Consultation on the oversight of emerging science and technologies

March 2019

This consultation formed part of a Wellcome project on the regulatory oversight of emerging science and technologies. It sought to gather views on what oversight of emerging science and technologies should look like in practice.

We defined emerging science and technologies as innovations still in a stage of development that may have a substantial impact on society in the future – though are still uncertain and yet to be fully harnessed.

The consultation posed four questions covering approaches to oversight, current opportunities, and horizon scanning.

We received 12 responses (see Annex) from organisations and individuals across a range of disciplines, including individual academics, academic groups at universities, learned societies and policy makers.

All the proposals contained in this report were drawn from submissions to the consultation. This document does not represent the views of Wellcome.

Overarching comments

Oversight in the UK

Many of the responses commented on the current state of oversight in the UK. The general consensus was that the UK is already in a strong position and currently carries out proportionate and appropriate oversight. The Academy of Medical Sciences (AMS) said that "the UK has a forward thinking and responsive regulatory system for science and technology, and it is important that this continues to be supported as new technologies arise" and cited mitochondrial replacement in in-vitro fertilisation as an exemplar of good practice.

Defining oversight

Oversight covers the overall system of checks in place during developing something new, and includes formal legislation, regulation and governance, non-regulatory standards and guidelines, and other informal elements like public engagement and international cooperation. The terms oversight, regulation, and governance are often used interchangeably – in this project we have considered the system as a whole.

A number of the respondents commented on and questioned the use of the term 'oversight', stating that the term needs to be broadened and does not encompass all that is involved. Nesta cautioned that "framing the consultation around oversight creates connotations of surveillance or supervision of emerging science and technology", and was therefore problematic. They outline that "setting agendas, defining positive outcomes and creating the right conditions for good innovation" are all part of what government and regulators can do which is "substantially more than oversight" – arguing that all of these should be acknowledged and that the term 'oversight' is not broad enough. The Nuffield Council on Bioethics said that "oversight should have a broader meaning, which includes shaping the aim and direction of research towards solving problems and meeting public interests, rather than simply responding to developments." This concept, the idea that oversight should be solving problems for society in their interests, and not vice-versa, was also highlighted by the Royal Institution (Ri).

Question 1: Key elements of good oversight

Thinking of approaches in the UK and internationally, what are they key elements of good oversight that should be in the UK's approach for emerging science and technology?

Respondents identified the following key principles of good oversight:

Engagement

There was consensus amongst all types of respondents that engagement was a key principle. As said by Nesta “engagement with a wider set of stakeholders – including the public, companies, innovators, NGOs, city authorities, local government and other regulators”. The sentiment of early engagement was iterated by most of the respondents, with a clear emphasis that engagement should be early, ongoing and with a wide range of stakeholders.

Different respondents focussed on engagement with different stakeholders. There was a clear focus on engagement with the public, which was highlighted as a key principle of oversight by many respondents. For example, the Health Research Authority (HRA) said that good oversight requires “better involvement of the public and patients in oversight mechanisms and a better understanding and appreciation of the role of culture”. The Engineering Life project at Edinburgh University explained that early engagement regarding the needs of the local population was needed to prevent ‘lock-in’ of a technology that wasn’t suitable for the users.

Other respondents emphasised engagement with other stakeholders. The Medicines and Healthcare Product Regulatory Agency (MHRA) emphasised “early engagement with regulatory bodies and policy makers”, such as themselves, would strengthen oversight, and the Wellcome Sanger Institute emphasised “early engagement with companies and research organisations, in order to develop regulation in real time alongside technological development”.

Responsive and timely oversight

There was a general consensus amongst responses that oversight should be timely. There needed to be early engagement with the innovators and other stakeholders to develop oversight in good time. The MHRA proposed that “the legal framework should enable but not put unnecessary detail in legislation otherwise there is a risk that it will not be updated in a timely manner to be kept up to date with science, technology and commercial changes.”

Along with the need for timely oversight, many respondents thought that oversight should be responsive and flexible. Nesta summarised this, “a flexible, iterative learning approach is needed rather than a solve and leave mentality”. Many noted that the UK already has a responsive oversight system. For example, the AMS said “the UK has a forward thinking and responsive regulatory systems for science and technology, and it is important that this continues to be supported as new technologies arise.”

Collaboration

Closely linked to engagement, there were a number of recommendations for collaboration and having a collaborative mindset, both within disciplines and across sectors.

Within sectors the Life Engineering Project believe their research has shown the value of long-standing and substantive collaborations with social sciences. While the BioIndustry Association (BIA), along with the MHRA, advocate for collaboration between sectors. The BIA believe that good oversight should “foster a collaborative mindset and partnership between industry, government and academia” and “bring partners and stakeholders together for brainstorming and networking (e.g. workshops).”

Trust

Trust was raised by several of the respondents, with the overriding message being that trust is an essential part of the oversight process for it to be successful. Many closely tied it with engagement, requiring engagement to build trust and confidence. Nesta summarised this, “without engagement, public trust in technologies may be undermined”, and gave genetically modified foods as an example.

The MHRA spoke about trust in regard to data driven technologies, “maintaining and enhancing public trust in the use of their data for these innovations is crucial to their successful development”.

One respondent (Dr John Appleby, Lancaster Medical School) summarised this issue of trust as a key question, “does the process or mechanism of oversight maintain, foster, and/or cultivate the trust of key stakeholders both in the UK and internationally?”

