wellcome

A blueprint for dynamic oversight

How the UK can take a global lead in emerging science and technologies

Contents

Published in March 2019

Written by Joseph Clift

For further information, contact the Wellcome policy team: policy@wellcome.ac.uk

Summary

Emerging science and technologies have the potential to improve our lives in many ways. AI is predicted to lift UK GDP by over 10% by 2030, with UK households on average seeing an extra £1,800-£2,300 a year.[1] Genome editing could reduce the risk of fatal disease, or significantly increase plant yields for farmers. The quantum technologies industry is estimated at being worth £1 billion to the UK in the future.[2] But these technologies are not without risks. Effective regulatory oversight is needed to ensure these technologies reach their full potential, with the public's trust, both quickly and safely.

By taking an ambitious approach, and by forging stronger links with other countries, the UK can become a global leader in the oversight of emerging technologies. This will create substantial rewards here – more investment into the UK, a stronger environment for science, and faster access to innovations that transform people's lives – but also around the world.

The UK's approach to oversight needs to shift from being inconsistent and sometimes sluggish, to become dynamic. Now is a unique moment for reform as the UK reflects on its regulatory choices as it leaves the EU. **The UK Government should seize this opportunity by setting out its vision and a package of reforms to make the UK the world-leader in the oversight of emerging science and technologies.**

Dynamic oversight can be delivered by reforms underpinned by the following principles:

Inclusive. Public groups need to be involved from an early stage to improve the quality of oversight while making it more relevant and trustworthy. **The Government should support regulators to involve public groups from an early stage and to maintain engagement as innovation and its oversight is developed**.

Anticipatory. Identifying risks and opportunities early makes it easier to develop a suitable approach to oversight. Emerging technology often develops quickly and oversight must develop with it. **UK regulators must be equipped by government to anticipate and monitor emerging science and technologies to develop and iterate an appropriate, proportionate approach.**

Innovative. Testing experimental oversight approaches provides government and regulators with evidence of real-world impacts to make oversight better. Achieving this needs good collaboration between regulators, industry, academia and public groups. The UK is beginning to support innovative approaches, but **the Government needs to create new incentives for the testing of new oversight approaches**.

Proportionate. Oversight should foster the potential benefits of emerging science and technologies at the same time as protecting against harms, by being proportionate to predicted risk. The UK should keep up its strong track-record in delivering proportionate oversight.

These changes will only be delivered effectively if there is clear leadership and accountability for oversight. This requires the Government to be flexible and decisive in responding to regulatory gaps.

Achieving this change would help to consolidate the UK's leadership in regulation for the responsible development of new science and technologies to benefit society. However, at a time when Brexit is reshaping the UK's geopolitical relationships, it is important for the UK not to strike out alone. Instead the UK should take a lead in shaping regulation internationally and will need to work harder than ever to maintain its influence abroad. **The Government must support regulatory diplomacy to ensure that the approaches the UK pioneers on oversight are shared globally.**

[1] PwC (2017). The economic impact of artificial intelligence on the UK economy.
[2] UK National Quantum Technologies Programme (2015). A roadmap for quantum technologies in the UK.

Introduction

Emerging science and technologies improve our lives in many ways, but they also present possible risks. For example, CRISPR genome-editing technology has begun transforming agriculture, biotechnology and medical research, but not without ethical concerns.[3] Data-driven technologies such as AI are rapidly developing in manufacturing, energy and health, and driverless vehicles are beginning to be commercially available,[4] both raising issues such as 'what happens when algorithms go wrong?'. New innovations are being developed at a fast rate. Recent examples, such as the drone disruption at Gatwick airport and the misuse of personal data by Cambridge Analytica, highlight the complex challenge of using new technology in society.

Oversight – including law and informal approaches – is used to manage the risks of emerging technology and guides their development (see Box 1).

Box 1: Managing risks of innovation through oversight

Regulatory oversight aims to control how something is done. For a new area of technology, oversight can set the conditions for development, focus research efforts, reduce the risk of harm to people and the environment, ensure ethical requirements are met, and help to create a new industry.[5]

In this report, the term 'oversight' means *regulatory oversight*, covering the full range of governance tools for controlling the development and use of emerging science and technology.

Oversight includes 'hard law' – legally-binding requirements and responsibilities set by governments in the form of formal legislation, regulation and treaties[6] – and informal tools such as industry self-regulatory standards, guidelines, codes of conduct, norms and forums for transnational dialogue.[7]

Law and informal approaches often interact – for example, standards may be developed to support compliance with a law, or may inform how law is developed.

The regulatory environment for emerging science and technologies is being considered by the UK Government, which recently set up a Ministerial Working Group to consider how this could be improved.[8] This report draws on analyses of recent and past examples of regulatory oversight for emerging science and technologies, the available literature on oversight in this area, and responses invited from other individuals and organisations[9,10] to identify principles and priorities for a new UK approach to developing oversight. We're grateful to all those who generously shared their time and views, but the recommendations here are Wellcome's alone.

