RAND EUROPE

Oversight of emerging science and technology

Learning from past and present efforts around the world

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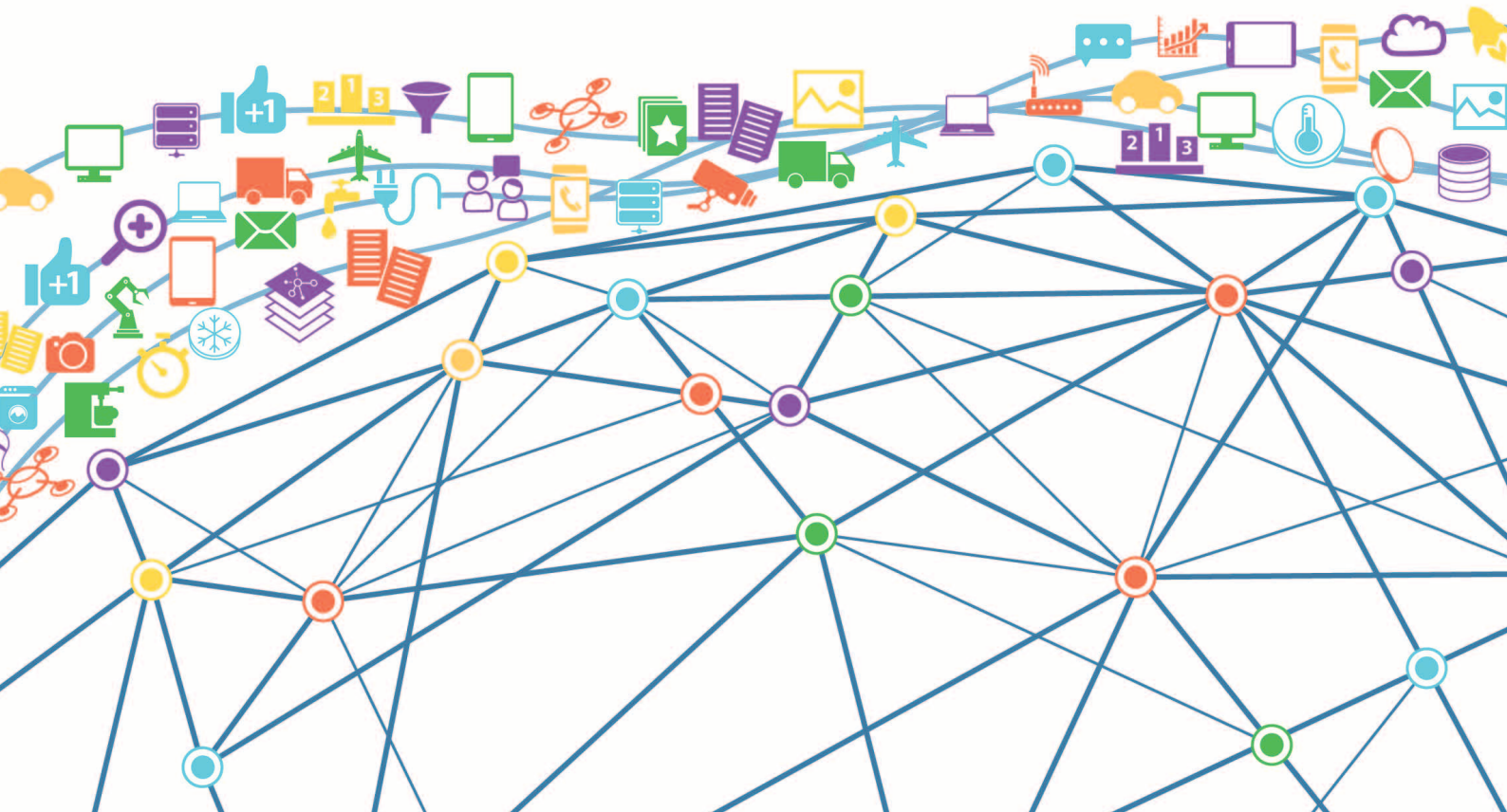

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Published in 2019 by the RAND Corporation, Santa Monica, Calif., and Cambridge, UK

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Preface

Oversight of emerging science and technology covers approaches or methods that encourage the development of scientific and technological innovations, and wider business arising from them, while also aiming to protect the interests of citizens and wider society. Science and technology oversight can take place through a range of mechanisms, including formal legislation, regulations, governance, non-regulatory standards and guidelines, as well as other informal elements like public engagement, agreements and international co-operation.

Wellcome commissioned RAND Europe to undertake a qualitative comparative study of the oversight of emerging science and technology in past and present cases, spanning different countries, sectors and time periods to draw out common learning from these examples. The study supports and feeds into a wider project that Wellcome is carrying out to identify steps that would be required to position the UK as a global leader in the effective, efficient and ethical oversight of emerging science and technology.

To address the primary objective of the study, we have developed a series of ten case vignettes, both historical and current, and encompassing diverse geographical contexts, sectors, and science and technology areas, to explore the effectiveness of different oversight methods and extract learning where possible. The study adopted a mixed-methods approach, employing a crowdsourcing exercise, desk research involving a rapid evidence assessment and key informant interviews, and a workshop.

The lessons we have drawn out in our analysis can be regarded as a set of guiding principles to help stakeholders think about effective ways in which to provide oversight with regard to emerging science and technology. We envisage that the lessons may be of interest to national and local government policymakers, industry, innovators, funders and academia, but also more broadly to anyone – including the public – interested in the development and adoption of new and emerging science and technology.

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Summary

Background and context

Emerging science and technology has a wide array of applications that cover many sectors and services. Most countries, including the UK, regard emerging science and technology as key drivers for achieving societal and economic benefits. This ambition, however, also presents numerous complex challenges. These include health, safety and environmental risks that may be associated with novel developments, together with public concerns and perceptions about new scientific techniques or technologies. The challenge is to establish structures that capitalise on the benefits and opportunities offered by emerging science and technology, while at the same time safeguarding the health and safety of citizens and minimising risk. This process of stewardship to shape the way emerging science or technology develops over time is referred to as the process of 'oversight'. We use an expansive interpretation of oversight in this study, broadly considering it to encompass methods that stimulate the development of science and technology, and business arising from them, while protecting the interests of citizens. This can include oversight approaches such as legislation, regulations, governance, standards and guidelines, and other informal elements like public engagement and international cooperation.

Objectives of the study

Wellcome commissioned RAND Europe to undertake a qualitative comparative study of the oversight of emerging science and technology in past and present cases, spanning different countries, sectors and time periods, to draw out common learning from these examples. The study supports and feeds into a wider project that Wellcome is carrying out to identify steps that would be required to position the UK as a global leader in the effective, efficient and ethical oversight of emerging science and technology. To address the primary objective, we have developed ten case vignettes, both historical and current, and encompassing diverse geographical contexts, sectors, and science and technology areas, to explore the effectiveness of different oversight methods and extract learning where possible.

Methodology

We adopted a mixed-methods approach to address the objectives of the study. Specifically, we employed the following methods:

- **Selecting the case vignettes**
  - A *crowdsourcing exercise* with stakeholders around the world to compile a long list of potential examples of emerging science

and technology oversight. (The stakeholders we approached included experts representing academia, government, regulatory and standards bodies, industry, and the third sector.)

- A series of *online searches* (using Google and Google Scholar) conducted in parallel with the crowdsourcing exercise to identify (additional) examples of emerging science and technology oversight.
- A *prioritisation exercise* with Wellcome to select the ten case vignettes around which to focus the study.

- **Developing the case vignettes**
  - Desk research involving an *accelerated evidence assessment* of the academic and grey literature related to each of the case vignettes.
  - A series of *interviews* with stakeholders connected to the case vignettes, in order to obtain deeper insights into the specific examples.
- **Comparative analysis of the case vignettes**
  - A *workshop* with Wellcome to cross-analyse the findings from the vignettes and extract common themes and lessons learnt in relation to the oversight of emerging science and technology.

Illustrations of emerging science and technology oversight in action

The case vignettes offer a 'real-life' illustration of how oversight has been carried out in practice in different contexts. Below we present short summaries of the ten case vignettes that the study focuses on.

The Cartagena Protocol on Biosafety

The growing use of genetically modified organisms during the 1990s, particularly in the area of agricultural biotechnology, brought with it growing public concern around the possible environmental and human health risks associated with GMOs. This particularly was seen in developing countries that were not yet participating in GMO trade and were concerned about the risks of entry of GMOs into their countries without their knowledge. To address these concerns, the 2003 Cartagena Protocol on Biosafety was developed as a legally binding international agreement to govern the transboundary movement of genetically modified organisms.

E-government and digital society in Estonia

From the mid-1990's onwards, Estonia emerged as an early promoter of both e-government and wider digital society related activities. Throughout the 1990s and 2000s, the government of Estonia took measures to support the integration of ICT into government services and lay the foundations for a digital society more broadly. Its oversight comprised wide-ranging mechanisms (and collaboration with private sector stakeholders), including: strategic policy documents; legislation; tax incentives; standardisation; technological infrastructure and capacity building; and educational programmes designed to build ICT skills.

Fintech regulatory sandboxes in the UK and beyond

The emergence of new, and potentially disruptive, financial technologies generates opportunities but also brings new risks, both for banking systems and

for consumers. Borrowing from 'sandbox' approaches deployed in other contexts, in 2015 the UK Financial Conduct Authority (FCA) developed the concept of a fintech 'regulatory sandbox'; a regulatory 'safe space' in which eligible firms can carry out limited tests on innovative fintech products while being exempt from certain regulatory requirements. The concept has proved popular with other governments, particularly in the Asia-Pacific region.

The Green Revolution: Agricultural technology in India

By the late 1950s, international agricultural research institutes had developed new High Yielding Varieties (or HYVs) of grain and wheat capable of being grown on a vast scale in a range of environments. Combined with a package of other agricultural innovations – including fertilizers, pesticides, and irrigation methods – HYVs promised a significantly higher agricultural yield than most 'traditional' crops. From the mid-1960s onwards, together with international stakeholders, the Government of India built an extensive public infrastructure focused on the promotion of these new agricultural technologies.

M-Pesa: Branchless mobile banking in Kenya

The M-Pesa service, delivered by the Kenyan mobile network operator, Safaricom, and the telecommunications company, Vodacom, in 2007, pioneered the use of mobile phones to extend basic banking services to populations previously without access. The development of M-Pesa prompted efforts by the Central Bank of Kenya to create an enabling environment for the growth of the service. The Bank worked closely with the service developers and citizens to facilitate the expansion of branchless mobile banking, while also trying to limit the potential financial risks associated with the technology.

DAMD: The Danish General Practitioners Database

From the late 1990s onwards, European countries began to promote digitalisation in healthcare systems. As part of this agenda, the digitalisation of patient data had the potential to dramatically improve the healthcare provision and the analysis of healthcare systems. Against this backdrop, from 2003 onwards, Danish General Practitioners (GPs) worked together with regional health authorities to develop a system that would automatically and continually capture and store the data collected by the ICT systems used by GPs.

The Global System for Mobile Communications

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 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 European Union, national governments and private stakeholders worked together to develop a pan-European standard for 2G cellular networks – the Global System for Mobile Communications (GSM).

The NIH Recombinant DNA Advisory Committee in the United States

Recombinant DNA (rDNA) technology began to emerge in the late 1960s with the development of techniques to splice DNA molecules. Recombinant DNA technology

offered a range of possibilities for molecular biological research, including gene therapy and genetic modifications. Recognising both the potential applications of rDNA, but also its multifaceted risks, the scientific community sought to develop fora in which the uses of rDNA could be discussed. In the United States, these efforts led to the formation, in 1973, of the National Institutes of Health (NIH) Recombinant DNA Advisory Committee.

The Human Fertilisation and Embryology Act in the UK

Responding to public and parliamentary concerns regarding the legal, social and ethical issues associated with developments in human fertility research and treatment, in 1990, the UK adopted the Human Fertilisation and Embryology Act. The Act regulated the licensing of clinics to ensure patient protection and established measures enabling scientific research to progress in a responsible manner. A key component was the creation of an independent regulatory body – the Human Fertilisation and Embryology Authority (HFEA) – to oversee assisted reproductive technologies.

