Bioethics after Brexit: Brexit an opportunity to rationalize bioethics governance in the United Kingdom

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Abstract: This paper considers the shape of bioethics governance in Europe, noting the interplay between the institutions and laws of the Union and those of the Council of Europe. It reviews the structures of UK bioethics governance and identifies weaknesses that Brexit provides an opportunity to address. It notes the ambiguous relationship of UK bioethicists with European institutions and discusses the importance of soft power. It explores what the UK should do to maintain its influence. It advocates, first, improved co-ordination of governance organisations within the UK. Second, a more strategic approach to 'soft power' and UK involvement with international organisations, both within the European region and more widely. Finally, it proposes that the UK become a signatory to the Oviedo Convention in order to consolidate its connections with European values. These steps are suggested as mitigation for the loss of influence that Brexit might otherwise bring.

Introduction

In her letter to President Tusk notifying the Union that the UK was triggering Article 50, the Prime Minister wrote of

> … shared European values. Perhaps now more than ever, the world needs the liberal, democratic values of Europe. We want to play our part to ensure that Europe remains strong and prosperous and able to lead in the world, projecting its values and defending itself from security threats.[1]

This paper considers what form that commitment might take in the governance of bioethical issues. By bioethics governance, I mean the practices through which societies mediate controversies, reach policy conclusions, and regulate behaviour to implement and incentivise adherence to such policies.[2] These practices have emerged despite continuing controversy about what constitutes a bioethical issue. Over time, the original use of the term in relation to what is more now commonly considered environmental ethics,[3] and also the sense of continuity between medical, business and military ethics,[4] has been supplanted by a dominant usage in relation to health technologies.[5]

The Council of Europe set out to draw up a convention on 'bioethics', but described it formally as concerning 'Human Rights and 'Biomedicine' and was driven (according to the preamble) by concern about the risks of 'misuse of biology and medicine'. This instrument, known as the Oviedo Convention, is discussed further below. The main point for this stage in the argument is that it proceeds from the assumption that the defining normative structure

derives from human rights rather than a separate discipline of bioethics. Thus, it was not, and is not, necessary to provide a precise definition but merely to indicate the scope of the enterprise that is being governed.[6] The term bioethics is used deliberately loosely in global governance to encompass, in the terms of the Universal Declaration on Bioethics and Human Rights, 'ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions'.[7] Following the usage of the drafters of the Universal Declaration, this paper will refer generically to 'bioethics issues' because that term 'facilitates reference to the questions relevant within the scope of the declaration',[8] avoids the distractions of debates about the best meaning of the term bioethics in academic discourse,[9] and enables the focus of the paper to remain on governance matters.

The practice of bioethics is a complex ecology, but it has taken some shape in the form of governance institutions. Article 19 of the Universal Declaration sets out an expectation that states establish committees to address research approvals, clinical ethics, develop policy, and foster public debate. Marcus Duwell has offered a tripartite classification of institutional functions. First, there are institutions concerned with ethical reflection (including, but not limited to national ethics committees). Second, there are bodies providing assurance that ethical standards are met, including 'gatekeeping' committees, such as research ethics committees without whose permission studies cannot proceed (and in the UK statutory licensing bodies such as the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority). Third, decision support for those grappling with challenging ethical problems to provide a sounding board or source of expert advice.[10] The United Nations Educational, Scientific and Cultural Organisation (UNESCO) engages in capacity building,[11] an exercise which has demonstrated the diversity of roles that national bioethics

committees play,[12] as well as establishing international standards.[13] There is this no simple blueprint for bioethics governance but it is a well- established area of activity.

The UK has disparate arrangements in place for these governance activities, and it will be argued that Brexit provides an opportunity and also an incentive to review their coherence. However, it would be too strong a claim that reform is required by Brexit as in many ways, the practice of bioethics in the UK has maintained a position that is on the 'edge' of Europe. In terms of substantive concerns, UK bioethics sits somewhere between European value-based bioethics (promoting autonomy, dignity, integrity, and vulnerability)[14] and North American principlism (organised around autonomy, beneficence, non-maleficence and justice).[15] While it shares the European commitment to solidarity in contrast to the individualism of the dominant US model, as Schotsmans has shown, UK bioethics remains resistant to the conceptualisation of human dignity that he characterises as 'one of the most foundational European concepts' in favour of a principle of autonomy that draws strongly from the version developed in North American principlism.[16] This idea of autonomy does not, however, trump the enduring importance in the UK of trustworthy institutions.[17] Nor has it displaced the historical pattern in which those disciplines and institutions that in the USA found themselves in conflict (medicine, law, theology),[18] have acted collaboratively in Britain.[19] So, while some British bioethicists think they have escaped 'American capture',[20] other commentators think that Britain is aligned with the USA against the European approach.[21]