[3] Adli M (2018). The CRISPR tool kit for genome editing and beyond. Nat Commun. 2018 May 15;9(1):1911. doi: 10.1038/s41467-018-04252-2.
[4] https://www.independent.co.uk/life-style/gadgets-and-tech/news/waymo-self-driving-taxi-service-google-alphabet-uber-robotaxi-launch-us-a8669466.html
[5] OECD (1996). Regulatory reform and innovation. OECD: Paris.
[6] Gonçalves ME, Gameiro M (2015). Hard Law, Soft Law and Self-regulation: Seeking Better Governance for Science and Technology in the EU.
[7] Marchant GE, Allenby B (2017). Soft law: New tools for governing emerging technologies. Bulletin of the Atomic Scientists, 73:2, 108-114.
[8] www.gov.uk/government/news/business-secretary-hosts-first-cross-government-working-group-on-future-regulation
[9] Gunashekar S, Parks S et al (2019). Oversight of emerging science and technology: Learning from past and present efforts around the world. RAND Europe.
[10] Chubb J, Montana J, Stilgoe J, Stirling A, Wilsdon J (2019). A review of recent evidence on the governance of emerging science and technology. UCL Consultants.

A vision for dynamic oversight

The UK is ranked fourth in the Global Innovation Index[11] and is also considered the fourth most promising market for innovation, disruption and technology.[12] London is the third most attractive city in the world for tech start-ups, the highest rated in Europe.[13]

This strength in innovation stems from a unique set of capabilities. The UK has a tightly-clustered, cutting-edge discovery science base, with world leading universities[14] and a strong industry R&D presence. The NHS – the world's largest universal health system – is a testing ground for innovations in the life sciences, such as cell and gene therapies.

The UK also has a good track record in developing oversight that promotes innovation while protecting consumers, the public and environment. But more can be done to capitalise on these assets to support the transformative areas of innovation that will define future decades, and to meet the aims of the Industrial Strategy and 2.4% R&D investment goal.

Reform of the UK's regulatory approach could bring substantial rewards:

- **Economic benefits, as the UK attracts inward investment**. Innovative oversight such as regulatory sandboxes (see Box 4) have helped maintain the UK's attractiveness within the global FinTech market – with over $16 billion in total fintech investment in 2018, the UK leads the rest of Europe.[15] Conversely, innovation will head elsewhere if the conditions aren't right: graphene was first isolated in the UK, but China, the US and South Korea now lead a graphene market that is set to reach $1.6bn by 2025.[16]
- **Scientific benefits, as the UK is seen as an attractive location to develop cutting-edge science and bring it through into practice**. For example, regulation on human embryos contributes to the UK as a world-leader in the study of how humans develop. Good oversight has also been shown to help entry to market for new products.[17]
- **Social benefits**, **as people in the UK gain faster access to transformative innovations**. In 2015, the UK became the first country in the world to pass law to allow mitochondrial donation. Regulatory certainty helped this innovative technique to develop, giving families affected by mitochondrial disease the chance of having healthy children (see Box 2).

The UK's withdrawal from the EU creates immediate choices about the UK's future regulatory approach. To ensure access to market and research collaboration in the EU, continued alignment will be important; alternatively, the UK could seek to align with a different jurisdiction through trade negotiations.[18,19]

Even if the UK continues to participate in the EU single market after Brexit, many emerging technologies fall outside EU competence, leaving the UK free to act. Whatever the future relationship between the UK and the EU, therefore, the UK has an opportunity to seize in developing its own approach.

The UK must redefine its approach to the oversight of emerging science and technology: moving from being inconsistent and sometimes sluggish, to become dynamic. This approach should be based on

[11] Cornell University, INSEAD, WIPO (2018). The Global Innovation Index 2018: Energizing the World with Innovation.
[12] Startup Genome (2018). Global Startup Ecosystem Report 2018.
[13] KPMG (2018). The Changing Landscape of Disruptive Technologies: Tech hubs forging new paths to outpace the competition.
[14] Times Higher Education (2019). World University Rankings 2019.
[15] KPMG (2018). The Pulse of Fintech 2018: Biannual global analysis of investment in fintech.
[16] BSI (2018). Developing a UK Standards Strategy for Graphene.
[17] Stern AD (2016). Innovation under Regulatory Uncertainty: Evidence from Medical Technology. J Public Econ. 2016;145:181-200.
[18] Wellcome (2018). Building a Strong Future for European Science: Brexit and Beyond.
[19] Wellcome (2019). Brexit and Beyond: Clinical trials.

the following principles, which we've drawn from our consultation,[20] a new comparative analysis and literature review:[21,22]

- **Inclusive**. Oversight should bring together different expertise and perspectives – for example from public groups, industry and academia – to improve approaches and make them more relevant and trustworthy. Engaging society on the need for an innovation and its oversight can help create sustainable change and avoid any damaging public backlash. This has not always gone well in the UK: restrictions set in response to strong negative views about genetically modified (GM) crops reduced the UK's role in the global market for GM seed, which has grown to over $17 billion.[23] There is some evidence that the lesson has been learnt, but further progress is needed.
- **Anticipatory**. Oversight should keep pace with science and adapt to changing societal concerns. Where regulatory challenges are identified ahead of time, there is a better opportunity to develop a suitable approach, and adapt it as further challenges emerge and technology develops.[24] While some individual regulators do this, the UK regulatory culture needs to shift from being reactive to applying an anticipatory approach routinely.
- **Innovative**. Testing experimental oversight approaches provides government and regulators with evidence of real-world impacts. This is now recognised in the UK, for example in the new Regulators' Pioneer Fund, but must be adopted at scale.
- **Proportionate**. Oversight should foster the potential benefits of emerging science and technology at the same time as protecting against harms, by being proportionate to predicted risk. The UK should keep up its strong track-record in delivering proportionate oversight.