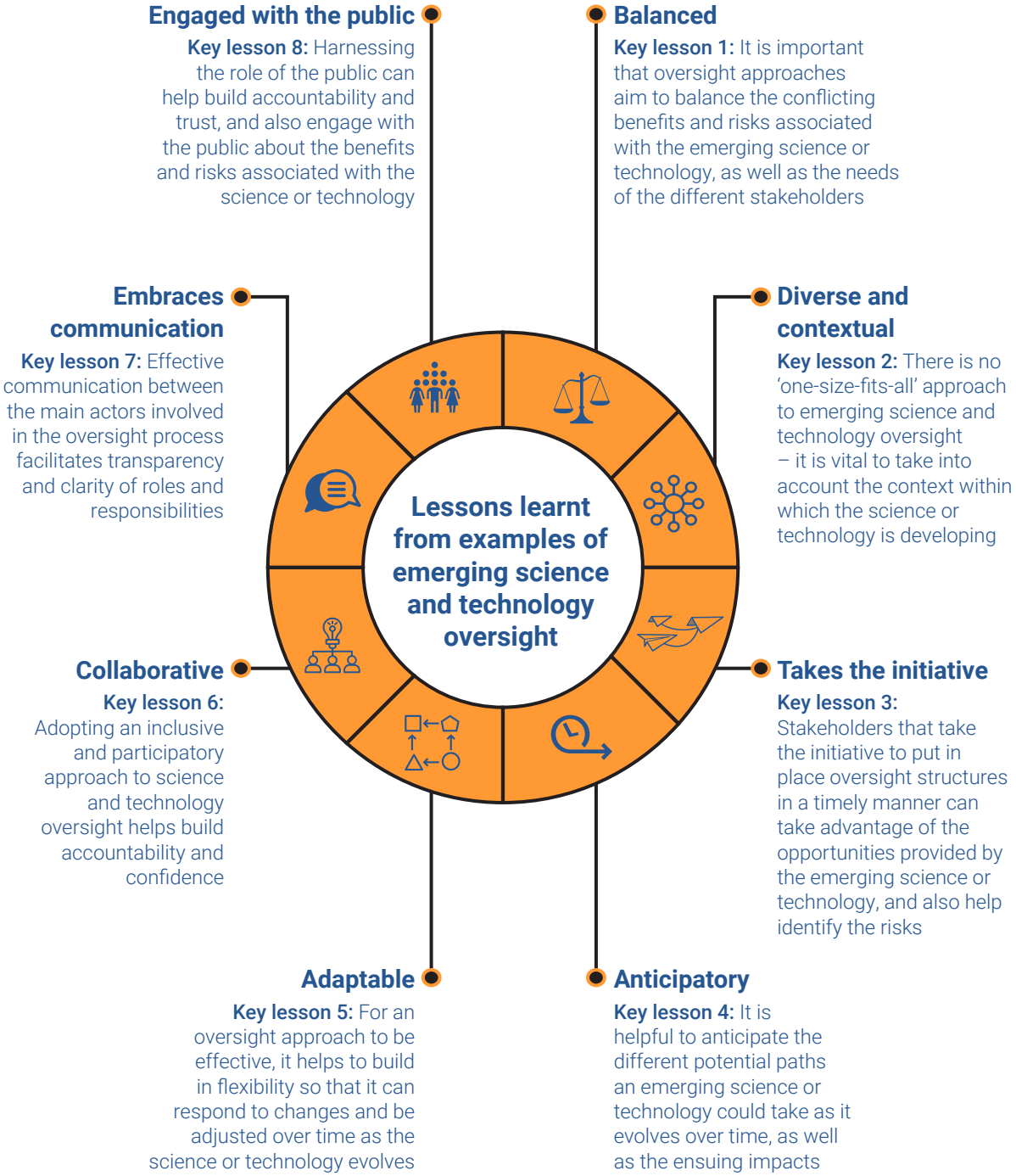
The first crypto-war: Public key cryptography in the United States

The invention of 'public key cryptography', in the mid-1970s, enabled two individuals to exchange encrypted messages between them. It therefore made it possible to incorporate complex encryption into everyday communication formats, such as phone and email-based networks, as these markets began to grow. Concerned about the impact of public encryption on their ability to monitor communications, agencies of the US Government sought to restrict public access to this technology. From the early 1990s onwards, they pushed programmes that would provide 'backdoors' into encryption systems. Meanwhile, a broad coalition of non-state actors – including cryptographers, privacy advocates and industrial interests – fought against the government's agenda. Driven by a range of interests, from the protection of civil liberties to concerns about industrial competitiveness, these groups tried to protect widespread, unmediated access to encryption systems.

Learning from past and present oversight efforts

In Figure 1, we reflect on the ten case vignettes and articulate what has been learnt across them. We have sought to better understand what we can learn from a historical review of the variety, progression and achievements – both positive and negative – of different oversight methods. These lessons can be regarded as a set of guiding principles to help stakeholders think about ways in which to provide oversight of emerging science and technology. The lessons are intertwined with each other and share some common aspects; they are not intended to be a 'silver bullet' or solution for emerging science and technology oversight. Rather, we offer them as key themes derived from historical and current examples that could be associated with the effective, efficient and ethical delivery of science and technology oversight. It is also worth noting that it is not necessarily possible for an oversight approach to use all of the different lessons at once. For example, being adaptable and taking initiative while also being collaborative and engaging the public can be difficult because of the challenge to act quickly and decisively while also taking in views from across the public and other stakeholders. It is necessary to consider the importance of the different lessons to the situation at hand, and trade-off between them to establish an oversight approach that works in a

Figure 1: Summary of lessons learnt from the examples of emerging science and technology oversight



particular context. In addition, it is important to acknowledge that the effectiveness of oversight approaches depends on the benefits and risks of the technology to which they are applied.

We envisage that the lessons may be of interest to national and local government policymakers, industry, innovators, funders and academia, but also more broadly to anyone – including the public – interested in the development and adoption of new and emerging science and technology. They are meant to stimulate discussion and debate about how oversight strategies could encourage and shape the advent of emerging science and technology – both in terms of businesses and industry that might develop over time, as well as the potential benefits reaching people swiftly and effectively. The lessons we present have been articulated to be science or technology 'agnostic'. As such, they could be applied in different current or future contexts where oversight strategies might be required to leverage the anticipated benefits of emerging science and technology while safeguarding against the potential risks and uncertainties. Developing a better understanding of what has happened in the past – both in terms of the oversight being effective and not so effective – can help inform decisions about science and technology oversight in the future. It is hoped that the analysis we have undertaken provides some important insights and learning about science and technology oversight that could potentially be applicable in future contexts.

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Abbreviations

AIA	Advanced informed agreement
AMPS	Advanced Mobile Phone System
ART	Assisted reproductive technology
CA	Communications Authority, Kenya
CEPT	Conférence des Administrations Européennes des Postes et Telecommunications
CIA	Central Intelligence Agency, United States
CIMMYT	International Maize and Wheat Improvement Center (From the Spanish 'Centro Internacional de Mejoramiento de Maíz y Trigo')
CKE	Commercial key escrow
COPD	Chronic pulmonary disease
CORE	Comment on Reproductive Ethics
CPSR	Computer Professionals for Social Responsibility
DAK-E	Danish Quality Unit of General Practice
DAMD	Danish General Practitioners Database (From the Danish 'Dansk AlmenMedicinsk Database')
D-AMPS	Digital-Advanced Mobile Phone Service
DfID	Department for International Development, United Kingdom
DI	Donor insemination
DLT	Distributed Ledger Technology
DNA	Deoxyribonucleic acid
DPSWG	Digital Privacy and Security Working Group
ETSI	European Telecommunications Standards Institute

FBI	Federal Bureau of Investigation, United States
FCA	Financial Conduct Authority, United Kingdom
FCC	Federal Communications Commission, United States
FDA	Food and Drug Administration, United States
1G	First generation mobile communications technology
2G	Second generation mobile communications technology
GMO	Genetically modified organisms
GOI	Government of India
GP	General Practitioner
GSM	Groupe Spécial Mobile
GSM Standard	Global System for Mobile Communications
GSMA	GSM Association
HFE Act	Human Fertilisation and Embryology Act
HFEA	Human Fertilisation and Embryology Authority, United Kingdom
HGTS	Human Gene Therapy Subcommittee
HYV	High Yielding Varieties
IBC	Institutional Biosafety Committee
ICAR	Indian Council of Agricultural Research
ICSI	Intracytoplasmic sperm injection
ICT	Information and communications technology
IPR	Intellectual property rights
IRB	Institutional Review Board
IRRI	International Rice Research Institute
IVF	In vitro fertilisation
LMO	Living modified organisms
MFA	Ministry of Food and Agriculture, India
NDP	National Demonstration Programme
NIH	National Institutes of Health
NMT	Nordic Mobile Telephony

NSA	National Security Agency, United States
OECD	Organization for Economic Cooperation and Development
PLO	Danish Organisation of General Practitioners
P2P	Person-to-person
RAC	Recombinant DNA Advisory Committee
rDNA	recombinant DNA
RIA	Information System Authority, Estonia
SAE	Serious adverse events
SIM	Subscriber Identity Modules
SMS	Short message service
SSI	Statens Serum Institut
TDMA	Time-Division Multiple Access
USAID	United States Agency for International Development
VLA	Voluntary Licensing Authority, United Kingdom
WTO	World Trade Organization
WTP	Willingness-to-pay

Acknowledgements

We are very grateful to Beth Thompson, Joseph Clift and Gemma Wardle at Wellcome Trust for their helpful guidance and support throughout the project. We would like to thank all of the respondents to our successful crowdsourcing exercise who provided examples of oversight, and the numerous individuals who contributed to the development of the case vignettes through interviews and discussions. We would also like to thank our reviewers, Advait Deshpande and Susan Guthrie, for their critical and constructive comments on earlier versions of this report during the quality assurance process.

1 Introduction

1.1. Background and context

Emerging science and technology has an array of applications that cover many sectors and services. Current examples – which are at different stages of development and adoption – include artificial intelligence, autonomous transport, biotechnology, blockchain/ distributed ledger technology, cloud computing, genomics, the Internet of Things, machine learning, nanotechnology, quantum computing, robotics, synthetic biology and social media platforms. Most countries, including the UK, regard emerging science and technology as key drivers for achieving societal and economic benefits (UK Government 2018). This ambition, however, also presents numerous complex challenges. These include health, safety and environmental risks that may be associated with novel developments, together with public concerns and perceptions about new scientific techniques or technologies

The challenge is to establish structures that safeguard the health and safety of citizens and minimise risks, while at the same time capitalising on the benefits and opportunities offered by emerging science and technology. This process of stewardship is referred to as 'oversight' (Marchant, Allenby and Herkert 2011). Science and technology oversight can take place through a range of mechanisms and instruments, both public and private, including regulations, governance, standards, consultations and civil society movements, all of which can take place at the regional, national and international level. Oversight can therefore involve a variety of stakeholders, including government departments, research funders, industry, academia and the public (Marchant, Allenby and Herkert 2011).

Effective oversight is important for instilling public confidence in new science and technology. In this sense, it should be seen as a part of the process through which technologies come to be adopted by society. Effective oversight can also help in establishing the broader market confidence needed for companies and other stakeholders to make investments in technologies, as well as the research that will ensure their continued development. At the same time, oversight performed ineffectively can have many negative consequences. Restrictive approaches designed to mitigate a new technology's risks to human safety, security or the environment, for example, have the potential to restrict the development of a new technology, creating barriers to both innovation and adoption. Equally, oversight that prioritises the opportunities of a technology, with limited consideration of the potential health and safety risks, can expose populations (and environments) to unnecessary dangers (Kuzma 2007; Marchant, Allenby and Herkert 2011).