In terms of the institutionalisation of bioethics governance, it can also be said that the relationship with European practices in ambiguous. The UK has established regulatory structures that have adapted to EU expectations but they were not driven by them. Thus, the

Human Fertilisation and Embryology Acts of 1990 and 2008 emerged from domestic reflection on the acceptability of advances in human reproduction and only subsequently incorporated European law on quality and safety. A similar point can be made about European human rights law; that it influences but does not determine the course of UK bioethics. The UK Supreme Court has established that the fact that bioethical issues are within the margin of appreciation from the perspective of the European Court of Human Rights does not preclude the domestic courts employing human rights arguments drawn from the Convention in order to explore the authority of Parliament on bioethics matters.[22] This suggests that litigation may be increasing in importance as a mechanism for progressing bioethical governance,[23] something that has largely been denied and hidden until recently.[24] The UK has thus retained a distinct and essentially pragmatic approach. While the Nuffield Council on Bioethics is widely respected in the international bioethics community, the European pattern of overarching national ethics committees has been resisted in favour of a combination of non-governmental bodies and sector-specific regulators.

This distributed regulatory approach could be considered a strength in its development of sector expertise, but it also exposes weaknesses that arise from the lack of a coherent foundation. The Government has stressed how important science is to the post-Brexit economy, and draws attention to the role of regulation in its hospitability. The Life Sciences Industrial Strategy pitches the UK's 'offer' to the wider world partly in terms of 'a more science friendly regulatory regime than that which is applied in other European countries'.[25] Science Minister, Sam Gyimah has proclaimed 'Britain's new unique selling point (USP): the go-to place for science and innovation' and explained that, amongst other features, the UK has the advantage of having

> 'a long track record of setting world-class regulations, standards and ethical norms. If we can be take the lead on setting these standards, regulation and ethics, we have the chance to take a global lead - and to realise our vision of being a global platform.'[26]

When it comes to explaining what the UK stands for in the area of bioethics, however, the ad hoc nature of its bioethics governance makes it hard to show how it intends to position itself as a world leader. If the promotion of science is not to constitute a 'race to the bottom' in terms of bioethics, such that friendliness to science means lowering ethical standards, then the robustness of regulation needs to be demonstrated.

Thus, while Brexit does not formally require change in the area of bioethics governance, it does give rise to a need for greater clarity. It provides an opportunity to revisit its institutional architecture in order to promote better governance. This paper proposes that steps are taken to make the UK's solidarity with the European tradition of bioethics more explicit, that a more strategic approach is taken to ensure the continuation of UK influence on the institutions that shape bioethical norms globally, and that there should be a more co-ordinated approach to the governance of bioethics within the UK itself.

Bioethics and Europe

Europe has a long history of activity in bioethics governance. France was the first European state to establish as national bioethics committee in 1983, but this has now become the norm. European institutions have played a significant role in shaping and facilitating such initiatives.[27] For the European Union, the Commission established its first advisory group in 1991, currently constituted as the European Group on Ethics in Science and New Technologies.[28] Brexit does not necessarily threaten UK influence here as members are

appointed on a personal basis and can come from outside the EU. However, the basis for the work is the treaties of the European Union.[29] Brexit thus threatens to divorce UK Bioethics from this activity even if individual bioethicists might remain involved. The European Commission also supports a European National Ethics Committee Forum,[30] which brings together the Committees from the EU member states, with others sometimes attending. There is also a broader 'International Dialogue on Bioethics' that goes beyond the EU.[31] Brexit will shift UK involvement from that of a European member to an international partner. Finally, it should be noted that the Council of Europe has also established machinery for bioethical reflection, with continuing interest from the Parliamentary Assembly, particularly through the standing Committee on Bioethics (DH-BIO).[32] Brexit will not affect *membership* of this body as it does not entail withdrawal from the Council of Europe, only the European Union. However, an express task of DH-BIO is to 'co-operate with the European Union and relevant intergovernmental bodies, in particular with a view to promoting consistency between the normative texts.' [33]