Combining these approaches in dynamic oversight will enable the UK to realise the potential benefit of each new innovation while maintaining safety, supported by enduring public trust. To deliver this, the UK does not have to start from scratch. Many of the elements are already in place, but these must be strengthened, coordinated and used consistently across government.

What the UK learns in pioneering new approaches should be shared with others globally to help others address the same challenges. The UK should also learn from ideas elsewhere. Using diplomatic links, international institutions and influence through future trade agreements, the UK should use this regulatory diplomacy to shape common international approaches.

Moments for taking bold new approaches to oversight are rare. The UK must seize this one.

Recommendation: The UK Government must now seize the opportunity to set out its vision and a package of reforms to make the UK the world-leader in the regulatory oversight of emerging science and technologies.

Part 1: Approaching uncertainty to build a better regulatory environment in the UK

Emerging technologies develop in unpredictable ways. For example, compared to their disruptive effect in the banking or entertainment sectors, mobile devices and apps have only had an incremental impact in healthcare.[25]

[20] Wellcome (2019). Consultation on the oversight of emerging science and technologies.
[21] Gunashekar S, Parks S et al (2019). Oversight of emerging science and technology: Learning from past and present efforts around the world. RAND Europe.
[22] Chubb J, Montana J, Stilgoe J, Stirling A, Wilsdon J (2019). A review of recent evidence on the governance of emerging science and technology. UCL Consultants.
[23] International Service for the Acquisition of Agri-biotech Applications (2018). Global Status of Commercialized Biotech/GM Crops in 2017. ISAAA Brief 53.
[24] Rae J, Armstrong H (2017). A working model for anticipatory regulation: Nesta working paper.
[25] Peiris D, Miranda JJ, Mohr DC (2018). Going beyond killer apps: building a better mHealth evidence base. BMJ Global Health 2018;3:e000676.

While emerging technologies have the potential to transform industries (or create completely new ones), they often develop at pace and may raise ethical issues or challenge social norms, and may be viewed in different ways by different parts of society.[26] In the absence of robust, complete evidence, decisions rely on the ability to predict what might happen.

This makes it challenging for governments and regulators to decide when, and how, to regulate emerging technologies.[27,28] Yet their actions will influence the development of any potential innovation – positively or negatively.[29] Acting too early, for example through disproportionately strict regulation, may 'lock in' an innovation to an ill-suited regulatory regime and stifle a new industry – as the UK experienced with GM crops. But regulatory action too late may mean that an innovation has negative outcomes that could have been avoided and can damage trust.

Applying the principles set out in the vision will help to manage this uncertainty. This section builds on these principles with recommendations on what the UK must do to adopt an approach that is inclusive, anticipatory, innovative and proportionate. Together, the following actions will create a clear and integrated approach to dynamic oversight for emerging science and technologies.

Inclusive: Engaging public groups

Emerging science or technology can raise ethical concerns. For example, gene drive could reduce the number of mosquitoes that spread diseases such as malaria, dengue and zika, but may also cause unpredicted long-term effects in an ecosystem.[30] Artificial Intelligence may improve productivity and create economic growth, but could have inequitable social impacts[31] – in recent polling of the UK public, 26% said their biggest concern with AI was "a lack of adequate oversight or government regulation of automated decisions to protect people if a decision made is unfair".[32]

Engaging people and understanding their views is therefore critical to build public confidence in the use and oversight of new technology.

Over the past 10 years there has been strong public support for science and technology in the UK, but this support is conditional.[33,34] Lack of engagement has contributed to high-profile public backlashes in the UK, with a significant negative impact on the success of the innovation – for example, on the use of genetically-modified crops,[35,36] and the care.data project aiming to use patient data from GP records.[37]

Conversely, good practice in engaging public groups has helped to build public understanding and confidence about an emerging science or technology, contributing to its uptake (see Box 2). This can

[26] Nuffield Council of Bioethics (2012). Emerging biotechnologies: technology, choice, and the public good.
[27] Butenko A, Larouche P (2015). Regulation for innovativeness or regulation of innovation? Law, Innovation and Technology, 7:1, 52-82.
[28] Marchant GE, Allenby BR, Herkert JR (2011). The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight: The Pacing Problem.
[29] Genus A, Stirling A (2018). Collingridge and the dilemma of control: towards responsible and accountable innovation. Research Policy, 47 (1), 61–69.
[30] National Academies of Sciences, Engineering, and Medicine (2016). Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values.
[31] www.weforum.org/agenda/2015/03/3-important-questions-about-emerging-technologies/
[32] RSA (2018). Artificial Intelligence: Real Public Engagement.
[33] Chubb J, Montana J, Stilgoe J, Stirling A, Wilsdon J (2019). A review of recent evidence on the governance of emerging science and technology. UCL Consultants.
[34] Macnaghten P, Chilvers J (2014). The future of science governance: publics, policies, practices. Environment and Planning C: 32: 530–548.
[35] Burke D (2004). GM food and crops: what went wrong in the UK? Many of the public's concerns have little to do with science. EMBO Rep. 2004;5(5):432-6.
[36] Rowe G, Horlick-Jones T, Walls J, Pidgeon N (2005). Difficulties in evaluating public engagement initiatives: reflections on an evaluation of the UK GM Nation? public debate about transgenic crops. Public Understand. Sci. 14 (2005) 331–352.
[37] Carter P, Laurie GT, Dixon-Woods M (2015). The social licence for research: why care.data ran into trouble. J Med Ethics. 2015 May; 41(5): 404–409.

also help decision-makers improve how they develop oversight by better understanding public views, values and attitudes around a particular innovation.