A major challenge regarding the oversight of emerging science and technology is the fact that, because the science/technology is emerging, the full extent of the risks and challenges associated with a new science or technology, and the most appropriate ways to mitigate these risks, may therefore not be known. Due to this indeterminacy, oversight is a process that can benefit from an understanding of how the respective benefits and drawbacks of new scientific and technological innovations have been managed – whether successfully or unsuccessfully – in the past (Kuzma and Priest 2010; Marchant, Sylvester and Abbott 2009). Past experiences can provide specific lessons about the oversight of certain types of technology – for example, genetically modified organisms (GMOs) – while also permitting the development of more general, overarching lessons concerning the components of effective oversight across all areas. They can therefore help identify the steps needed for the development of effective, efficient and ethical

systems of science and technology oversight in the future.

1.2. Objectives of the study

Wellcome commissioned RAND Europe to undertake a qualitative comparative study of the oversight of emerging science and technology in past and present cases, spanning different countries, sectors and time periods, to draw out common learning from these examples. The study supports and feeds into a wider project that Wellcome is carrying out to identify steps that would be required to position the UK as a global leader in the effective, efficient and ethical oversight of emerging science and technology. To address the primary objective, we have developed ten case vignettes, both historical and current, and encompassing diverse geographical contexts, sectors, and science and technology areas, to explore the effectiveness of different oversight methods and extract learning where possible.

1.2.1. What do we mean by oversight in the context of this study?

For this study, we have relied on a holistic and inclusive characterisation of oversight: we broadly consider it to cover approaches or methods that encourage the development of scientific and technological innovations, and wider business arising from them, providing both economic and societal benefits, while at the same time aiming to protect the interests of citizens and wider society. In other words, we regard oversight to include any attempt to shape the pathway that an emerging science or technology takes within society and the economy. This can include approaches such as formal legislation, regulations, governance, and non-regulatory (i.e. non-mandatory) standards and guidelines, as well as other informal elements like public engagement, agreements and international co-operation. In addition to the different ways in which oversight can be implemented, we are interested in the different stakeholders that are involved in the oversight process. For example, we are interested in the oversight of science and technology that is performed by governments (both at the central and regional level) and government-appointed bodies, as well as by other non-state actors, including, but not limited to, private sector entities, international organisations and wider civil society.

1.3. Summary of the methodology

We adopted a mixed-methods approach to address the objectives of the study. Specifically, we employed the following methods:

- **Selecting the case vignettes**
  - A *crowdsourcing exercise* with stakeholders around the world to compile a long list of potential examples of emerging science and technology oversight (and to the extent possible, information related to the examples, e.g. sources of literature, interviewee suggestions). (The stakeholders we approached included individuals and science/technology experts representing academia, government, regulatory and standards bodies, industry, and the third sector.)
  - A series of *online searches* (using Google and Google Scholar) conducted in parallel with the crowdsourcing exercise to identify (additional) examples of emerging science and technology oversight.[1]

1 In the online searches we conducted, we found examples identical to those suggested in the crowdsourcing exercise, as well as a number of additional examples.

  - A *prioritisation exercise* with Wellcome to select the ten case vignettes to focus the study around.
- **Developing the case vignettes**
  - Desk research involving an *accelerated evidence assessment* of the academic and grey literature related to each of the case vignettes.
  - A series of *interviews* with stakeholders connected to the case vignettes, in order to obtain deeper insights into the specific examples.[2]
- **Comparative analysis of the case vignettes**
  - A *workshop* with Wellcome to cross-analyse the findings from the vignettes and extract common themes and lessons learnt in relation to the oversight of emerging science and technology.

1.4. Outline of the report

The ten case vignettes illustrating different approaches to emerging science and technology oversight in diverse contexts are presented in Chapter 2. In Chapter 3, having looked across these vignettes, we reflect on some common themes and 'lessons' that can be learnt from the examples presented in Chapter 2, and discuss the findings in relation to effectively approaching the oversight of emerging science and technology. Chapter 3 ends with some concluding reflections. In Appendix A, we present a detailed description of the methodological approach and highlight some of the limitations of the analysis.

2 Interviewee inputs are cited within the report using the identifier 'INTXX', where XX is a number between 01 and 10.

2 Illustrations of emerging science and technology oversight in action

This chapter presents the ten case vignettes that the study focuses on to draw out common themes and lessons in relation to the oversight of emerging science and technology. As noted in Chapter 1, we use a holistic interpretation of oversight, broadly considering it to encompass methods that stimulate the development of science and technology, and business arising from them, while protecting the interests of citizens. This can include oversight approaches such as legislation, regulations, governance, standards and guidelines, and other informal elements like public engagement and international co-operation.

The ten case vignettes cover different oversight types/methods and science/technology areas, and cut across different geographical contexts, sectors and time periods. For each of the vignettes, we collected and analysed the following information: the background and context (i.e. what the emerging science or technology area was and when the oversight took place); why oversight was needed; how the oversight was carried out; the effectiveness of the oversight; and the lessons that can be learnt from the oversight example. To get a balanced understanding of the effectiveness, we were interested in what worked well and not so well in the context of the oversight.

The ten vignettes, each of which is discussed in turn below, are:

1. The Cartagena Protocol on Biosafety
2. E-government and digital society in Estonia
3. Fintech regulatory sandboxes in the UK and beyond
4. The Green Revolution: Agricultural technology in India
5. M-Pesa: Branchless mobile banking in Kenya
6. DAMD: The Danish General Practitioners Database
7. The Global System for Mobile Communications
8. The NIH Recombinant DNA Advisory Committee in the United States
9. The Human Fertilisation and Embryology Act in the UK
10. The first crypto-war: Public key cryptography in the United States

2.1. Case vignette 1
The Cartagena Protocol on Biosafety

Summary

This case vignette concerns the oversight of the use and release of genetically modified organisms (GMOs) in the context of agricultural biotechnology.

The growing use of genetically modified organisms during the 1990s, particularly in the area of agricultural biotechnology, brought with it growing public concern around the possible environmental and human health risks associated with GMOs. This particularly was seen in developing countries that were not yet participating in GMO trade and were concerned about the risks of entry of GMOs into their countries without their knowledge. To address these concerns, the 2003 Cartagena Protocol on Biosafety was developed as a legally binding international agreement to govern the transboundary movement of genetically modified organisms.

2.1.1. Background and context

The creation of genetically modified organisms (GMOs) through genetic engineering techniques presented a number of opportunities for agriculture and food production. Genetic engineering of crops involves directly modifying the DNA of crops to introduce specific, desirable traits; for example, making crops that are: more resistant (e.g. to increasing temperatures, decreased water availability, infectious diseases), more nutritious, or that produce beneficial compounds, such as pharmaceuticals (Jaffe 2005; Ronald 2011). The advent of GMOs presented opportunities to improve food security, as well as health and nutrition, in developing countries. However, at the same time, there has been public concern that GMOs may pose risks to biodiversity and human health (Jaffe 2005).[3]

Genetic engineering technologies became available in the late 1970s and early 1980s (Falck-Zepeda and Zambrano 2011). During the early 1990s, genetically modified crops became commercially available, leading to a high use of GMOs in agriculture in a number of countries worldwide; for example, in the United States over 90 per cent of soybean, cotton and corn grown are GM varieties (Gupta 2000).

2.1.2. Why was oversight required?

In the 1990s, the use and release of GMOs, particularly in the area of agricultural biotechnology, was rapidly increasing (Eggers and Mackenzie 2000). Genetic engineering of crops had the potential to increase agricultural productivity and reduce the need for environmentally harmful pesticides by producing plants that are more resistant to

3 Opposition to GMOs has been particularly present in the EU where public opinion was influenced by previous food safety scandals such as Bovine spongiform encephalopathy (or mad cow disease), strong campaign groups and NGOs, and the media, which played a significant part in highlighting the potential dangers of GMOs, especially at the end of the 1990s and at the beginning of the 2000s (Cheng 2007; Bonny 2003). At the same time, public research organisations remained relatively silent on the subject of GMOs, which further strengthened public concern (Bonny 2003).

disease, cold, heat, drought and flood (Kohm 2009).

However, at the same time, there was growing public concern around the possible environmental and human health risks associated with GMOs (Newell and Mackenzie 2000; Kohm 2009). This particularly was seen in developing countries which were not yet participating in GMO trade and were concerned about the risks of entry of GMO products into their countries without their knowledge (Gupta and Falkner 2006). Although national regulatory frameworks for the safe use of biotechnology already existed in a variety of developed and developing countries, a number of stakeholders felt there was a need for an international agreement to harmonise existing frameworks (Gupta 2000).[4]

2.1.3. How was the oversight carried out?

In the early 1990s, developing countries suggested that there was a need for a provision on biosafety under the pre-existing Convention on Biological Diversity (Gupta 2000).[5] This desire was supported by environmental groups and some Nordic countries (Gupta 2000). By contrast, other developed countries, including the United States, those in the EU, and Japan, did not feel there was a need for a legal instrument that might restrict the development of their biotechnology industry (Gupta 2000).

In 1995, the Conference of the Parties to the Convention on Biological Diversity decided to initiate negotiations on a Protocol on the safe transfer, handling and use of GMOs, focusing in particular on transboundary movement (Newell and Mackenzie 2000). An Ad Hoc Working

4 The harmonisation of biosafety frameworks was felt to be needed to avoid trade disruptions caused by delayed authorisations due to regulatory uncertainty and unpredictability (Escaler, Teng and Powell 2012).

5 The Convention on Biological Diversity is an international convention signed by 168 countries and which aimed to help countries develop national strategies for conservation and sustainable use of biological diversity (Convention on Biological Diversity 2018).

Group on Biosafety was established, whose purpose was to develop a draft text of the Protocol (Gupta 2000). In 2000, following over three years of negotiations between more than 100 countries,[6] a Protocol was finally agreed to that aimed to represent a balance between market access for biotechnology products and the promotion of environmental and health policy concerns.

The Cartagena Protocol on Biosafety ('the Protocol') is the first legally binding international agreement that governs the transboundary movement of genetically modified organisms (GMOs) (called living modified organisms (LMOs) under the Protocol) (Biosafety Unit 2013). The Protocol entered into force in 2003 and is implemented in 171 countries (Kinderlerer 2008; Convention on Biological Diversity 2012). The Protocol restricts the movement of GMOs in accordance with the precautionary principle, i.e. that GMOs should not be used until there is scientific consensus that they are safe[7] (Kohm 2009). The Protocol regulates two types of GMO: (1) those that will be intentionally introduced into the environment (e.g. seeds for planting); and (2) those used for food, feed or processing (FFP) (e.g. GM products such as soybeans or maize) (Jaffe 2005). The Protocol does not cover consumer products (e.g. foods) that contain ingredients derived from GMOs (Jaffe 2005).

The key element of the Protocol is a prior notification and consent procedure for the export and import of GMOs, known as an 'advanced informed agreement' (AIA). The AIA requires that GMO-exporting countries provide a notice with detailed information about the GMO to importing countries, to allow the importing country to assess the potential risks to biodiversity and human health posed by such transfers (Newell and Mackenzie 2000). For GMOs in FFP, which are less likely to impact on the biodiversity of an importing country,[8] exporting countries are required to communicate their safety decision through the 'Biosafety Clearing House', an online platform that facilitates information exchange.

Countries that are signed up to the Protocol must establish national biosafety laws and regulations to implement its provisions (Jaffe 2005).[9] Therefore, the Protocol also contains provisions for capacity building to help developing countries set up national biosafety frameworks and expand scientific, regulatory and administrative capacity (Gupta and Falkner 2006). This includes providing scientific and technical training in the management of biotechnology and in the use of risk assessment and risk management for biosafety and institutional strengthening. Developed countries provide financial assistance primarily through the Global Environment Facility (an independently operating financial organisation), as well as through bilateral, regional and multilateral channels. The global 'Action Plan for Building Capacities for the Effective Implementation of the Protocol', developed

6 In the negotiating process, countries split into five interest groups, spanning countries that were mainly exporters (including the US) who wanted to avoid excessive trade restrictions on GMOs, through to developing countries that were mostly importers, and whose primary concern was to protect those countries without the capacity to refuse GMO imports, with the EU broadly in between these polarised opposites (Newell and Mackenzie 2000).

7 The precautionary principle puts the burden of proof on proving GMOs are safe, rather than assuming they are safe and proving they are dangerous

8 GMOs used for feed, food or processing are considered lower risk, as they are not capable of transferring or replicating genetic material.