In terms of such normative instruments, the continent has developed its own codification of bioethics principles in 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* (the Oviedo Convention) and its associated protocols. While not all states are signatories of this Convention (Germany and the United Kingdom are not) it provides a benchmark around which European bioethics can be explored and is the only internationally legally binding bioethics instrument. The European Court of Human Rights has become increasingly engaged with bioethics. It has referred to the Oviedo Convention or the work of the Steering Committee on Bioethics of the Council of Europe in at least twenty one cases.[34] Article 8 of the European Convention on Human Rights has proved very

significant in this jurisprudence, including high profile UK cases that have helped establish its relevance and scope in relation to bioethics issues, such as *Pretty*,[35] *Glass*,[36] *Nicklinson*[37] and *Gard*.[38] In contrast, attempts to use Article 2 to cement either pro-life or pro-autonomy positions have largely been evaded by the ECtHR judges.[39]

At the time of writing, the Court of Justice of the European Communities has made only limited reference to the Oviedo Convention, partly because the European Union is not a signatory. It has acknowledged the Convention's requirement of consent before removal of tissue in the context of medicine, but concluded that this did not limit the patentability of biotechnological inventions.[40] The Oviedo Convention's ban on germ-line interventions was noted in discussions of the patentability of stem cell lines, but was not found to be material to the decision.[41] The exclusion of the use of the human body and its parts for financial gain under the Convention has also been considered, but it was held that this did not preclude the application of taxation rules to the transportation of human organs and samples.[42]

European Union health law is concerned primarily with the smooth running of the internal market not more substantive questions of bioethics,[43] which are generally left to member states and subject to human rights law not that of the EU. The authors of the leading academic text conclude that EU health law is concerned with consumerism, human rights, the internal market (regulating competition, solidarity, and risk) not independently with bioethics. Thus, there is no convergence in European internal market law on issues such as abortion and euthanasia, as one would expect if bioethics was a core interest. Of course, EU legislation embodies ethical principles, but it is driven by more social solidarity than bioethics.[44] The dominant framing in the EU regulation of technologies is neither ethics, nor rights, but markets.[45]

There is, here, an established European tradition of social bioethics in which the UK has played a significant role. The guardian is the Council of Europe rather than the European Union, reducing the risks that Brexit separates the UK from this tradition. A number of individual UK bioethicists are well regarded by colleagues and regularly called upon to contribute to debates. However, the express intention of travel, as indicated by the tasks allocation to DH-BIO, is to convergence on European bioethics principles, albeit that this does not necessarily imply harmonisation.

The UK's de facto national ethics committee,[46] the Nuffield Council on Bioethics, is generally regarded as one of the most experienced and effective examples. Amy Guttman, then chair of the US Presidential Commission for the Study of Bioethical Issues has commented on the desirability of learining from international bodies 'particularly, from the most successful ones, of which Nuffield Council is certainly up there.'[47] its work is usually considered as a model in international reflections.[48] However, a brief review of the way in which bioethics governance is organised in the UK will demonstrate how precarious this position is and suggests that proactive steps would be advisable to avoid risking a loss of influence and authority after Brexit.

Bioethics Governance in the UK

The British infrastructure for bioethics governance is fundamentally an ad hoc set of arrangements that are more the result of accidents of history than design. It has grown organically out of 'club regulation,'[49] and has rarely been systematically reviewed. The picture is complex. The UNESCO Global Ethics Observatory database identifies 41 'ethics

institutions' in the UK, but is incomplete.[50] It does not, for example, include the statutory regulators that exist in relation to particular areas of bioethics; the Human Fertilisation and Embryology Authority, the Human Tissue Authority, and (for England) the Health Research Authority. These bodies play a key role in the assurance function that the institutions of Bioethics Governance are expected to play, but also contribute to the establishment of norms and sometimes take direct responsibility for specific bioethics decisions (such as licensing the use of mitochondrial replacement therapies on a case specific basis.[51]

The situation is both confused and confusing. Some UK bodies have legal status and powers (such as those just mentioned, which have a statutory basis). However, there are many examples of bodies that have been established informally by government; such as the Human Genetics Commission, the short-lived Emerging Science and Bioethics Advisory Committee, the Committee on the Ethics of Pandemic Influenza, and the Organ Donation Taskforce. Some are Non-Government Organisations that assert themselves as significant, with varying degrees of recognition and respect, such as the Nuffield Council on Bioethics, The Scottish Council on Bioethics, The Anscombe Centre, and the Falconer Commission on Assisted Dying. Health professional regulators deal with some bioethics issues. Thus, the General Medical Council has issued important guidance on consent, confidentiality, end of life care, each of which has been in some way considered by and endorsed by the courts.[52] Various bodies that are not specifically set up to examine bioethical matters, nevertheless issue reports into specific bioethical questions; these include the Royal Society,[53] Academy of Medical Sciences,[54] Wellcome Trust,[55] Medical Research Council,[56] and even the Royal Academy of Engineering.[57]