Box 2: Public engagement on mitochondrial donation

Approximately 1 in 200 children in the UK are born with faulty mitochondrial DNA. While many grow up with mild symptoms or none, some develop more serious mitochondrial disorders that can lead to disability and death at an early age.

In 2015, the Human Fertilisation and Embryology Authority (HFEA) was asked to seek public views ahead of any regulatory change to legalise mitochondrial donation, new techniques that would enable a woman at risk of passing on mitochondrial disease to have a healthy child related to her and her partner.

With support from the Sciencewise programme, the HFEA undertook a comprehensive public dialogue exercise.[38] This work focused on how people's views change when introduced to different information and provided the opportunity for public groups to learn about mitochondrial donation and give it fair consideration.[39] A separate survey covered the views of the UK population by sampling a representative group.

The results of the public dialogue and consultation indicated that there was overall public support for permitting mitochondrial donation, giving the Government confidence to proceed.[40] The public engagement element was praised for its role in leading to the legislative change.[41]

Engagement can take numerous forms, such as deliberative forums, citizens juries, stakeholder dialogue, surveys and polling.[42] Dialogue exercises are better than one-way information gathering exercises because they increase understanding of the concerns that public groups may have and how they respond to new information.[43] For example, there is some evidence that public perception of driverless cars in the UK has worsened as the technology has developed.[44]

Ongoing engagement with a variety of public groups is therefore important to ensure that oversight is responsive to changes in societal concerns, especially regarding technologies such as AI that the Government is prioritising within its Industrial Strategy. This engagement must start early in the process and be an active partnership.

Recommendation: The UK Government should support regulators to ensure that public groups are engaged from an early stage as oversight is being developed, and to ensure active engagement continues as the innovation develops.

Since 2004, the Sciencewise programme has helped government and regulators to develop policy informed by the views, concerns and aspirations of public groups.[45,46] Recent projects include the use of human tissue and linked health data in research, and attitudes towards drones.[47] The programme is now part of UKRI, which is developing a new public engagement vision and strategy.[48] **Expanding**

[38] Human Fertilisation and Embryology Authority (2013). Mitochondria replacement consultation: Advice to Government.
[39] Herbrand C, Dimond R (2018). Mitochondrial donation, patient engagement and narratives of hope. Sociology of Health and Illness 40 (4) , pp. 623-638.
[40] Department of Health (2014). Mitochondrial Donation: A consultation on draft regulations to permit the use of new treatment techniques to prevent the transmission of a serious mitochondrial disease from mother to child.
[41] Craven L, Murphy J, Turnbull DM, Taylor RW, Gorman GS, McFarland R (2018). Scientific and Ethical Issues in Mitochondrial Donation. New Bioeth. 2018;24(1):57-73.
[42] www.involve.org.uk/resources/knowledge-base/what/public-engagement-public-policy-making
[43] Eaton W, Wright W, Whyte K, Gasteyer S, Gehrke PJ (2014). Engagement and Uncertainty: Emerging Technologies Challenge the Work of Engagement. Journal of Higher Education Outreach and Engagement, v18 n2 p151-177 2014.
[44] Richardson E, Davies P (2018). The Changing Public's Perception of Self-Driving Cars.
[45] https://sciencewise.org.uk
[46] RPA (2015). Evaluation of the Sciencewise Programme 2012-2015. Report for Sciencewise/Ricardo-AEA.
[47] https://sciencewise.org.uk/projects-and-impacts/impacts/
[48] UK Research and Innovation (2018). Strategic Prospectus: Building the UKRI Strategy.

its activities of Sciencewise through this could be a good route to strengthen support for regulators to engage public groups.

When government creates new bodies that will be important for decisions on oversight for emerging science and technologies, such as the newly-created Centre for Data Ethics and Innovation, **government should ensure that these are supported with public engagement budgets.**

Public engagement on emerging science and technologies is also conducted outside government. For example, in 2018 the Academy of Medical Sciences worked with Ipsos MORI and Understanding Patient Data on a programme of public dialogue to explore opinions on the use of emerging 'data-driven' medical technologies.[49] Such exercises provide a useful body of information that regulators should take into account when making oversight decisions. **Research funders, learned societies and professional organisations should continue to fund this work and engage regulators on the findings.**

Anticipatory and proportionate: Foresight and adaptation

An anticipatory approach[50,51] involves acting early and iterating oversight around an innovation as it develops. This approach relies on identifying early indicators of change and potential challenges through effective horizon scanning and foresight;[52,53] early engagement with public groups; and flexibility in oversight tools. In the UK, Nesta has promoted an anticipatory approach as a way of securing the benefits of innovation while managing risks.[54]

Although not adopted systemically, anticipatory approaches have been used to good effect in the past. The US Recombinant DNA Advisory Committee, while formed reactively in 1974 to guide the use of recombinant DNA molecules, has adapted the oversight it provides, anticipating areas of science such as gene therapy.[55] Because of this, effective oversight has been in place without further formal government legislation or regulation.[56]

In the UK, the Government took an anticipatory approach to mitochondrial donation (see Box 2), placing provision in legislation that allowed research in this area to continue while adding flexibility for the HFEA to consider the need for clinical use in the future.