9 While the protocol is legally binding there is no enforcement mechanism to ensure requirements are followed.

by the Intergovernmental Committee for the Cartagena Protocol on Biosafety in 2001, also helps governments address capacity building. The Protocol provides regulatory procedures for the use of GMOs released into the environment or for FFP, which can be copied into national biosafety systems, and are proportionate, depending on the intended use of the GMO (Jaffe 2005). The Protocol also provides risk assessment information (Jaffe 2005). The Protocol leaves it up to each individual country to establish the safety standards that it believes must be satisfied before consenting to a GMO (Jaffe 2005). The Protocol also primarily addresses environmental issues and does not substantively address food safety concerns surrounding GMOs.

2.1.4. How effective was the oversight?

The Protocol has been ratified by 171 countries to date (Biosafety Unit 2018). It has contributed to capacity building in developing countries that have established biosafety regulations and protocols as a result of the Protocol (Convention on Biological Diversity 2015). It has also contributed to the sharing of information about GMOs through the Biosafety Clearing House (Convention on Biological Diversity 2015). While it has provided guidance and assistance with capacity building, it has also allowed countries to make decisions they feel are appropriate to their situations. For example, the Protocol allows countries to take into account any potential socio-economic consequences that might arise from an adverse impact on biodiversity, such as genetically modified seeds replacing traditional ones and affecting the local environment, culture and tradition (Ricci 2004).

While it did not initially contain a process for a liability mechanism for any potential health or environmental risks resulting from GMOs, this has now been added with the adoption, in 2010, of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress (the 'Nagoya Supplementary Protocol') (Tung 2014). In general the Protocol is seen as a success of the precautionary principle, allowing countries that wish to follow this principle to do so.

The Protocol has also faced a number of criticisms (Jaffe 2005; Adenle et al. 2018). It has been implicated in the delaying of agricultural research and innovation in a number of ways. First, as countries are allowed to decide for themselves whether products are safe, the Protocol is thought to have delayed research and innovation that may help provide solutions to food security in developing countries (Adenle et al. 2018). For example, in India, where the precautionary principle is being used relatively strictly, some GM crops have been heavily regulated and involved in numerous legal challenges, reducing consumer confidence. There have also been a number of delays in risk-assessment decisions (Adenle et al. 2018). The protocol is also felt to have made it more difficult to share genetic materials across borders, affecting what research can be carried out and how it can be carried out, (Welch et al. 2017).

Since the adoption of the Protocol, there have also been issues related to the harmonisation of national biosafety regulations, with fragmentation of the policy environment increasing the complexity of conducting publically-funded agricultural research using genetic materials (Welch et al. 2017). The Protocol tries to balance the needs of individual countries to retain their national sovereignty, while at the same time attempting to establish harmonised global biosafety regulations in GMO trade (Jaffe 2005). It is therefore not prescriptive regarding the frameworks countries should put in place, which has led to countries developing regulatory frameworks with different standards. The fragmentation

of national biosafety regulations can have negative impacts on industry, in terms of barriers to trade and increased cost (Tung 2014). There have also been concerns raised about conflicts between the Protocol and World Trade Organisation (WTO) rules (Gupta and Falkner 2006). The precautionary principle approach of the Protocol is thought to conflict with WTO rules, which state that members should not restrict trade unless there is firm scientific consensus that such trade may be harmful (Gupta and Falkner 2006). The Protocol has therefore been seen by a number of GMO-exporting countries as constituting an excessive barrier to trade, and many GMO-exporting country, including the United States, Canada and Argentina, have not ratified the Protocol (Gupta and Falkner 2006). This transatlantic GMO conflict hinders the development of a shared global approach to biosafety regulation and potentially also hinders the development and implementation of the Protocol (Gupta and Falkner 2006).

2.1.5. What lessons can be learnt from this example?

The Cartagena Protocol is an example of a heavily negotiated international agreement that attempts to achieve a compromise between several complex and contradictory issues.[10] Specifically, in this case, this involved protecting the environment, enabling free trade in biotechnology products, and ensuring both global governance and allowing for national sovereignty in regulatory decisions (Tung 2014). This example exhibits the trade-offs that arise when balancing the need for prescription of regulatory structures and systems in order to have a harmonised international system, and the need for discretion in national oversight decisions to account for local cultures, needs and expectations. The needs of societies individually and their independence is traded off against business interests and also the interests of rapid innovation. In the case of the Cartagena Protocol, there is flexibility in how countries can implement their regulatory processes, but this has been criticised in leading to the slowing of innovation (Adenle et al. 2018).

The Protocol also provides provisions for capacity building in developing countries related to regulation of GMOs. A number of countries have developed regulatory acts and bodies; however, the capacity building has also been criticised for adopting a short-term rather than a long-term approach, thus failing to deliver the kind of capacity required to develop functional biosafety systems (Adenle et al. 2018). This highlights the need to accompany approaches that are intended to foster independent decision making with appropriate resources and support for implementation, while acknowledging that independent decision making may take time to put into place.

10 It is worth noting that the Protocol is still being negotiated, modified and used (Convention on Biological Diversity 2015).

2.2. Case vignette 2
E-government and digital society in Estonia

Summary: This case vignette discusses the development of e-government and digital society within Estonia from the 1990s to the present day.

E-government refers to the use of information and communications technology (ICT) to improve public sector activities. The concept of a digital society is an extension of e-government, where ICT solutions are adopted widely throughout society. From the mid-1990s onwards, Estonia emerged as an early promoter of both. Throughout the 1990s and 2000s, the government of Estonia took proactive measures to support the integration of ICT into government services and lay the foundations for a digital society more broadly. Its oversight comprised wide-ranging mechanisms including: strategic policy documents; legislation; tax incentives; standardisation; technological infrastructure and capacity building; and educational programmes designed to build ICT skills. Across many of these areas, collaboration with private sector stakeholders, particularly the banking sector, was key.

2.2.1. Background and context

E-government refers to the use of information communication technology (ICT) to improve public sector activities (Björklund 2016). These activities could include completing tax returns, participating in censuses and voting, as well as communication between the government, public institutions and citizens. The concept of a digital society is an extension of e-government, where ICT solutions are adopted widely throughout society. In a digital society, individuals can use the Internet to perform services such as accessing medical records, obtaining prescriptions, managing finances, registering a company, and even applying for digital citizenship (Enterprise Estonia 2018a).

E-government through ICT promises a wide range of short- and long-term benefits. As well as increasing the effectiveness and efficiency of public administration, it has the potential to increase public engagement with government. The development of digital skills can also support future economic growth in the knowledge economy.

The public sector has generally lagged behind the private sector in the integration of ICT solutions (Björklund 2016). Moreover, while some governments began integrating ICT in the 1980s and 1990s,[11] this work was commonly siloed within institutions and usually outsourced to the private sector (Margetts and Naumann 2017). Since the mid-1990s, however, Estonia has emerged as an early adopter of ICT approaches. Despite being in the bottom quartile of European countries by gross domestic product (International Monetary Fund 2018), Estonia has led Europe in the provision of digital public services since the turn of the century (DESI 2018).

2.2.2. Why was oversight required?

For the Estonian government, the development of a digital society provided a means to revitalise Estonia's democracy and

11 Such as the UK government (Margetts and Naumann 2017).

economy following independence from the Soviet Union in 1991 (Runnel, Pruulmann and Reinsalu 2009). In particular, the Estonian government saw digitisation as a means to improve competitiveness, boost administrative capacity, increase social cohesion and facilitate more interaction between individuals and the government (Runnel, Pruulmann and Reinsalu 2009; Björklund 2016). The decision to prioritise digital transformation was by no means an automatic one for an impoverished post-Soviet nation (INT01).[12] The Estonian government's embrace of the digital agenda must be understood as the result of number of inter-related processes, including: an aspiration to follow similar processes then occurring in the European Union (the joining of which was an important national goal at the time); an inherited Soviet view of technology as a modernising force; and the coincidence of a group of influential political figures who shared the view concerning the benefits of digitisation (Runnel, Pruulmann and Reinsalu 2009; INT01).[13] Despite having very limited ICT infrastructure (due to a historic inability to import freely under the Soviet regime), during the early 1990s the government decided that ICT should be a priority for the country and this vision became a core feature of the political agenda (Runnel, Pruulmann and Reinsalu 2009).

Governmental oversight activities aimed to support the envisioned digital change (Runnel, Pruulmann and Reinsalu 2009). Integrating ICT throughout society was a challenge of such scale that actors across the public, private and commercial banking sectors all had to be involved (Kitsing 2010). Additionally, while Estonia was seen as being well-positioned for an ICT revolution due to factors such as a high average level of education (Runnel, Pruulmann and Reinsalu 2009), integrating ICT into education programmes was seen as vital to capturing the full benefits of a digital society. Reservations from some social scientists regarding the possibility of ICT increasing societal stratification highlighted the need to bring all of Estonian society into the information age (Runnel, Pruulmann and Reinsalu 2009). Government-level oversight was required to address these core challenges.

2.2.3. How was the oversight carried out?

The Estonian government followed a top-down approach to driving the vision of a digital society, focusing on state-initiated projects without substantial meaningful public consultation about the future society (Runnel, Pruulmann and Reinsalu 2009). While there were some attempts to foster citizen participation and interaction through online consultation websites (such as Täna Otsustan Mina and later Osale.ee),[14] a top-down emphasis of central control and coordination – the public sector leading the way – has been a consistent theme of Estonian government oversight (Margetts and Naumann 2017). Broadly, the forms of oversight conducted have included high-level policy strategies; ICT capacity building and educational programmes; legislation and tax incentives; the development of technological infrastructure; and the development of standards to protect privacy and security. At the same time, the growth of digital society has also relied on the engagement and initiative of other stakeholders, in particular the banking sector (Kitsing 2010).

12 Interviewees are cited throughout the report using the identifier 'INTXX', where XX is a number between 01 and 10.

13 These visionaries included the former foreign minister, Toomas Hendrik Ilves, and the former prime minister, Mart Laar (Runnel, Pruulmann and Reinsalu 2009).

14 These websites were established to act as democratic forums where legislation could be proposed and discussed.

Strategic policy documents such as the 1994 Estonian Way to the Information Society laid out the guiding principles of the Estonian information policy and functioned as an action plan for government agencies (Runnel, Pruulmann and Reinsalu 2009; Margetts and Naumann 2017). The targeted actors were not just public institutions but also private sector entities and commercial banks (Kitsing 2010). The government took a non-prescriptive approach to commercial regulation (Kalkun and Kalvet 2002), so while the private sector benefitted from positive publicity around ICT, it was not held back by excessive regulation. The Principles of the Estonian Information Policy, adopted in 1998, set out new guiding principles for the digital transition and emphasised the need for public consultation (Runnel, Pruulmann and Reinsalu 2009; Margetts and Naumann 2017). Strategic oversight activities have continued throughout the 2000s with a string of strategies and policies, including a broadband strategy in 2011, a cyber security strategy in 2012 (updated in 2014), and a series of information society strategies culminating in the most recent 2014–2020 strategic plan (Riigikogu 2014).

The government also sought to build ICT skills within the population to harness the benefits of a digital society and avoid social exclusion risks. In 1996, they launched the Tiger Leap programme, a Ministry of Education-funded initiative focused on the development of ICT capacity in education. Key features of the programme included the provision of Internet access and computer equipment to all schools, a target to increase digital literacy, and the availability of computer science classes.[15]

The Estonian government also used the tools of legislation and tax incentives to support their digital agenda (Ott 2014). Legislation was used to support standardisation, protect intellectual property rights, fight monopolies and support fair competitions, and tackle the threat of the digital divide (the potential for access to ICT and the associated opportunities to differ according to factors such as location and socio-economic conditions (Kalkun and Kalvet 2002)). Legislation such as the Public Information Act served to lay the foundations for a digital society. The Act obliges government agencies and public institutions to have online interaction and to give every individual the opportunity to access information intended for public use (Riigikogu 2000b). This transparency is part of a series of measures to build public trust in the digital society. Another key measure is that citizens can see a digital log of exactly which administration has accessed what personal data of theirs. Tax benefits have been offered to incentivise key investments for the future (Ott 2014).