There is no apparent consistent pattern, nor rationality, to the way in which bodies are matched with the tasks. Some important areas of bioethics are overseen by administrative appointments, such as the National Data Guardian. Others are left to civil society. There is some democratic oversight, and important inquiries have been held by Parliamentary select committees; topics include reproductive technologies,[58] abortion,[59] genomic medicine,[60] gene editing,[61] genetically modified insects,[62] clinical trials,[63] mitochondrial donation,[64] physician assisted suicide.[65] In general, however, these remain discrete inquiries and bioethical matters are generally regarded in the UK Parliament as matters of individual conscience.[66] It is thus rare for UK Governments to take the lead on issues such as abortion or euthanasia.

The Timeliness of a Fundamental Review

The last systematic government review of bioethics governance machinery was undertaken in 1999, leading to the establishment of the Human Genetics Commission (since disbanded).[67] It identified a series of main concerns that remain relevant to the current position; that the complexity of arrangements made it difficult for the public to understand, that the architecture did not properly reflect the broader ethical and environmental questions nor the views of potential stakeholders, and finally that they were insufficiently forward looking. The review also established some useful questions and implicit criteria via its consultation exercise. First, the importance of mapping gaps and weaknesses in the regulatory frameworks. Second, the need for enhanced and more consistent transparency; including more public consultations and open meetings. Third, the need for clarity on what is expected in terms of ethics contributions; with views including both the reliance on expert-ethicists and also on representativeness. Fourth, stakeholder views needed to be incorporated; although

there was no consensus on how and some concerns about building delay or creating mechanisms that lacked 'tightly defined objectives' (para 33). Fifth, flexibility was required and there was perceived to be a need for 'greater foresight and greater capacity to change quickly' (para 34). Finally, it was vital to ensure public confidence and 'several respondents saw… the establishment of higher-level bodies as a key step in improving public confidence' (para 35).

Subsequent formal reviews of official bodies have been driven by either the more general desire to rationalize,[68] or an ideological commitment to abolish non-government organisations.[69] There are regular performance assessments of individual government arm's length bodies in the form of triennial reviews. These consider whether they are still needed, but do not look at the wider context of bioethics governance. The future of the HFEA and HTA as independent bodies, and the possible merger of the two has been closely examined and proposed on two separate occasions.[70] In both cases the focus was on regulatory overlap and efficiency rather than their effectiveness as means for facilitating public deliberation on challenging bioethical issues. Indeed, their role in supporting bioethics policy was ignored in the consultations.

Commentators have long made a case for a more systematic review, especially in the form of a national ethics committee,[71] They have presented their arguments to Parliamentary Select Committees when they have considered individual bodies or legislative areas.[72] Thus, the Select Committee on Science and Technology reviewed a range of suggestions when examining the operation of the Human Fertilisation and Embryology Act 1990.[73] The Committee noted both the variety of options and also concerns, such as those from Professor

Margaret Brazier, that such a body might be little more than a talking shop, hugely expensive, and extremely politicised.

These arguments were aired in the debates around the Human Fertilisation and Embryology Act 2008. Those discussions probably constitute the most comprehensive publicly available recent consideration of what Baroness Helena Kennedy, former chair of the Human Genetics Commission, described as 'the ecology of the advice given to the Government on ethics,' suggesting that 'while the ground is rather divided in this country, it is covered.' [74] Given the abolition of the HGC since that debate, she might now have a different view. A wide range of views was raised. Concern was expressed about the lack of statutory authority for existing bodies, [75] although it was also suggested that it would be hard for a new body to establish the public trust and confidence that had been achieved by the Nuffield Council and that formal authority was not the key issue. [76] Some supported the use of ad hoc committees because the wide range of the field precluded a single body of 6 to 8 members being able to fulfil the task.[77] This was the view expressed on the part of the Government by Baroness Royall, while recognising the challenges: [78]

> The current system means that there is a collective responsibility for bioethical debate, which ensures that ethical discussion is embedded in decisions across all committees. This distributed system of bioethical advice works well. It remains our view that a national human bioethics commission would not bring sufficient benefits in comparison. Indeed, it could lead to ethical issues being marginalised and ignored by committees that are responsible for guidance or policy on any number of aspects of medicine or the life sciences.