The HFEA took a more reactive approach to admixed embryos containing human and animal material, where it had not been clear if this fell within HFEA's regulatory remit.[57] Admixed embryos had been identified through its horizon scanning programme, but consultation with public groups was delayed until licence applications began to reach the HFEA. While clarity was provided through changes to the HFE Act, the failure to approach this issue earlier was criticised for its impact on research.[58]

---

[49] Castell S, Robinson L, Ashford H (2018). Future data-driven technologies and the implications for use of patient data: Dialogue with public, patients and healthcare professionals.
[50] Chubb J, Montana J, Stilgoe J, Stirling A, Wilsdon J (2019). A review of recent evidence on the governance of emerging science and technology. UCL Consultants.
[51] Nelson N., Geltzer A., Hilgartner S. Introduction: The anticipatory state: Making policy-relevant knowledge about the future. Science and Public Policy. 2008;35(8):546–550.
[52] Amanatidou E et al (2012). On concepts and methods in horizon scanning: Lessons from initiating policy dialogues on emerging issues. Science and Public Policy. 39. 208-221.
[53] Laurie G, Harmon SHE, Arzuaga F (2012). Foresighting Futures: Law, New Technologies and the Challenges of Regulating for Uncertainty. Law, Innovation and Technology 4 (1) 1-36.
[54] Armstrong H, Gorst C, Rae J (2019). Renewing regulation: 'Anticipatory regulation' in an age of disruption.
[55] Khan S et al (2016). Role of Recombinant DNA Technology to Improve Life. International Journal of Genomics 2016.
[56] Wivel N (2014). Historical Perspectives Pertaining to the NIH Recombinant DNA Advisory Committee. Human Gene Therapy 25 (January): 19–24.
[57] Haddow G et al (2010). Not "Human" Enough to be Human but not "Animal" Enough to be Animal - the Case of the HFEA, Cybrids and Xenotransplantation in the UK. New Genetics and Society, vol. 29, no. 1, pp. 3-17.
[58] House of Commons Science and Technology Committee (2007). Government proposals for the regulation of hybrid and chimera embryos.

An anticipatory approach is valuable to keep pace with science, and to adapt to changing societal concerns, which are important for issues such as the 14-day limit for maintaining human embryos in culture (see Box 3).

Box 3: Revisiting the 14-day rule

The 14-day rule states that no human embryo should be grown in vitro for longer than 14 days after fertilisation. It is a staple of human embryo research governance internationally.[59]

When the 14-day rule was set, it was largely theoretical, as human embryos could not be grown in culture for more than a few days. However, scientists have since managed to keep embryos alive for up to 13 days. There have been calls for the limit to be extended so that scientists can investigate early human development, the causes of early miscarriages, and ways to produce stems cells to treat diseases.[60]

There have also been calls to clarify the 14-day rule since the discovery that human pluripotent cells, under certain culture conditions, can self-organise in ways similar to the human embryo. It is unclear whether these 'gastruloids' fall within the definition of embryos subject to the regulation.[61]

With technical capabilities still improving, now would be an appropriate time for the UK Government to begin dialogue activities to explore views of public groups on potentially reviewing the 14-day rule.

Recommendation: The UK Government and regulators need to anticipate and monitor emerging science and technologies to develop and iterate an appropriate, proportionate approach. Regulators must be equipped by government to do this.

Embedding an anticipatory approach within government departments and regulators requires a cultural shift to enable them to be more dynamic as new science and technologies emerge and develop. **This will require regulators and government to engage with a range of different stakeholders to better identify potential risks and opportunities, and evaluate impact.**

Good horizon scanning is essential to deliver anticipatory oversight and should be a core function for all regulators. In the UK, a number of bodies perform intelligence gathering through horizon scanning, including government departments (particularly the Government Office for Science), regulators, national academies, learned societies and think tanks. Research Councils and Innovate UK are also well placed to identify early signals of emerging science and technology through the research they fund. UKRI should, as a core role, coordinate the communication of this information into the Government's horizon scanning activities.

The Government has recently recognised the need for a strategic horizon-scanning function to support regulators.[62] We welcome this as the current approach is too fragmented and does not include enough external expertise.[63,64] **A central coordinating function for anticipatory oversight would provide a centre of expertise, greater leadership and a stronger strategic approach to identifying and responding to opportunities and challenges for emerging science and technologies.** This could operate through a 'hub & spoke' model, with the Better Regulation Executive well-placed to establish this function.

[59] Nuffield Council on Bioethics (2017). Human embryo culture: Discussions concerning the statutory time limit for maintaining human embryos in culture in the light of some recent scientific developments.
[60] www.theguardian.com/commentisfree/2016/may/06/extend-14-day-limit-embryo-research
[61] Chan S (2018). How and Why to Replace the 14-Day Rule. Curr Stem Cell Rep 2018 4: 228.
[62] Clark G (2018). Letter to Dr Patrick Vallance and Professor Dame Nancy Rothwell. Department for Business, Energy and Industrial Strategy.
[63] House of Commons Science and Technology Committee (2014). Government horizon scanning.
[64] Cabinet Office (2013). Review of cross-government horizon scanning.