The creation of a suitable technological architecture was another important feature of governmental oversight. The infrastructural backbone of Estonia's digital society is the 'X-road', a data exchange layer that connects public registers, private companies and the banking industry (Runnel, Pruulmann and Reinsalu 2009; Björklund 2016; Kalvet 2007). The platform was first introduced in 2001 by the Information System Authority (RIA) to create a secure and standardised environment

15 Improving ICT-related skills through education has been a long-term oversight activity. The Information Technology Foundation for Education (known as HITSA), a non-profit association established jointly by the Republic of Estonia, the University of Tartu, Tallinn University of Technology, Eesti Telekom and the Estonian Association of Information Technology and Telecommunications in 2000, has led this pursuit (HITSA n.d.). Two key objectives of HITSA were to ensure graduates of each education level had modern digital competences and that ICT was used effectively to increase the quality of teaching more broadly (HITSA 2014). These objectives are met through actions such as developing assessment models, integrating ICT use into curricula and offering intensive ICT study options.

to enable interoperability between public institutions. X-road does not hold data centrally, but rather links individual servers with end-to-end encryption pathways (Björklund 2016). As encapsulated in systems like the X-road, the notion of exchange of information between parties was a central feature of Estonia's push for a digital society. This also, however, raised privacy and security concerns. One government strategy for addressing such concerns was the development of robust identification and authentication systems that reduced the possibility of fraud resulting from participation in online processes. The issuance of electronic ID cards was the chosen mechanism to meet this challenge (Priisalu and Ottis 2017). These cards contain a chip carrying cryptographic keys that enable citizens to provide a digital signature with the same legal standing as a manual signature (Priisalu and Ottis 2017; Riigikogu 2000a).[16] The card system ensures that the content of data cannot be changed by intermediaries, while also enabling citizens to track who has accessed their data (Priisalu and Ottis 2017). If a citizen suspects that their personal records have been accessed by an unauthorized entity, they can report it to the government for investigation (Priisalu and Ottis 2017). Cooperation and standardisation between the public sector, private sector and banking sector was key to ensuring engagement with the electronic ID cards (Margetts and Naumann 2017).

The Estonian banking sector was a willing participant, and to some extent an active driver, of Estonia's digital transformation more

16 The Estonian Digital Signatures Act was repealed in 2016 and replaced with the Electronic Identification and Trust Services for Electronic Transactions Act to align with the EU eIDAS regulation (No 910/2014) (Riigi Teataja n.d.)

generally (Kitsing 2011). Before most other European banking sectors, Estonian banks embraced 'Internet banking' and ICT-based banking solutions as a means of reducing transaction costs, creating opportunities for the cross-selling of services and anticipating future market demands (Kerem 2003). The quality and simplicity of Internet banking solutions, first established in 1996, not only laid the foundations for the government's own digital infrastructure (the electronic ID system was in part based on an earlier identification verification system developed by banks), but also helped to encourage citizen use of online services (Kitsing 2011; INT01). The initiative of Estonian banks, in this regard, was in part due to the fact that they were very young (commercial banking having only been legalised in the Soviet Union in 1988), with little in the way of legacy infrastructure (Kerem 2003).[17]

2.2.4. How effective was the oversight?

In many respects the Estonian government's attempts to foster a digital society have been effective. Almost all (98 per cent) of Estonians now have an ID card for interacting with electronic services and 88 per cent use the Internet regularly (E-Estonia 2018a).[18] Each year around 95 per cent of tax declarations are filed electronically, with an average time of three to five minutes spent (Enterprise Estonia 2018b).[19] Estonia was also the first country to implement electronic voting (i-Voting) for local (2005) and parliamentary (2007) elections (E-Estonia 2018b). While initially i-Voting was not used by much of the population (5.4 per cent in 2007), by 2014 around one third of voters cast their votes online (Runnel, Pruulmann and Reinsalu 2009).[20] The Estonian government's extensive efforts to promote the development of ICT-driven public services have thus positioned Estonia as a pioneer of e-government services and the digital society concept. As noted above, however, the success of Estonia's digital transformation must be understood in the context of the proactive oversight role undertaken by other stakeholders, especially the banking sector (Kitsing 2011). The development of Internet banking, in particular, was of fundamental importance in facilitating the government's own efforts to build a digital society (Kitsing 2011).

Public oversight focused far more on the promotion of a digital society than on understanding society's views on the subject. One of the initial aims of Estonia's digital society was to improve citizen-state interactions, with online consultation forums such as Täna Otsustan Mina and Osale.ee created to achieve this goal (Runnel, Pruulmann and Reinsalu 2009). Questions have been raised, however, as to whether these online fora have offered citizens real participation, or pseudo-participation with limited opportunity for dialogue; either way the fora are not widely used (Runnel, Pruulmann and Reinsalu 2009; Riigikantselei n.d.).[21]

17 Cheque books, for example, had never been introduced in Estonia (Kerem 2003)

18 In neighbouring Latvia, 78.5 per cent of 16–74 year olds were regular – at least once per week – Internet users in 2017 (Central Statistical Bureau of Latvia 2017); in the UK, 90 per cent of adults were recent Internet users in 2018 (ONS 2018).

19 In the United States, 88 per cent of individual tax returns were filed electronically in 2017 (Internal Revenue Service 2017).

20 The i-Voting system saves over 11,000 working days per election (Enterprise Estonia 2018c).

21 As of 31 October 2018, osale.ee has 4,493 users.

The benefits of a digital society also came at a price, namely dependence on ICT systems and the Internet (Cardash and Cilluffo 2013). This dependence left society vulnerable to system failure or malicious attacks, if not adequately planned and provisioned for. In 2007, both government systems and private systems in Estonia were affected by a distributed denial of service (DDoS) cyber-attack (Czosseck and Geers 2009).[22] Since the attack, Estonia has strengthened its focus on cyber security, including innovative approaches, such as the formation of a cyber defence organisation now known as the Defence League Cyber Unit. This unit aims to strengthen the cyber defence skills of volunteers as a means of increasing defence capacity against a cyber-attack or crisis situation in the future. Other countries have looked towards this model to help meet the perceived growing threat of cyber warfare (Cardash and Cilluffo 2013).

2.2.5. What lessons can be learnt from this example?

The Estonian population was generally favourable towards using technology as a societal and economic tool (Runnel, Pruulmann and Reinsalu 2009). Furthermore, when initial proposals regarding a digital society were made, Estonia had a population of approximately 1.5 million and very little ICT infrastructure. As such, the existing systems could be discarded and new systems — such as the X-road data exchange and electronic ID – could be integrated throughout society. Effecting the necessary changes to institutions and infrastructure to create a digital society may be more challenging in other countries. Notwithstanding these favourable conditions, the Estonian example highlights the important role that proactive government intervention, backed by private sector support and initiative, can play in catalysing the adoption of new technologies within society. The government of Estonia undertook wide-ranging, multifaceted measures to lay the foundations for e-government. In doing so, it helped Estonia to reap the benefits of a digital society sooner than virtually all of its European counterparts.

In the case of Estonia's digital society, oversight focused overwhelmingly on the development and adoption of new technologies. The threat of the digital divide was mitigated – though not entirely avoided – through oversight approaches to increase access to the Internet, infrastructure, and training to gain digital skills. However, the government's agenda only gave limited space for public feedback or participation in the infrastructure it was creating. The question of whether or not a more concerted effort to engage society would have slowed down progress, thereby delaying the benefits that digital society had to offer, is of course a difficult one to answer.

The Estonian case also highlights the need to anticipate, so far as possible, the unintended consequences of a new technology. In the initial stages of the e-government programme, the Estonian government failed to take adequate measures to address the increased risk of cyber-attacks resulting from reliance on ICT systems. At the same time, the subsequent (and thus far successful) actions taken to address this threat, in the form of the Defence League Cyber Unit, highlight the virtues of an adaptive approach to oversight, in which quick steps are taken to mitigate emerging risks.

22 A denial of service (DoS) attack involves flooding a target system with requests in order to overload the system, rendering the resource unavailable to the intended users. To make the attack harder to defend against, perpetrators often send the spurious requests from many different sources – this is a distributed denial of service (DDoS) attack (Czosseck and Geers 2009).

2.3. Case vignette 3
Fintech regulatory sandboxes in the UK and beyond

Summary: This case vignette discusses the use of regulatory sandboxes for regulating innovative financial technology in the UK and beyond.

The emergence of new, and potentially disruptive, financial technologies generates opportunities but also brings new risks, both for banking systems and for consumers. Borrowing from 'sandbox' approaches deployed in other contexts, in 2015 the UK Financial Conduct Authority (FCA) developed the concept of a fintech 'regulatory sandbox'; a regulatory 'safe space' in which eligible firms can carry out limited tests on innovative fintech products while being exempt from certain regulatory requirements. The concept has proved popular with other governments, particularly in the Asia-Pacific region.

2.3.1. Background and context

Fintech (financial technology) is an umbrella term that describes the use of digital technology within the context of the financial services sector. It includes a range of technologies, such as machine learning, digital currencies, blockchain and mobile payments (GO Science 2015), which are changing the way many traditional financial services (e.g. lending, payments, investing) are delivered (Young and Labbé 2017). For example, fintech includes Internet or mobile applications that enable consumers to compare what lenders offer and move between banks more easily. The development and application of fintech may result in new business models, applications or products that could have an effect on financial institutions, financial services and financial markets (FSB 2017). Fintech is also changing the relationships between companies operating in the financial sector (Young and Labbé 2017). For instance, fintech start-ups are providing alternative lending and payment systems services, which were traditionally the monopoly of large lenders (Young and Labbé 2017).

The interaction between finance and technology has existed since the late 19th century (e.g. with the appearance of the telegraph and the telephone). However, the term 'fintech' and the ensuing numerous applications have risen to prominence from 2015 onwards,[23] and the term now increasingly refers to the new wave of fintech characterised by the speed of technological change and the diversity of actors in the financial sector (e.g. fintech start-ups) competing with traditional financial institutions (Arner, Barberis and Buckley 2017; Zetzsche et al. 2017; Fáykiss, Papp and Tőrös 2018). Two important factors, among others, have spurred the development of the current fintech landscape: rapid technological change, and regulatory reforms that followed the global financial crisis of 2008 (Arner, Barberis and Buckley 2017). Oversight of fintech through the concept of a regulatory sandbox was established in 2015 by the UK Financial Conduct Authority (FCA), while fintech was still a relatively nascent sector (FCA 2017).

23 See Fintech: Interest over Time, GOOGLE TRENDS, As of 16 December 2018: https://www.google.com/trends/explore#q=fintech

2.3.2. Why was oversight required?

Following the 2008 financial crisis, efforts have been made by both global and national regulatory authorities to improve the resilience of the financial system to shocks through stringent regulatory reforms (Fáykiss, Papp and Tőrös 2018). The emergence of new and potentially disruptive financial technologies generated opportunities, but also brought new risks – as these technologies could have an impact on financial stability and consumer protection. Examples of technological innovations included the provision of financial services bypassing regular financial service providers (e.g. peer-to-peer lending or insurance), automated, algorithm-driven data analysis and processing (e.g. automated financial advisory or investment management services) (Fáykiss, Papp and Tőrös 2018), and the use of Distributed Ledger Technology (DLT)[24] for payments (FCA 2017). These, and other fintech innovations, could lead to efficiency improvements in the financial system by reducing the complexity and costs of a number of activities and processes (Fáykiss, Papp and Tőrös 2018).