A further problem, relating to Parliamentary sovereignty, was identified when an amendment was debated in the House of Commons Public Bill Committee in June 2008. This proposed the establishment of a Parliamentary Human Fertilisation and Embryology Committee, to comprise fifteen MPs and fifteen members of the House of Lords.[79] Robert Key MP set out what he saw as the key principle of Parliamentary sovereignty in the following terms and argued that 'Both Houses of Parliament are, de facto, the national bioethics committee of this country. We should be jealous of that. It would not be possible to create another body, independent of Parliament, that would have anything like the authority that we have.[80] Not all Parliamentarians saw Parliamentary sovereignty as incompatible with a national ethics committee. The Bishop of St Albans did not regard such a public body as 'outsourcing' ethics, but as an institution at national level to 'assist the ethical thinking that everyone in our country should do.[81] Lord Brennan suggested a national bioethics commission could be used to promote a 'culture of democracy' in which bioethical reflection would no longer be limited to 'regulators with ethical committees, an unaccountable private body [Nuffield] and the Government'.[82] On 28 January 2008, Baroness Williams of Crosby had moved, but did not press to a vote, an amendment at the Report stage of the Bill that would have created National Human Bioethics Commission. [83] She saw complementary roles for legislators and a national commission, noting that the gaps between Parliamentary discussions were too great to accommodate the speed of change.

Going further, Baroness Williams specifically linked the need for a national bioethics committee with the opportunities to influence international thinking and raised concern about the lack of standing in European discussions, long before Brexit. [84] In summarising her observations on the internationalisation of bioethics, Baroness Williams pointed out that

> We are moving on to a time when it is not national legislation but European and to some extent international legislation that will determine the limits and constraints that are placed on bioethics and not least on the area of human fertilisation and embryology. This is exactly the area in which, as many of our leading scientists know, the pressures are on to weaken the principles laid down by the HFEA and others—pressures that will grow, not decrease. A body such as a bioethics commission or, I agree, a parliamentary Joint Committee, would be able to bring to the Government's attention the position that it takes on the Council of Ministers of the European Union or, more widely, on international treaty and other organisations. We are on the cusp of moving away from a purely national basis and do not have the proper machinery to deal with that. [85]

The general case for reviewing the UK's institutions for bioethics governance based on fragmentation is thus enhanced by greater exposure that Brexit brings to this internationalisation when the UK will lose the benefit of its influence on the regional voice.

To this we should add two other specific concerns whose impact is likely to be increased as a consequence of Brexit. First, the need to reconsider the nature of the democratisation of bioethics in a country that has had a taste of rule by plebiscite. A number of jurisdictions have seen direct democracy being deployed to determine issues through votes rather than committee deliberation. These include assisted dying in Oregon,[86] stem cell research in California,[87] and abortion in the Republic of Ireland.[88] Consideration should be given to whether this is a tradition that might be attractive in the UK. Second, the constitutional transition that Brexit necessarily brings, in which the UK courts take on a stronger role,[89] something they were already asserting in the area of health care ethics.[90] In the next section,

the shape of the challenge is explored, setting the scene for some proposals for navigating the post-Brexit bioethics landscape.

Shaping the Case for Change

A contemporary comprehensive review of the bioethics landscape in the UK would quickly identify issues of overlap and areas where responsibility is unclear. The details would be different, but the general picture would be essentially the same as was found in the 1999 Review. There is considerable complexity. There is no obvious coherent principle or ethical framework underpinning the system. Accountability is varied, limited, and inconsistent. Consequently, the legitimacy of bioethics positions is often obscure. If the UK plans to present a strong case to be a world leader in responsible scientific innovation once it leaves the EU, for whom this is already a claimed strength, then it needs to bring together its strengths into a more coherent 'offer'.