Innovative: Testing new approaches

Testing experimental oversight approaches provides government and regulators with evidence of real-world impacts.[65] This can be done through derogation (allowing a temporary exception from existing rules or laws), devolution (where a local decision-making body is empowered to explore a different approach) or open texture (where regulatory aims are broadly defined to allow self-regulation to generate approaches that can be compared and evaluated).[66,67]

Singapore is testing innovative approaches to oversight, adapting the regulatory sandbox pioneered in the UK (see Box 4) to a number of settings including Fintech, environmental services and the energy sector. Its testbed for autonomous vehicles has helped make Singapore the top-rated country for policy and consumer acceptance in this area.[68] Motor vehicles no longer require human drivers by law – the first country to legislate for this ahead of widespread adoption.[69] This reflects the Singapore Government's aim to create an environment that anticipates and accelerates disruptive innovation.[70]

Box 4: Testing regulatory oversight in Fintech

The emergence of new financial technologies generates opportunities and risks for banking systems and consumers. Borrowing from 'sandbox' approaches in other contexts, the UK Financial Conduct Authority (FCA) developed the concept of a regulatory sandbox in 2015, while fintech was still emerging. This provided a regulatory 'safe space' in which eligible firms were able to carry out limited tests on innovative products while being exempt from certain regulatory requirements.[71]

The regulatory sandbox balanced traditional regulatory objectives of financial stability and consumer protection with promoting growth and competitive innovation.[72] It enabled firms to trial ideas and receive feedback from customers, which also benefited the regulator by providing insight into developing ideas that might need regulating in the future, as well as potential risks.

FCA oversight of testing provided increased regulatory certainty to investors. Around 40 per cent of firms that completed testing in the first cohort received investment during or following their sandbox tests.[73]

Since its inception, the UK sandbox has accepted four cohorts of participants – approximately 90 firms, the majority from the retail banking sector. Australia, Hong Kong, Indonesia, Malaysia, Singapore, South Korea and Thailand have developed similar models.

Recommendation: The Department for Business, Energy and Industrial Strategy needs to create new incentives for the testing of new oversight approaches.

For innovative approaches to succeed, the views of public groups, industry and other stakeholders must be included to evaluate and improve oversight. The launch of the M-Pesa mobile banking service in Kenya, without a fixed regulatory structure but with heavy scrutiny from the Central Bank of

[65] Fenwick MD, Kaal WA, Vermeulen EPM (2017). Regulation Tomorrow: What Happens When Technology Is Faster than the Law? American University Business Law Review, Vol. 6 (3).
[66] Haomiao D, Heldeweg MA (2018). An experimental approach to regulating non-military unmanned aircraft systems. International Review of Law, Computers & Technology,
[67] Fosch Villaronga E, Heldeweg MA (2016). Rethinking Regulation for Experimenting with Emerging Robotics Technologies. Paper presented at Staatsrechtconferentie 2016, Enschede, Netherlands.
[68] KPMG (2018). Autonomous Vehicles Readiness Index.
[69] www.cio-asia.com/article/3294207/innovation/how-singapore-is-driving-the-development-of-autonomous-vehicles.html
[70] Siddiqi L (2017). Three lessons from Singapore, with or without Brexit. LSE Business Review: Blog Entry.
[71] Zetzsche DA, Buckley RP, Arner DW, Barberis JN (2017). Regulating a Revolution: From Regulatory Sandboxes to Smart Regulation. Fordham Journal of Corporate & Financial Law.
[72] Financial Conduct Authority (2017). Regulatory Sandbox Lessons Learned Report.
[73] Ibid.

Kenya, was used to develop regulations for branchless mobile banking.[74] User experiences were sought throughout to help find out whether they had trust in the service.[75]

The strength of this approach has been recognised in the UK but needs to be applied much more widely. As part of the UK Industrial Strategy, the Government's Regulators' Pioneer Fund aims to create additional live testing environments for innovations, and to encourage regulators to work across sectors. Funding has been awarded to 15 projects in the Industrial Strategy's Grand Challenge areas.[76] **BEIS needs to equip regulators to foster collaborations with public groups and industry to test new approaches.**

Ensuring leadership and accountability

Where science and technologies emerge outside existing regulators' remits or span multiple sectors, there is a danger of oversight falling through the gaps.[77] For example, digital pills and connected inhalers create challenges by crossing regulatory areas for drugs, devices and data.[78,79] Using AI to deliver healthcare may exacerbate existing gaps in liability when decisions are made by machine not man.[80] The UK Government is seeking to address potential regulatory gaps for data and AI through the newly-created Centre for Data Ethics and Innovation, although creating a new body may not be possible to address every new science or technology.

A further challenge is when innovations are used in settings that were not considered in earlier testing[81] (see Box 5).

Box 5: Neurotechnologies and regulatory gaps

Neurotechnology research has the potential to help develop new ways of understanding and treating brain disorders. But neuromodulatory devices and brain–computer interfaces are already being sold direct to consumers (DTC) without the involvement of medical professionals.[82]

As long as they do not make therapeutic claims, manufacturers of most DTC devices for cognitive enhancement only have to follow basic safety standards for their products, despite uncertainty around possible long-term risks.[83]

This has led to criticism that regulatory oversight of DTC neurotechnologies is insufficient. The number of products, the dynamic nature of software applications that can change with each update and the potential ethical issues surrounding these innovations all create challenges.[84] There are no industry wide safety standards, and the market has many companies that sell products with little evidence to back up their claims.[85]