However, there were also a number of risks associated with fintech innovations, which could ultimately harm consumers. Fintech innovations could fundamentally change existing business models of incumbent institutions, which could introduce systemic risks. Operational risks included issues around data quality and data protection, as well as information security risks – since fintech technologies could lead to more entry points for attack (Fáykiss, Papp and Tőrös 2018) (INT02). Some fintech activities also fell outside the scope of existing financial regulatory requirements as they involved new technologies or unconventional business models (EY 2017). These often crossed traditional sectoral boundaries, meaning they could shift from one regulatory category to another (Eggers, Turley and Kishnani 2018). Requiring fintech firms to comply with existing financial regulatory requirements would protect against a number of risks, but this could restrict entry into the market, and thus potentially stifle wider innovation in this space. Moreover, recent years have seen growing pressure on regulators to support innovation through appropriate regulation (Zetzsche et al. 2017; Fáykiss, Papp and Tőrös 2018). The UK is a leading fintech hub in Europe; in 2014 the FCA estimated that the UK hosts about half of total European 'disruptive' fintech start-ups (FCA 2015).[25] The creation of an appropriate regulatory framework was (and continues to be) important for the UK to maintain its position because, in an emerging sector that is disruptive and uses novel business models, regulation that is outdated or maladapted can sometimes inhibit innovation (INT03). Therefore, oversight was required that would support competitive innovation occurring in the financial sector, while also supporting financial stability and consumer protection.

2.3.3. How was the oversight carried out?

The UK FCA introduced the concept of a regulatory sandbox as an attempt to balance traditional regulatory objectives of financial stability and consumer protection with objectives of promoting growth and

24 DLT is an innovative type of online distributed database (i.e. spread over multiple locations) that can be used as a digital ledger to securely record, manage and verify transactions. See Deshpande et al. (2017)

25 'Disruptive' fintech refers to small, innovative firms disintermediating incumbent financial services firms with new technology. It is estimated that the fintech sector in the UK generates approximately £20bn in annual revenue, of which £3.6bn is 'disruptive' fintech (FCA 2015).

competitive innovation in the financial market (FCA 2017). The sandbox concept was first employed in the technology sector, where it represented a virtual environment to test new processes or software (Arner, Barberis and Buckley 2017; Zetzsche et al. 2017). In finance, the sandbox is more akin to clinical trials in the pharmaceutical sector that aim to keep consumers safe while testing new innovations. The sandbox represents a regulatory 'safe space' where eligible firms may carry out limited tests on innovative products, services and business models in a live market environment, while being exempt from certain regulatory requirements (Zetzsche et al. 2017). It gives firms the opportunities to test ideas for which they can obtain feedback from customers, while also giving the regulatory authority advanced insight on the ideas that are developing and might need regulating in the future, as well as insight on potential risks that could materialise (INT02).

The UK sandbox initiative was launched in June 2016 (FCA 2017) by the FCA's Project Innovate, a programme launched in 2014 to promote innovation in the financial regulatory system, which also hosts an innovation hub (the Advice Unit) offering informal investment advice and regulatory support to businesses (Cambridge Centre for Alternative Finance 2018). The FCA, and hence the sandbox as a regulatory tool, is governed by the Financial Services and Markets Act 2000, which outlines the scope of regulated financial services activities and the regulatory objectives of the FCA, stating that any firm carrying out a regulated activity must be authorised or registered by the FCA, unless they are exempt.

The sandbox provides access to regulatory expertise, including a dedicated case officer, and a set of regulatory tools to facilitate testing of the technology, which include restricted authorisation, individual guidance, waivers,[26] no enforcement action letters[27] and informal steers[28] (Cambridge Centre for Alternative Finance 2018). The tool used most frequently in the sandbox is granting restricted authorisation (FCA 2017), meaning that a firm is authorised to carry out a test of their product in a restricted way, as agreed with the regulator (Young and Labbé 2017). For example, if the test involves selling insurance via a mobile app, the regulator may limit the test to basic insurance (such as travel insurance), rather than allowing sales of more complex insurance products (such as life insurance). The regulator can also request safeguards be put in place, such as guarantees or compensation (INT02). For example, during the FCA sandbox tests, firms testing the use of digital currency for payment transfers were required to guarantee the funds being transferred and pay full refunds if they were lost in transfer (FCA 2017). The tests are carried out with a limited number of real consumers for a specific time period (typically for 6 to 12 months) (Zetzsche et al. 2017; Fáykiss, Papp and Tőrös 2018).

The sandbox process involves four steps: application, authorisation, testing and exit (Box 1):

26 A 'waiver' enables firms to test before they have complied with all relevant rules.

27 No enforcement action letters provide firms with certainty that the FCA will not take enforcement action regarding testing activities, provided the firm keeps to what is agreed.

28 Informal steers refers to advice given by the FCA informally to companies in the sandbox on the potential regulatory implications of an innovative product or business model that is at an early stage of development; firms rely on the information at their own risk.

Box 1 Overview of steps involved in the UK regulatory sandbox process

1. Application: Firms must submit an application to enter the sandbox, setting out the innovation and how it meets the eligibility criteria.

2. Authorisation: If the proposal is accepted, the firm is allocated a dedicated case officer for the duration of the test.

3. Testing: Together with the FCA, the firm establishes and agrees to a testing approach for the technology, including testing parameters, outcome measures, reporting requirements and safeguards. The firm starts testing alongside continuous engagement with FCA.

4. Exit: At the end of the testing period, the firm must submit a final report summarising the outcomes of the test. At this point, the firm must also decide whether it will offer the innovation outside of the sandbox or abandon the idea. If the firm wishes to continue the regulated activity, the report must state how the project meets all current regulatory requirements before the technology can be granted full authorisation and be made accessible to the public. Firms interested in continuing with the tested technology have to apply for a 'variation of permission' to either continue the activity without the restrictions imposed during the test (e.g. remove the limits on the number of customers) or apply for a different authorisation (e.g. if any changes occurred during the test; for example, changes to the business model).

Source: Adapted from Cambridge Centre for Alternative Finance 2018; Deloitte 2018; (INT03).

Since its inception, the UK sandbox has accepted four cohorts of participants (a total of approximately 90 firms), a majority of which come from the retail banking sector (FCA 2017).[29] Most firms involved in the sandboxes are start-up companies based in Greater London, and not yet authorised by the FCA to carry out financial transactions in the real world.

The concept of the fintech regulatory sandbox has also proved popular with other governments, particularly those in the Asia-Pacific region (Zetzsche et al. 2017).[30] Australia, Hong Kong, Indonesia, Malaysia, Singapore, South Korea and Thailand are among those countries to have developed their own similar models (Zetzsche et al. 2017). Fintech growth in the Asia-Pacific region has been rapid and the fintech sector is becoming an important feature of financial market development, leading to challenges for financial regulation (Bromberg, Godwin and Ramsay 2017). Therefore, governments in the region have been keen to develop more innovative regulatory initiatives in order to reflect market strengths (EY 2017).

As with the UK, Asian sandboxes are supported by legislative acts (Fáykiss, Papp and Tőrös 2018). There are, however, some differences in how the sandboxes run in terms of organisation coverage, structure and scope (EY 2017). The differences reflect varying objectives and areas of focus between countries. For example, regulators with a mandate to promote market competition may have higher risk tolerance. Moreover, countries have their own unique national regulatory and legal characteristics which may limit the options of a regulator (Cambridge Centre for Alternative Finance 2018).

29 Other sectors included general insurance and protection; wholesale; retail investments; retail lending; pensions and retirement income.

30 By June 2018, fintech regulatory sandboxes existed in 19 countries (Australia, Bahrain, Brunei, Canada, Denmark, Hong Kong, Indonesia, Jordan, Malaysia, Mauritius, Netherlands, Russia, Saudi Arabia, Sierra Leone, Singapore, Switzerland, Thailand, the UAE and the UK) and had been proposed in 5 other countries (India, Japan, South Korea, Taiwan and the United States) (Eggers, Turley and Kishnani 2018).

The UK sandbox is flexible regarding the scope of the applicants, allowing both incumbents and start-ups, as well as licensed and non-licensed firms, to compete in the sandbox – provided they meet certain eligibility criteria (EY 2017; Fáykiss, Papp and Tőrös 2018). Firms must offer genuine innovation (i.e. the innovation is either ground breaking or offers something significantly different from what is available in the market already), offer benefits to consumers, support the UK financial services market, display a need for the sandbox (i.e. demonstrate that the innovation is not covered by existing regulations) and demonstrate they are ready for testing (i.e. have entered the development stage of the innovation and engaged in appropriate risk management, for instance) (Cambridge Centre for Alternative Finance 2018). By contrast, Asian sandboxes have different participant requirements. For example, South Korea's sandbox is solely for automated advisory innovations,[31] requiring firms to test the algorithms (EY 2017). In the Hong Kong sandbox, start-ups must partner with authorised institutions (EY 2017). In Australia, the sandbox is mainly for start-ups (EY 2017). It has been argued that sectoral restrictions can be counter-productive as they risk entrenching existing regulatory borders and not necessarily achieving economies of scale, and thus the value of innovations (Zetzsche et al. 2017).

2.3.4. How effective was the oversight?

Given that regulatory sandboxes are still an emerging concept, comprehensive data are not available yet on their effectiveness

31 Automated advisory innovations include financial advice that is generated by automated, algorithm-driven systems, rather than by a human financial adviser as is conventionally done (EY 2017).

and economic impact. A 2017 progress report by the FCA suggests that the UK sandbox has been effective in a number of ways. Access to regulatory expertise has reduced the time and cost of getting innovative ideas to market (FCA 2017). Around 90 per cent of firms (~16 firms) that completed testing in the first cohort and 77 per cent (~24 firms) in the second cohort are continuing toward a wider market launch following their test, and similar figures are anticipated for the third cohort (FCA 2017). Having FCA oversight of testing as well as FCA authorisation provides 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 (FCA 2017). Testing in a live environment has helped assess consumer uptake and commercial viability, and has allowed innovators to revise their innovation at an earlier stage than if they had not tested in the sandbox (INT02). Around a third of firms that tested in the first cohort used findings to significantly alter their business model ahead of launch in the wider market (FCA 2017).

The FCA progress report also states that the sandbox has helped to promote competition and stimulate wider innovation in the UK financial market, with firms developing products or services that deliver better value for consumers and other financial service users (FCA 2017). As a result of sandbox testing, a range of new technology applications have appeared on the market, covering areas such as distributed ledger technology, online platforms, application programme interfaces, and biometrics. These have the potential to help improve the efficiency, effectiveness and transparency of financial processes. The 2017 FCA report also indicates that the sandbox is helping to develop innovations that deliver better value for consumers and other financial services users. Fintech regulatory sandboxes have attracted a number of overseas investors to the UK for whom the sandbox signals a positive environment for entrepreneurs (EY 2017).

Despite its early successes, the implementation of the UK sandbox has experienced challenges. Although firms found the support through the dedicated case officer useful, several found the sandbox authorisation process to be costly and time-consuming, particularly if they were not familiar with financial services regulation (Deloitte 2018). Nonetheless, firms found that having participated in the sandbox tended to make the authorisation process quicker and easier if they did decide to apply for full authorisation post-testing (Deloitte 2018). Regarding testing, common challenges encountered by smaller and newer firms included difficulty in acquiring customers and opening a business bank account (Deloitte 2018). In practice, there are also limits to some of the regulatory tools in a sandbox, such as the waivers and no action letters, since the FCA also has to comply with other legislation (Young and Labbé 2017; Cambridge Centre for Alternative Finance 2018). The FCA also found it challenging to assess some potential applicants against the conditions for authorisation as non-traditional firms may have business models that are structured differently (FCA 2017).

There is some evidence that the sandbox may have benefitted the public, as working with the FCA has allowed firms to build appropriate consumer protection safeguards into new products and services before wider market launch (FCA 2017). For example, a number of firms have used the sandbox to test the accuracy of their robo-advice[32] innovations. In one test, an experienced qualified financial

32 Robo-advice is advice that is generated by automated, algorithm-driven systems, rather than by a human financial adviser as is conventionally done (EY 2017).

adviser checked, and if necessary amended, the automated advice outputs generated by the algorithms before they were delivered to the client, and this was then used to amend the underlying algorithm (FCA 2017). Despite safeguards, there is still a risk that customers of participating businesses may not be completely protected during the testing stage (Bromberg, Godwin and Ramsay 2017). However, imposing more stringent safeguards on participating firms may favour larger businesses and hinder competition. Additionally, the existence of the sandbox can affect competition as it may provide competitive advantage to firms that are allowed to participate in it (Young and Labbé 2017; Deloitte 2018).