A few examples can quickly illustrate these points, beginning with complexity. The UK is rightly proud of its introduction of the world's first legislative framework for the use of mitochondrial replacement therapies.[91] This avoids the precipice effect of having to classify techniques as either licit or illicit, without the ability to control purposes or uses. It also counter-acts the 'slippery slope' risk by retaining a case by case oversight by the licensing authority. However, the history of the legislation indicates the complexity of the processes and lack of overall oversight.[92] The final decision-maker was Parliament, but the responsibility for deliberating on the bioethical issues was shared between the Human Fertilisation and Embryology Authority and the Nuffield Council on Bioethics, both of whom

held public consultations (of different types). Safety matters were reviewed under the auspices of the HFEA by an expert group established for the purpose. Draft regulations were consulted upon by the Department of Health. Two Parliamentary debates were called by backbenchers. A special meeting of the House of Commons Science and Technology Committee heard oral evidence on a single day. The net result of these activities seemed reasonably comprehensive, but it could hardly be described as a systematic approach and there was no obvious co-ordination, except perhaps through the strategic vision of the Wellcome Trust (arguably the poacher turning gamekeeper).[93]

The continuing problem of gaps is illustrated by the limitation of the Nuffield Council of Bioethics, which usually sits at international bioethics meetings in the UK chair, to 'ethical questions raised by recent developments in biological and medical research that concern, or are likely to concern, the public interest'.[94] This has precluded discussion of long-standing bioethical challenges such as abortion and euthanasia and also health service rationing,[95] issues that are staples for most national ethics committees. Duncan Wilson has shown how this limitation of scope originated from a demarcation of roles to ensure the newly created Council on Bioethics did not tread on the toes of established institutions dealing with research or clinical ethics, essentially self-regulating.[96] However, the legitimacy of this separation looks suspect in the contemporary context. When the Nuffield Council was established in 1991, it might have been acceptable to leave research ethics in the hands of researchers at the Medical Research Council and clinical ethics in those of doctors at the BMA. It would now be expected that there was a more independent responsibility. The remit of the Health Research Authority is to take into account the ethical standards set elsewhere, not to create them: 'A reference to research that is ethical is a reference to research that conforms to generally accepted ethical standards.'[97] There is a gap in the structures; no one is accountbale

for developing those generally accepted standards. Similarly, there is a legal process for research ethics committees to be legally recognised by the Health Research Authority under the Care Act 2014. However, there remains no requirement for clinical ethics committees to be established in NHS hospitals, despite Article 19 of the UNESCO Declaration on Bioethics (2015) referring to the expectation of 'independent, multidisciplinary and pluralist ethics committees... to … provide advice on ethical issues in clinical settings' and long-standing interest in their value.[98] Those clinical ethics committees that exist are supported by an informal network, based within Warwick Medical School.[99] The governance framework is thus far from comprehensive.

There are other challenges of legitimacy too. The reliance on a non-government body to play the role of a national ethics committee may be consistent with traditional British political pragmatism, but it is problematic when judged in relation to democratic accountability. There are many different ways to integrate bioethics into constitutional government. National Ethics Committees can be part of the executive, constituted to provide advice to the Government (as with most of the recent US national Bioethics Commissions, although some were established by Congress).[100] They can be established within the legislative process in order to ensure parliaments are properly informed of bioethical issues when they arise for consideration. The French Comite Consultatif National d'Ethique currently has this function.[101] In other systems, bioethics deliberation may be established as a representative form of democracy (as in Belgium, where people from the main communities need to be appointed to the national Advisory Committee on Bioethics).[102] The political authority of bodies in each of these approaches can be explained in terms of constitutional law. In the UK, however the position of the Nuffield Council is based on tacit acceptance and the absence of a formally recognised national ethics committee. [103] Its reputation has been established over time,[104] by its virtues

and practices, [105] but these provide only limited democratic legitimacy. [106] Post-Brexit, the need for constitutional recognition is likely to become more important as the UK seeks to establish that it conforms to international expectations in relation to bioethics. The informality of bioethics oversight, consequent apparent lack of compliance with the expectations of the UNESCO Declaration and its failure to endorse the Oviedo convention may undermine the UK's claim to be a strong regulator of ethically problematic scientific advance.