[74] Muthiora B (2015). Enabling Mobile Money Policies in Kenya. Fostering a Digital Financial Revolution. London: GSMA.
[75] Alliance for Financial Inclusion (2010). Enabling Mobile Money Transfer: The Central Bank of Kenya's Treatment of M-Pesa.
[76] www.gov.uk/government/news/projects-lay-the-groundwork-for-a-future-of-robolawyers-and-flying-cars
[77] Miller C, Ohrvik-Stott J, Coldicutt R (2018). Regulating for Responsible Technology: Capacity, Evidence and Redress: a new system for a fairer future.
[78] Duggal R, Brindle I, Bagenal J (2018). Digital healthcare: regulating the revolution. BMJ 2018;360:k6
[79] Blakey J, Clift J (2017). Smart asthma. Asthma UK.
[80] www.phgfoundation.org/briefing/legal-liability-machine-learning-in-healthcare
[81] Felt U, Wynne B, Callon M et al (2007). Taking European Knowledge Society Seriously. Report of the Expert Group on Science and Governance to the Science, Economy and Society Directorate, Directorate-General for Research, European Commission.
[82] Fernandez A, Sriraman N, Gurewitz B, Oullier O (2017). Market Report on Pervasive Neurotechnology: A Groundbreaking Analysis of 10,000+ Patent Filings Transforming Medicine, Health, Entertainment and Business.
[83] Garden H, Bowman DM, Haesler S, Winickoff DE (2016). Neurotechnology and Society: Strengthening Responsible Innovation in Brain Science. Neuron. 2016 Nov 2; 92(3): 642–646.
[84] Wexler A, Reiner PB (2019). Oversight of direct-to-consumer neurotechnologies. Science. 2019 Jan 18;363(6424):234-235.
[85] Ibid.

Anticipatory approaches to oversight may help guide neurotechnologies to address societal needs and incentivise user-centred development to enhance efficacy, safety and security.[86,87]

Recommendation: The UK Government should be flexible and decisive in how it responds to regulatory gaps that emerge.

Fragmented approaches can cause a lack of accountability and a lack of legal clarity for developers. The lack of a joined-up approach and clear lead for the use of patient data in medical research has been highlighted, with a range of different bodies making it complicated and costly to navigate.[88] **Where multiple regulatory bodies could be involved, the Government should pick a lead regulator to work with others to develop an approach, ensuring a central point of accountability and clarity for developers.**

The Government should also promote initiatives to make it easier for developers to navigate regulatory requirements, such as the MHRA Innovation Office's one-stop-shop regulatory advice service for regenerative medicine, which provides joined-up regulatory information, advice and guidance from over five separate regulators.[89]

Part 2: Strengthening global links and networks

An inclusive, anticipatory, innovative and proportionate approach to the oversight of emerging science and technologies is likely to bring competitive, first-mover advantages if the UK is seen as an attractive setting to test new areas of science and innovative technologies. However, if pioneering approaches to oversight are developed in isolation there is a danger of increasing divergence from the rest of the world.

Common standards play an important role in reducing barriers to international trade and regulation is an important element of trade deals.[90] International standards open up import and export markets and allow companies to participate in global supply chains – standards add an estimated average of £6.1 billion a year to the value of UK exports.[91,92] Many voluntary standards make international trade or collaboration easier – for example, the ICH guidelines developed in 1990 to reduce the complexity of medicines development across the EU, the US and Japan.[93]

At a time when Brexit is changing the nature of the UK's geopolitical relationships, it is important for the UK not to strike out alone, but to lead in shaping regulation internationally.

A single state can spread its laws and regulations through market mechanisms.[94] For example, the EU used the incentive of market access to encourage other nations to adopt its General Data Protection Regulation.[95] This approach benefitted the UK as a member of the EU, as it was significant player in shaping GDPR and other EU legislation such as the EU Clinical Trials Regulation.

Indirectly, international research funding can also shape standards and regulation for emerging science and technology: for example, a collaboration funded by the EU is creating a Code of Conduct

[86] Ienca M, Haselager P, Emanuel EJ. Brain leaks and consumer neurotechnology. Nat Biotechnol. 2018 Sep 6;36(9):805-810.
[87] Garden H, Bowman DM, Haesler S, Winickoff DE (2016). Neurotechnology and Society: Strengthening Responsible Innovation in Brain Science. Neuron. 2016 Nov 2; 92(3): 642–646.
[88] Academy of Medical Sciences (2011). A new pathway for the regulation and governance of health research.
[89] www.gov.uk/government/groups/mhra-innovation-office
[90] Owen J, Stojanovic A, Rutter J (2017). Trade after Brexit: Options for the UK's relationship with the EU. Institute for Government
[91] Swann G (2010). International Standards and Trade: A Review of the Empirical Literature. OECD Trade Policy Papers #97.
[92] Centre for Economics and Business Research (2015). The Economic Contribution of Standards to the UK Economy.
[93] www.ich.org/products/guidelines.html
[94] Bradford A (2012). The Brussels Effect, 107 Nw. U. L. Rev. 1.
[95] Benady D (2018). GDPR: Europe is taking the lead in data protection.

for Health Research on how to apply the GDPR in practice.[96] The UK should negotiate associate membership of the EU framework programmes after Brexit to maintain this route of influence.

After Brexit, the UK will no longer be able to rely primarily on market size to influence the international environment, but the UK has other strengths through regulators' international activity, which offer a good foundation.

The UK was influential in the development and promotion of the European GSM standard for mobile phones (see Box 6) and around 60 countries have begun to use standards on smart cities developed first in the UK.[97] Within finance, the UK FCA is increasingly collaborating on new bilateral trade agreements called 'FinTech Bridges' that build links between governments, regulators and the private sector in order to open up international markets.[98] It has also developed a Global Financial Innovation Network with 29 other financial regulators and related organisations to explore cooperation based on the UK regulatory sandbox (see Box 4).[99] And the UK Government recently announced a partnership with the World Economic Forum to develop future regulation for emerging technologies.[100]

Box 6: Developing the GSM standard

Digital mobile cellular technology was the second generation of mobile communications technology (2G), following and largely replacing first generation analogue systems (1G). By the early 1980s, most Western European countries had analogue (1G) cellular networks in place. The fragmentation and lack of standardisation that characterised these networks, however, stood as a barrier to the successful implementation of 2G.

