these. The citizen thereby bears the main responsibility, should these agreements prove inadequate or fail. This is particularly relevant within modern biotechnology, where the ability to relate to the choices we face as a citizen, as well as the ability to foresee their consequences, is under pressure. The more unclear and hypothetical the choice facing the citizen, the more the foundations of the informed consent crumble, leaving it an empty structure that perhaps first and foremost serves the paradoxical purpose of signalling that the citizens 'themselves' decide. In this light, the Danish Genome Centre might not be as controversial as it looks. However, it certainly exemplifies the complexity and need for thorough development of improved legal and ethical tools and guidelines that respect individuals in data sharing within health and life sciences law.⁷⁰

⁶⁹ The Ministry's policy document is entitled 'Personalised Medicine for the benefit of the patients', *supra* note 13. Page 5 discusses how a large proportion of the medicine used in the health system does not work and harms patients. 'This is both a hardship for the individual patient and a financial challenge for society'.

⁷⁰ P. Borry et al., 'The challenges of the expanded availability of genomic information: an agenda-setting paper', *Journal of Community Genetics* 9(2)(2018)103-116, p.113.