Legal framework

Many of the responses thought that there should be a strong legal framework, particularly those commenting on the medical/health sector; “the law should be backed up by a system of standards, assessment, inspection and enforcement with criminal sanctions where necessary” (MHRA). The MHRA expanded further by posing how to make sure that innovation is enabled while ensuring safety and effectiveness. Numerous responses commented on this difficult balance, with Dr John Appleby stating that oversight needed to be both “sustainable and enforceable”.

A common theme running throughout the responses was that there needs to be clear communication regarding regulation, who was providing the oversight, and how they interact with each other. The Wellcome Sanger Institute outlined key elements of good regulation including “providing clear and certain regulatory frameworks for organisations to operate within, and offers advice and expertise to those operating under that regulation.”

Expertise

There were many respondents who thought that expertise was a key principle in good oversight. There were two main ways this was interpreted; regulators providing the expertise to the innovators on the rules and regulations and experts/innovators providing expertise to the regulators and government to aid in supporting the decision-making process.

Expert and scientific advice was considered necessary and the MHRA highlighted that “when making policy or regulatory decisions in these areas Ministers should seek independent expert advice”.

Question 2: Current Opportunities

From your perspective, what current/future areas of emerging science and technology offer opportunities for the Government to improve how oversight is provided?

There were many suggestions for areas of emerging science and technologies where government oversight could be improved.

A few responses also spoke more broadly, not on specific technologies but on how the oversight is carried out. The Wellcome Sanger Institute asked for greater clarity for the public on which guidance/regulation is applied and when it is applied. The Ri also echoed this point asking for simpler regulation that is easier for the public to understand and take ownership of.

A range of areas of emerging science and technologies that were proposed as opportunities for government to improve how oversight is provided. Including:

- Advanced therapies.
- Use of genetic profiling in relation to historic treatment outcomes being used to determine individual treatment.
- Extending the 14-day rule for embryo research to 28 days.
- Introducing a requirement that radically new reproductive technologies must be introduced into clinical practice via clinical trial.
- Consumer health technologies.
- Drone technology.
- Blockchain.

Data and data-driven technologies were suggested frequently suggested by respondents. The MHRA outlined these as including “artificial intelligence, algorithms, software and computer driven diagnoses” and the AMS said they “have the potential to transform research and healthcare through enabling the linkage and analysis of many different types of data, and potentially deriving fast, more accurate or new insights from these data”. The HRA highlighted the positive potentials saying that data-driven technologies in combination with big data “have the potential to improve patient care and are an exciting area of healthcare research and development”. They also highlighted that there is evidence that patients welcome the use of patient data in way in which can improve healthcare, but that it was crucial that public support and patient confidence is maintained. However, the HRA cautioned “not to focus too heavily on a particular novel technique, but instead pay attention to how the technique might be applied and the ethical implications of that application. “

The AMS proposed a useful outline, that data-driven technologies and use of patient data present two different types of challenge – “regulation and governance of the use of patient data” and “safety and effectiveness of the technology itself”. Therefore, regulation must be carefully considered to ensure it covers the whole technology life cycle.

The AMS explained that artificial intelligence may present regulatory challenges because “the AI examined at the initial regulatory phase will not be the same version operating at a future date.” They highlighted that although this will demand more considerations for ethics, it also is an opportunity for the UK to lead on developing an adaptive or rolling system of regulation.

Question 3: Horizon Scanning

a. Thinking in the longer term about what may present challenges to existing regulation, which areas of science and technology still in their early stages of development should the Government be aware of?
b. In the future, how do you think the Government should ensure that it is aware of emerging areas of science and technology in good time?

There were many suggestions of areas that may present challenges to existing regulation or that the government should be aware of, these often overlapped with suggestions in response to Q2.

Suggestions included:

- Next generation sequencing technologies.
- Quantum computing.
- Artificial intelligence and machine learning.
- Genomic medicines.

Radically new reproductive technologies, such as gonadal organoids, ectogenesis and in-vitro derived gametes, were suggested as emerging technologies that could present challenges to existing areas of regulation particularly the Human Fertilisation and Embryology Act.

The final question in the consultation asked for respondents to make recommendations on how the government can make sure that it is aware of emerging areas of science and technology.

A number of novel ideas for horizon scanning were suggested, for example the BIA suggested the government create a “network of seekers to scout future areas of biomedical sciences”.

The Ri highlighted the need for the government to “ensure the horizon scanning team in GO-Science is well resourced”, and the AMS outlined their support for the GCSA and CSAs as “these positions play an important role in the horizon scanning for new innovations”.

Government having access to a wide network was suggested by many respondents. Some of these suggested networks include:

- Trade associations, research institutes and universities that work with companies are on the frontier of emerging science and technology. The BIA made this suggestion because these are often small companies with limited resources to feed into government horizon scanning.
- Core innovation hubs, such as those that have formed around centres of excellence in Cambridge, Oxford and London, this was suggested by the Wellcome Sanger Institute as "they will have far-sighted views of what the next wave of emerging technology will look like".
- Institutions and scientists involved in early stage research and development to provide engagement with the emerging technology whilst it is still at the "interesting but not urgent stage" (suggested by the HRA). This closely links with engagement being a key theme proposed for Q1.

Annex – Submissions

Responses are available on request.

- The Academy of Medical Sciences
- Dr John Appleby
- Dr Richard Ashcroft
- The BioIndustry Association
- Dr Stuart Calimport
- The Engineering Life project
- The Health Research Authority
- The Medicines and Healthcare Products Regulatory Agency
- Nesta
- The Nuffield Council on Bioethics
- The Royal Institution
- The Wellcome Sanger Institute