The regulatory sandbox concept has also spread to non-financial regulators. For example, Ofgem, the UK government regulator for electricity and downstream natural gas markets, has recently launched a regulatory sandbox (Ofgem 2018). A recently launched project by the UK Civil Aviation Authority, Innovation in Aviation Engagement Capability, includes the establishment of a regulatory sandbox that aims to test innovations and help identify future legislative and regulatory barriers to innovations in aviation (HM Government 2018). Beyond the UK, in 2016 the Australian government of New South Wales started implementing regulatory sandboxes to improve the competitiveness of doing business in the state (NSW Government 2016).

2.3.5. What lessons can be learnt from this example?

One of the key reasons the oversight has been effective is that the sandbox facilitates enhanced communication and collaboration between regulators and innovative firms early on (Zetzsche et al. 2017). The test environment has enabled fintech firms to communicate openly with regulators, helping them to navigate potential authorisation requirements, while at the same time allowing regulators to familiarise themselves with innovations which could lead to the updating of regulatory frameworks, if necessary (INT02). For example, some regulators have updated their guidelines after sandbox tests, including information about good practice, and then have shared this with other banks or firms looking to test similar technologies in the sandbox (INT02). However, to date, regulations have not necessarily been updated in a significant way (INT03). By mitigating regulatory risk and providing real-world data, sandboxes provide greater certainty to potential investors (Agarwal 2018).

Regulatory sandboxes have been successful in the fintech context as they offer a dynamic and responsive regulatory approach that is particularly important in a sector characterised by disruptive technological innovation, in which rapidly emerging innovations often do not fall neatly within existing regulatory frameworks (Bromberg, Godwin and Ramsay 2017). Firms are able to test new innovations without facing a hefty penalty for non-compliance. Sandboxes could also be applied to other heavily regulated sectors experiencing unprecedented innovation, such as healthcare, energy, agriculture and the automobile industry (especially for autonomous vehicles) (Agarwal 2018) (INT02).

There are, however, some challenges associated with regulatory sandboxes in general. Activity within a sandbox is not fully regulated, which means that risks to consumers and the financial system can potentially materialise in practice (Zetzsche et al. 2017).[33] Additionally, as the sandbox

33 To the best of our knowledge, these risks have not yet materialised.

requires tests to be done on limited samples, even if the technology is shown to be safe in those samples, it cannot always be generalised that it is safe on a wider scale. Another limitation of sandboxes as currently conceived is that they are not scalable (FCA 2017; Zetzsche et al. 2017). The sandbox involves the input of FCA staff as case officers, as well as reviewing the growing amount of data generated from the tests. The FCA, therefore, is only able to grant access to a limited number of applicants (Fáykiss, Papp and Tőrös 2018).

2.4. Case vignette 4
The Green Revolution: Agricultural technology in India

Summary: This case vignette discusses the development of agricultural technology in India to increase food production in India in the 1960s and 1970s.

By the late 1950s, international agricultural research institutes had developed new High Yielding Varieties (or HYVs) of grain and wheat capable of being grown on a vast scale in a range of environments. Combined with a package of other agricultural innovations – including fertilizers, pesticides and irrigation methods – HYVs promised a significantly higher agricultural yield than most 'traditional' crops. From the mid-1960s onwards, together with international stakeholders, the Government of India built an extensive public infrastructure focused on the promotion of these new agricultural technologies.

2.4.1. Background and context

The 'Green Revolution' is the name given to an international movement to increase food grain productivity in developing countries through the introduction of new agricultural technologies. Reaching its peak between the late 1960s and early 1970s, the movement promoted a package of novel scientific techniques, including the introduction of new high-yielding varieties (HYVs) of seed, chemical fertilizers and pesticides, as well as new irrigation methods, to help move developing countries from a position of chronic grain shortage and dependency on grain imports towards self-sufficiency in food production. As the movement's centrepiece, HYVs were 'early-maturing', 'semi-dwarf' strains of rice and wheat, produced through selective crop breeding.[34] Combined with fertilisers and intensive irrigation, these new varieties promised a significantly higher yield per hectare than many of the crops grown in developing countries at the time (Borlaug 2000).

Prior to the Green Revolution, several countries had made use of HYV strains of wheat and rice in agricultural production. Having been discovered in Japan in the 1870s, semi-dwarf wheats were grown in Japan, Italy and the United States during the first half of the 20th century, and were taken to Mexico in the early 1950s. Early maturing rice, meanwhile, are thought to have grown in parts of China since as early as 1000 AD (Dalrymple 1974). It was not until the late 1950s, however, that the foundations for the widespread use of HYVs in agriculture were put into place. During this time, in research centres such as the International Maize and Wheat Improvement Center (CIMMYT) in Mexico, and the International Rice Research Institute (IRRI) in the Philippines, agronomists developed new forms of HYV. The new varieties were bred to be more resistant to insects and diseases, and more amendable to consumer acceptance (Dalrymple 1974). With

34 Semi-dwarf plant varieties are characterised by a shorter, stronger stalk than most other crops. They can therefore withstand stronger winds and heavier grain loads. They also take less time to grow to the height needed to produce grain (Athwal 1971).

these new breakthroughs, the widespread use of HYVs (Varshney 1989) became a very real prospect.

2.4.2. Why was oversight required?

In India, the emergence of new HYVs ran alongside serious concerns about the country's inability to meet its own food production needs.[35] To a number of key stakeholders, the take-up of these new agricultural innovations offered an opportunity to rapidly boost domestic food production and escape an impending 'Malthusian trap', while also modernising the country's agricultural system.[36] Subscribers to this view included a small group of politicians, officials and scientists within the Government of India (GoI), specifically its Ministry of Food and Agriculture (MFA) (Varshney 1989). Led by the new Minister for Agriculture, C. Subramaniam, this group advocated for a shift in India's rural development policy towards the goal of increasing grain production through new scientific approaches to agriculture, in particular the use of HYVs.[37] American governmental and non-governmental organisations, including USAID and the Ford and Rockefeller foundations, actively supported the MFA's arguments in this regard. In the age of the Vietnam War, American interest in India's agricultural development reflected, in part at least, a desire to address the country's food-population imbalance as a means of combatting the perceived relationship between poverty and communism (Seshia and Scoones 2003).

From the perspective of these stakeholders, oversight was required in order to encourage the use of new agricultural technologies on the ground. HYVs would only deliver the perceived benefits if incorporated into everyday agricultural practices. The challenge, therefore, was to create an infrastructure that would facilitate the adoption of these new agricultural technologies on a grand scale. This would include overcoming barriers, such as a lack of accessibility to the new seeds and the perceived inertia of 'traditional' agricultural methods (Parayil 1992). Propelled, it seems, by the urgent need for solutions to the food problem, stakeholders promoting the use of HYVs demonstrated little awareness or understanding of the risks and drawbacks that would later become apparent.

Several senior scientists and members of India's Planning Commission did oppose the large-scale introduction of HYVs, nearly leading to prohibition on their importation and use. The concerns expressed, however, related principally to the high costs of importing HYVs and fertilisers, and the impact of importation programmes on India's foreign exchange allocations (Varshney 1989). Concerns were also raised regarding the possibility that the use of price control mechanisms to support HYVs (see below) would increase food prices, with negative implications for the economy at large (Varshney 1989). Some also argued that

35 Following independence in 1947, India had consistently failed to achieve significant increases in agricultural productivity during the 1950s, rendering it highly susceptible to drought-induced food shortage and heavily dependent on grain imports from international donors (Parayil 1992).

36 Named after the economist and demographer, Thomas Malthus, the 'Malthusian trap' refers to a condition in which a society's population growth exceeds its food supply to the extent that the latter becomes inadequate to feed the population, leading to starvation.

37 Prior to the mid-1960s, the principal focus of India's rural development policies had been land reform and 'Community Development' schemes, rather than the increase of grain production through scientific agriculture (Varshney 1989).

HYVs were 'not suited to Indian conditions' (Parayil 1992).

2.4.3. How was the oversight carried out?

Following a decisive shift in policy, the Government of India threw its weight behind HYVs. In August 1966, India's Fourth Five Year Plan declared the 'long-term objective' to 'organise the use of high-yielding seeds together with a high application of fertilisers over extensive areas where irrigation is assured' (Varshney 1989). The Plan provided the strategic direction for an extensive framework of governance intended to promote the use of HYVs, a programme steered by the MFA but also involving other government agencies. American interests acted in a supporting role to these endeavours, providing financial and technical assistance to the GOI's endeavours wherever they could (Varshney 1989). This multi-stakeholder process of oversight took a number of forms.

First, following successful trials of the new strains of wheat and rice in 1962 and 1964, respectively, the MFA authorised the first large-scale import of HYV wheat from Mexico, in time for the 1965–66 growing season. Further large-scale imports of wheat, rice and fertilisers followed during the late 1960s, supported by collaboration between the MFA and the Ministry of Finance, as well as foreign exchange agreements with bilateral and multilateral donors (Parayil 1992). Second, the GoI established new financial mechanisms to promote the use of new seeds and fertilizers. The MFA distributed seeds to farmers at subsidised rates (Parayil 1992). Price control mechanisms were also instituted. These guaranteed the purchase of agricultural outputs at a fixed price, thereby protecting producers in the event of falling prices due to market oversupply.[38] To oversee this dual strategy, two new institutions, the Agricultural Prices Commission and the Food Corporation of India, were established in 1965. The new institutions were created by an MFA Resolution and the passing of new legislation (the 1964 Food Corporation's Act), respectively (Varshney 1989).

A third form of oversight was the commencement of a large-scale public information campaign designed to raise awareness of new agricultural technologies. Beginning in the 1965–1966 agricultural season, the MFA's National Demonstration Programme (NDP) saw thousands of extension agents[39] traverse the countryside with the aim of encouraging adoption of the new 'miracle seeds' (Parayil 1992). Under the NDP, a minimum of two hectares[40] of selected fields were devoted to the new technology, with extension officers and agricultural scientists supporting farmers efforts to use the new seeds. During the initial phase, the government made a commitment to recompense farmers for any losses made using the new crops (Varshney 1989).

Finally, GoI and other stakeholders undertook concerted efforts to strengthen India's own agricultural research capacity, building on the strong foundations already laid in this respect during the 1950s (Parayil 1992). During the 1960s, the MFA brought all existing

38 This was balanced by a parallel commitment to protect consumers by releasing reserve food stocks at times of supply shortfall in order to lower consumption prices.

39 'Agricultural extension' refers to the dissemination of information to farming communities, specifically in the form of new agricultural methods and techniques. Extension agents were public officials employed by the MFA to perform this educational role.

40 One hectare is equivalent to a thousand metres squared.

agricultural research institutes under the purview of the Indian Council of Agricultural Research (ICAR). Together with the Ford and Rockefeller foundations, the MFA facilitated visits from leading agronomists, such as Norman Borlaug, to India.[41] This strengthening of the domestic agricultural research system not only created domestic expertise necessary for the government's demonstration programme, it also enabled Indian scientists to adapt imported HYVs to suit local consumer preferences (Parayil 1992).

2.4.4. How effective was the oversight?

The mechanisms of oversight put in place by the GoI during the 1960s and 1970s met their primary objective: increasing food productivity (Singh 2000). As is widely recognised, new seeds and fertilisers, where used, not only improved yields per hectare, but also reduced the 'time to maturity' of crop batches, thereby allowing for increased cropping intensity (Pingali 2012). By the 1970s, this had already helped to ensure India's domestic procurement of food grains

41 Considered by many to be the 'father' of the Green Revolution, Normal Borlaug was an American agronomist who pioneered the development of new HYVs at the CIMMYT and was influential in their spread to South and Southeast Asia. Borlaug was awarded the Nobel Peace Prize in 1970 for his contributions to world peace through increasing food supply.

exceed its overseas imports (a significant reversal of the situation in the early 1960s). This early success was followed by more prolonged increases in agricultural output, contributing significantly towards India's eventual achievement of 'self-sufficiency' in food production (Evenson and Gollin 2003; Parayil 1992).[42] Increases in agricultural output brought with them a range of broader societal benefits, including reductions in real food prices, diversification of nutritional intake and associated health benefits (Pingali 2012). It also produced important socioeconomic changes. Farmers increasingly sold their excess produce to market, creating new sources of incomes and improved standards of living (Parayil 1992). The package of policies, institutions, research frameworks, subsidies and engagement programmes orchestrated by the MFA helped to ensure the uptake of new agricultural innovations on a scale that would not have been achieved through market forces alone. Moreover, the GoI's public infrastructure ensured the distribution of new agricultural technologies to segments of India's rural population that would not otherwise have experienced them (INT04).