Between 1982 and 1987, the EU, national governments and private stakeholders worked together to develop a pan-European standard for 2G cellular networks – the Global System for Mobile Communications (GSM). This was widely considered as a successful piece of industrial policy, to accelerate a technological advance.[101]

What was intended initially as a pan-European mobile network became so successful that it was the dominant worldwide standard for over a decade, with GSM-based networks as a major driving force behind the rise of worldwide mobile phone users to five billion worldwide in 2018.[102]

Many other UK regulators have strong, long-standing links with international organisations that will remain after Brexit. For example, the British Standards Institute and Food Standards Agency represent the UK on the Council of the International Organization for Standardization and the Codex Alimentarius Commission for food standards, respectively.[103,104]

Bilateral relations are also important (see Box 7). The Animals in Science Regulation Unit within the Home Office has collaborated with the Chinese Association for Laboratory Animal Sciences since 2013 to develop national standards in China for the ethical use research involving animals, embedding the '3Rs' principles (replacement, reduction and refinement). Developing these standards is likely to increase confidence and ease of research collaborations between the UK and China.[105]

Recommendation: The Foreign and Commonwealth Office, working with BEIS and the Department for International Trade, needs to support regulatory diplomacy to help ensure that the UK shares globally the approaches to oversight that it pioneers.

[96] http://code-of-conduct-for-health-research.eu
[97] Government Office for Science (2017). Technology and Innovation Futures.
[98] HM Treasury (2018). Fintech Sector Strategy: Securing the Future of UK Fintech.
[99] www.fca.org.uk/firms/global-financial-innovation-network
[100] www.gov.uk/government/news/uk-and-world-economic-forum-to-lead-regulation-revolution-to-foster-industries-of-the-future
[101] Hillebrand F (2013). The Creation of Standards for Global Mobile Communication: GSM and UMTS Standardization from 1982 to 2000. IEEE Wireless Communications 20 (5):24–33.
[102] GSMA Intelligence (2018). The Mobile Economy 2018. GSM Association.
[103] www.bsigroup.com/en-GB/about-bsi/uk-national-standards-body/standards-policy-on-the-uk-leaving-the-eu/
[104] www.food.gov.uk/about-us/codex-alimentarius-commission
[105] www.sciencemag.org/news/2016/03/china-finally-setting-guidelines-treating-lab-animals

Following Brexit, the UK must work harder than ever to maintain its influence abroad. **The Government must support regulators to increase their international presence, in addition to proactively engaging other nations on regulatory issues through trade agreements and international treaties.**

Existing networks can support this, including the UK Science and Innovation Network, which is active in over 40 countries and territories around the world, building partnerships in support of UK policy.[106] The UK could also build on existing 'science diplomacy' through international collaborations, cooperation between national academies and dedicated funding programmes.[107]

The UK must continue to meet high levels of ethical standards to be recognised as a leader in oversight for emerging science and technologies. Brexit leaves open the possible perception of a UK 'race to the bottom', with innovation-enabling measures considered to be at the expense of ethical considerations. To guard against this, the UK must continue to engage with institutions such as the World Health Organization and UNESCO.[108]

Box 7: Fostering dialogue globally on genome editing

Genome editing allows scientists to change genome sequences by adding, replacing or removing sections of DNA. The emergence of the CRISPR-Cas9 gene editing system has made targeted, highly efficient editing of genome sequences increasingly accessible.

One application is to change human reproductive cells and produce genetically edited babies. In November 2018, Dr Jiankui He, a Chinese researcher, claimed to have performed genome editing to provide resistance to HIV, resulting in a viable pregnancy and the birth of twins. Such developments have spurred jurisdictions across the world to find appropriate national and international oversight. There has even been a call for a moratorium to stop any clinical use of germline editing.[109]

The UK already has a clear framework to oversee genome editing. It embeds scientists, ethicists and members of the public in horizon scanning and decision making. Although not the only approach, this provides a strong basis to foster discussions and share expertise with other countries, and keeps open ethical routes to innovations in health. The UK, through the HFEA, should position itself as a thought leader supporting sensible dialogue and further refine its own approach by learning from others.

[106] www.gov.uk/world/organisations/uk-science-and-innovation-network
[107] Bunn S, Ledgerwood E (2018). Science diplomacy. Parliamentary Office of Science and Technology.
[108] Montgomery J (2018). Bioethics after Brexit: Brexit an opportunity to rationalize bioethics governance in the United Kingdom. Medical Law International, 18 (2-3) pp. 135-156.
[109] Lander E, Baylis F, Zhang F et al (2019). Adopt a moratorium on heritable genome editing. Nature 567, 165-168.

Wellcome exists to improve health by helping great ideas to thrive.

We support researchers, we take on big health challenges, we campaign for better science, and we help everyone get involved with science and health research.

We are a politically and financially independent foundation.

Wellcome Trust, 215 Euston Road, London NW1 2BE, United Kingdom
T +44 (0)20 7611 8888, E contact@wellcome.ac.uk, wellcome.ac.uk