The constitutional authority over bioethical issues is currently in a state of flux. The UK judiciary are testing the demarcation between issues of human rights, with which bioethics governance structures must comply and matters of judgments that fall to Parliament or the institutions that it creates or tacitly recognises. We have moved a great distance from the view expressed by the House of Lords in the Pretty case that Article 8 ECHR rights were not engaged by limitations on assisted suicide, a view that was premised on bioethics issues being outside of the scope of human rights law because they were more appropriate for democratic deliberation.[107] The European Court of Human Rights took a different view, and held that Article 8 was engaged, but that the limitations were justified by the need to protect the rights and freedoms of others under Article 8(2).[108] Thus, bioethical issues that engage human rights are suspect to judicial supervision, albeit with a significant margin of appreciation.[109]

The demarcation of responsibilities between judiciary, executive and legislature is an important aspect of the constitutional legitimacy of a more explicit governance framework for bioethics issues. In the *Nicklinson* case, the majority of the Supreme Court asserted the right to judge the proportionality of legislative interference with autonomy of those who are

terminally ill.[110] The analysis in *Nicklinson* also suggests that the buffer that has been created in the jurisprudence of the European Court of Human Rights, under the concept of the margin of appreciation, does not apply to the domestic context. Consequently, the assessment of proportionality is asserted to lie with the courts rather than Parliament, applying the tests from the *Aguilar Quila* case.[111] Some recent case law suggests that the judiciary may be wary of pushing the logic of *Nicklinson* too far and the Court of Appeal in *Conway* has reiterated a fairly traditional account of why judges should generally defer to Parliament on matters of 'moral value-judgment' as it is 'the conscience of the nation'.[112] However, the Supreme Court was clear that abortion law in Northern Ireland was incompatible with the Convention, even though it held that the NI Human Rights Commission lacked standing to bring the case placed before it.[113] The need for clarification on the proper scope of democratic deliberation in bioethics is apparent.

The challenge of explaining who has legitimate authority in UK bioethics deliberations is exacerbated by the longstanding resistance to principle in this area of law, something that has contributed to the ambiguities discussed earlier over how 'European' UK approaches have been. This resistance to formalising bioethics can be seen in the courts persistent use of professional standards to facilitate an arms-length approach to oversight.[114] The UK has no fundamental law on bioethics. It has not signed the Oviedo Convention. Its institutions tend to avoid seeking consistency through the articulation and application of principles in favour of a case by case approach. There are some exceptions, such as the Human Genetics Commission's discussion of genetic solidarity and altruism in *Inside Information*, which were then used as a reference point for its future work.[115] More common, however, is the approach of the Nuffield Council on Bioethics, which has avoided a principle-based approach in favour

of a procedural sense of legitimacy based on the inclusiveness of its listening processes, and the rigorous quality of the tests of rationality it applies to the arguments.[116] It seeks, through open calls to evidence, the publication of working papers, and consultative processes, to ensure that no voices are excluded but that they are engaged with through a form of public reason.[117] It has articulated an approach based on the quality of public discourse.[118] The long-standing British approach, exemplified by the Warnock Committee's proposal of the 14 day limit on embryo research, has tended to assume that public policy should be driven by acceptability as much as principle.[119]

On this approach, public bioethics proceeds as much by jurisdictional demarcation than resolution. I have argued elsewhere, that the prohibition on embryo research after the emergence of the primitive streak (deemed to appear not later than the end of the fourteenth day) is better understood as a jurisdictional device aimed to ensure that any change was reserved to Parliament than as a statement about the moral status of the biological entity.[120] This points again to the importance of understanding the constitutional structure of British bioethics governance and the basis of its claims to legitimacy.

The case for undertaking a review of the institutions of UK bioethics governance is thus based on a number of strands that have been explored in this section. First, the need to simplify the complexity of the ecology of oversight that has evolved rather than been designed. Second, the importance of plugging gaps to ensure that the system is comprehensive. Third, to clarify and resolve the constitutional issues that will demonstrate the legitimacy of decision-making. A review should also result in more streamlined procedures and provide substance to the claim that the UK can be a world leader in regulation

and ethics that the Minister made in July 2018. In that sense, it would assist the UK in setting out its stall for promoting responsible scientific innovation post-Brexit

The need for review must be put in perspective, however. Despite the issues just explored, the reputation of UK in the international bioethics community is currently very high; the concern is not to establish it but to retain it. In particular, whether Brexit might diminish it. The Nuffield Council on Bioethics plays a leading role in the international activities of national bioethics committees (even though it has no official status), with the Director frequently invited to be part of organising committees for the WHO Global Summit of National Bioethics Committees and of the European NEC Form. The UK has a number of leading bioethics centres and, largely thanks to the Wellcome Trust, there is significant investment in bioethics research. The UK hosts two of the leading journals in the area, *Bioethics* and the *Journal of Medical Ethics*. The question is how to maintain this reputation. Brexit may be marginal to this matter, but it has raised questions about the UK's commitment to continuing engagement to regional institutions that it would be advisable to address.

Next Steps

In summary, the challenge of Brexit to bioethics lies in establishing a more coherent 'brand' for the currently disparate governance institutions. We need to do this in order to demonstrate that the UK is a safe and attractive place to carry out responsible science even though we have distanced ourselves from the European project to this effect.[121] We also need to ensure that we maintain our presence in what Pete Mills, Assistant Director of the Nuffield Council of Bioethics has described as the 'debating chambers' in which global bioethics is pursued

and from which we may become 'distanced' if we do not take proactive steps.[122] To achieve this we should address three challenges; those of co-ordination, influence, and principle.

First, we need to reshape our ad hoc, distributed, network of bioethics bodies into a co-ordinated network. It would be possible to introduce a new national bioethics commission, or a standing Parliamentary Committee, as discussed above. However, this would fail to build on the reputations of our current bioethics organisations. A more successful model could be built from the experience of the Professional Standards Authority,[123] which was introduced (initially as the Council for the Regulation of Health Care Professionals) to oversee the work of the separate regulators for professional groups (e.g. medicine, nursing and midwifery, dentists, pharmacists etc) following the Bristol Royal Infirmary Inquiry.[124] Under the NHS Reform and Health Care Professions Act 2002, the new council was charged with promoting good practice, formulating principles relating to good professional self-regulation and promoting co-operation.[125]

Rather than supplanting established regulators, it sought to harness their expertise and encourage a levelling up of performance. Something similar was suggested to the 1999 review of bioethics advisory machinery: that 'better co-ordination could be achieved through the establishment of a standing body comprising the Chairs of existing committees'.[126] There was also a call for 'an over-arching ethics committee (perhaps comprising representatives of all the key advisory/regulatory committees)'.[127] The creation of a Council of Bioethics Advisory Bodies would enable the UK to speak with a single voice when necessary, but without compromising the different functions of the existing institutions. Devolution will, no doubt, provide some significant challenges, as bioethics is an area where there are important variations. However, it will be hard for the UK to explain why its bioethics is well-governed

if it cannot co-ordinate oversight. If it cannot explain this, then its reputation for progressive but regulated science will be at risk.

Linked with this, is the importance of a strategic approach to 'soft power' in bioethics. Pete Mills raised concerns that membership of key groups at European level, such as the NEC Forum and European Group on Ethics in Science and New Technologies, might be at risk (although at present both are open to non-EU members). [128] The UK does not currently have a member on the UNESCO International Bioethics Committee, but perhaps needs to seek to secure a place if it is to maintain influence. The last UK member of the IBC was Professor Sheila Maclean, whose term ended with the 2012-3 session. Brexit will mean loss of influence at the International Council for Harmonisation, which sets guidelines for pharmaceutical development, and which is dominated by the three key regulated markets of Europe, Japan and the USA. It is a non-profit association, but its decisions are crucial for successful drug development which is now a global enterprise and in which the UK will be concerned not to lose ground.[129] After Brexit, the UK will not necessarily have a place at the table. Similar issues arise in relation to the work of the World Health Organisation. The UK does not host a WHO Collaborating Centre for Bioethics. A strategic approach to securing influence may prove essential if we want UK bioethics to thrive after Brexit.

Finally, there is the issue of the UK's resistance to principle. It might be that the judges will develop through the Human Rights Act an elaboration of bioethics that will serve to underpin the UK's approach. It might also be the case that bringing together the bioethics bodies in the manner that has been suggested will lead to the articulation of common principles. However, the most symbolic act that the UK could take to show that it was part of the international bioethics community would be to sign the Oviedo Convention. This is not necessarily

straightforward. The Convention is showing its age; some of the terminology is difficult to interpret in the light of current science, and the subtleties of the genealogy of articles has not always been kept in mind.[130] Following the 20th Anniversary Conference in 2017, [131] there is to be a 'Strategic Action Plan aimed at defining the main axes and objectives of the work of DH-BIO in the next few years, where appropriate in cooperation with other committee and/or intergovernmental organisations, to address key human rights challenges raised by developments in the biomedical field.'[132] It would be an opportune time for the UK to show its commitment to the European tradition of bioethics by signing the Convention and for it to play a full part it the promised exploration of its implications. That would show that, despite Brexit, we have not rejected participation in the global common purpose in bioethics and that we remain committed to the liberal democratic values of Europe; exactly as Prime Minister May stated in her letter of 29 March 2017, triggering Article 50.

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