At the same time, however, the GoI's efforts to oversee the adoption of agricultural technologies had several important shortcomings. Most notably, the oversight of the Green Revolution was driven by a 'one-size-fits-all' approach that failed to appreciate the broader social and economic factors influencing the uptake of new agricultural technologies (INT04). Because HYVs performed better when grown in large-scale plots with good access to irrigation sources, their use was most suited to farmers with substantial landholdings in well-irrigated areas. By contrast, those with smaller holdings and/or in rain-fed areas were often not in a position to make use of the new seeds. The programmes established to promote the use of HYVs paid little heed to these disparities (Pearse 1980; Pingali 2012; Frankel 1974). As such, India's Green Revolution was one experienced predominantly by certain geographical regions and certain social groups. According to many commentators, existing patterns of rural inequality actually became more entrenched as a result (Pearse 1980; Frankel 1974).

The promotional package constructed by the GoI also failed to either anticipate or mitigate the negative environmental consequences of new agricultural technologies. HYVs, fertilisers and pesticides contributed significantly to land and water degradation in areas where the new land-use patterns took hold (Pingali 2012; Singh 2000). Fertilisers, for instance, had a detrimental impact on both soil fertility and water quality, and caused chemical run-off into surrounding areas. Because they required extensive irrigation, HYV rice and wheat crops also led to a marked decline in the water table in intensively farmed states (Singh 2000). In the longer term, land-use changes associated with the new crops and fertilisers have also contributed to increased levels of air pollution in cities as well as rural areas (Biswas 2018). These environmental costs, which might have been prevented by the adoption of appropriate policy mechanisms, were overlooked by stakeholders in their efforts to promote the rapid uptake of new agricultural innovations.

2.4.5. What lessons can be learnt from this example?

Some accounts of the Green Revolution, both in India and beyond, stress

42 The Indian experience was mirrored by record harvests in other countries making use of new Green Revolution technologies. Between 1960 and 1985, total food production across developing countries more than doubled (Conway 1999).

its successes, seeing it as an effective mobilisation of new technologies for a quantifiable social good (Parayil 1992). Others, meanwhile, view it as a cautionary tale – one that exemplifies the destructive consequences that can result from the overzealous promotion of new technologies without full consideration of their societal and environmental impact (Pearse, 1980). One way to think about the Green Revolution, however, is to see it as both of these things. With respect to the oversight of new technologies, India's Green Revolution provides both a set of examples for how oversight can be effective and a series of warnings concerning the limits of certain approaches.

Undoubtedly, the extensive package of policies instituted by the GoI and its allies during the 1960s and 1970s did provide a foundation for the rapid adoption of new agricultural technologies, a process that, as noted, made technologies accessible to groups that might not otherwise have experienced them. In this sense, it provides an important example of how governments have proactively pursued societal adoption of new technologies in the past and delivered substantial benefits to society in the process. This lesson is of particular importance given the general shift in the role of the state in the development and dissemination of technologies since the period of the Green Revolution. In a post-liberalisation world, in which public bodies typically take a back seat to processes of technology diffusion led by the private sector, the Green Revolution serves as a reminder of the dramatic impact that proactive public oversight can have in mobilising technologies for societal change (Seshia and Scoones 2003; Parayil 2003).

However, perhaps an enduring lesson of the Green Revolution, so far as the oversight of new technologies is concerned, is the inherent limitation of a 'top-down', maladaptive approach to oversight. The oversight of India's Green Revolution represented a narrow, elite-driven vision of what new technologies would do for society, a vision that tended to emphasise technological benefits in isolation from social, economic and environmental realities. Driven by prevailing societal issues, notably national food security, its pioneers were either not cognisant of these realities, or chose to ignore them. As such, they created a one-directional public infrastructure focused overwhelmingly on the promotion of new technologies. The infrastructure lacked mechanisms for societal 'participation' or 'feedback' in the planning process. Subsequently, it was not designed to adapt to the undesirable consequences that new technologies were having on the ground, even as awareness of these consequences was growing (Paddock 1970). Issues that ultimately served to offset the benefits of the new technologies therefore went unaddressed. Moreover, as groups benefiting from the subsidy and price control mechanisms associated with the Green Revolution demanded their continuation, the aspects of the infrastructure also became 'locked-in' to Indian agricultural policy in the longer term (INT04) (Seshia and Scoones 2003; Pearse 1980).

This, of course, raises the counterfactual question of whether a more participatory approach would have slowed down the rapid progress that *was* made in promulgating new technologies. In view of the considerable social and environmental fallouts, however, the Green Revolution has more often been understood as a case that highlights the need for more engaged, participatory and 'bottom-up' forms for technology development, rather than the virtues of speed (INT04).

2.5. Case vignette 5
M-Pesa: Branchless mobile banking in Kenya

Summary: This case vignette discusses the branchless mobile banking service M-Pesa, its emergence in Kenya and the oversight of this technology.

The M-Pesa service, delivered by the Kenyan mobile network operator, Safaricom, and the telecommunications company, Vodacom, in 2007, pioneered the use of mobile phones to extend basic banking services to populations previously without access. The development of M-Pesa prompted efforts by the Central Bank of Kenya to create an enabling environment for the growth of the service. The Bank worked closely with the service developers and citizens to facilitate the expansion of branchless mobile banking while also trying to limit the potential financial risks associated with the technology.

2.5.1. Background and context

Branchless mobile banking, or branchless mobile payments, is defined as banking or payment using mobile devices such as mobile phones, smartphones or tablets. Typical mobile financial transactions include payments or purchases of goods or services, and payments/transfers from consumer-to-business, business-to-business and person-to-person (P2P). Unlike traditional banking services, branchless mobile banking services are not necessarily operated by banking institutions and they do not require customers to undertake financial transactions in official banking branches. Branchless mobile banking services were seen as particularly beneficial in developing countries, as large parts of their populations often live in rural areas and do not have access to regular banking services (Alliance for Financial Inclusion 2010; Bourreau and Valletti 2015; Tarazi and Breloff 2010).

The first branchless mobile banking service was launched in the Philippines in 2001. By 2006, only six services in four countries existed. From 2007, when the M-Pesa service was launched in Kenya, branchless mobile banking started to spread across developing countries in East Asia, the Pacific region and Africa (GSMA 2017). The main idea of M-Pesa was to provide access to basic banking services via mobile phones to the Kenyan population at low cost (i.e. no registration fees, and flat fees for transactions). At the time of its launch, more than 70 per cent of Kenyan households did not have access to banking services at all, while at the same time access to mobile phones steadily increased in the late 2000s/early 2010s (Kimenyi and Ndung'u 2009; Mas and Radcliffe 2011; Vaughan, Fengler and Joseph 2012).

2.5.2. Why was oversight required?

Against this backdrop, Kenya was seen as a promising market for offering a branchless mobile banking service, and the Kenyan government thought that offering alternatives to traditional banking to their citizens may help correct the financial access imbalance in the country, i.e. increase the number of people with access to banking services, which was 30 per cent at the time of M-Pesa's launch (Alliance for Financial Inclusion 2010; Buku and Meredith 2013; Etzo

and Collender 2010; Kimenyi and Ndung'u 2009; Mas and Radcliffe 2011; Vaughan, Fengler and Joseph 2012). Increasing the level of financial inclusion in Kenya had the potential to lead to more equality in Kenyan society, as well as having impacts on the Kenyan economy, both through providing a revenue stream for the commercial telecommunications providers and through the likely increase in economic activity of the population with access to banking services (Buku and Meredith 2013; Kimenyi and Ndung'u 2009; Mas and Radcliffe 2011; World Bank n.d.).

Branchless mobile banking services, however, brought with them a number of potential risks, particularly if the services were not regulated in the same way as banks (where regulations seek to protect consumers from these risks). These risks included security risks related to the technology (e.g. insecure storage of data, inadequate protection of customers' account information and data, identity theft); risks related to coverage, i.e. that providers may not always be able to provide users back the money that they have paid in; and risks of lack of clarity over who is liable in case a problem arises (INT05; USAID 2010).

2.5.3. How was the oversight carried out?

The idea of M-Pesa came from a London-based team of the telecommunications company Vodafone. It was eventually developed and launched by the Kenyan mobile network operator Safaricom, which is part of Vodafone, and the telecommunications company Vodacom, with financial support from Vodafone and the UK Department for International Development (DfID)[43] (Etzo and Collender 2010; Mas and Radcliffe 2011; Vaughan, Fengler and Joseph 2012).

As highlighted by Vaughan et al. (2012), regulation in the banking sector can help increase potential users' trust in a service, yet regulation can also be a barrier to an innovation's success and its wider diffusion – as it can potentially restrict what innovators are allowed to do. In the case of M-Pesa, Safaricom and Vodacom worked closely with the Central Bank of Kenya from the outset – involving them in the development of the service and planning of its introduction. The Central Bank of Kenya had an interest in collaborating with Safaricom and Vodacom as they wanted to address the financial access imbalance in the country, and M-Pesa was seen as a way to achieve this goal (Buku and Meredith 2013). The bank decided to let Safaricom and Vodacom operate M-Pesa outside Kenyan banking law provisions, as there had not been anything similar to M-Pesa on the market before and it would therefore have been difficult to apply formal banking law provisions to M-Pesa (Buku and Meredith 2013). Additionally, they felt that to give M-Pesa the biggest chance of succeeding, the service needed tailoring to the needs of Kenyans; thus, it was not possible to develop formal regulations for it in advance of M-Pesa's launch (INT05). The bank closely monitored the service and continuously invited feedback from Safaricom and Vodacom, as well as from users through surveys (Alliance for Financial Inclusion 2010; Buku and Meredith 2013; Etzo and Collender 2010; Mas and Radcliffe 2011; Muthiora 2015; Vaughan Fengler, and Joseph 2012).

Part of the regulatory agreement between Safaricom, Vodacom and the Central Bank

43 Vodafone applied for and received funding from DfID's 'Financial Deepening Challenge Fund', which was set up to improve access to financial services (Centre for Public Impact 2016).

Fiona Graham / WorldRemit

of Kenya was close collaboration between Safaricom, Vodacom and the Central Bank of Kenya, and allowing the Central Bank of Kenya to monitor M-Pesa transactions (individual transactions and en masse), providing them access to electronic audit trails as well as monitoring the use of Safaricom's internal risk assessment and safety procedures. This monitoring enabled the Central Bank of Kenya to ensure that M-Pesa meets financial risk and safety requirements, which would usually be regulated by banking law provisions, and Safaricom and Vodacom were able to relatively freely design and run their service (Alliance for Financial Inclusion 2010; Mas and Radcliffe 2011). In addition to being closely monitored, Safaricom and Vodacom also had to demonstrate prior to launch that appropriate risk assessment and safety procedures and policies were in place, the addition of a limit on the size of transactions to prevent potential money laundering, as well as agreeing to pay any interest on deposited balances to a not-for-profit trust (Alliance for Financial Inclusion 2010; Buku and Meredith 2013; Mas and Radcliffe 2011). It was key to the agreement that interest accumulated was donated, as otherwise M-Pesa would have had to be regulated like a bank (Alliance for Financial Inclusion 2010; Mas and Radcliffe 2011; Mbiti and Weil 2011; Muthiora 2015; Vaughan, Fengler and Joseph 2012). Safaricom's internal anti-money laundering and risk assessment procedures and policies included: comprehensive training of M-Pesa agents (i.e. individuals who check individuals' IDs at the

registration and who conduct cash M-Pesa cash withdrawals) to ensure that they comply with Safaricom's anti-money laundering, counter-terrorist financing and 'Know Your Customer'[44] policies; and transaction control and monitoring, including transaction limits and the online capturing and storage of transaction information (Buku and Meredith 2013).

Part of the Central Bank of Kenya's oversight approach was also to assess users' experience with the service and to find out whether they have trust in it (Alliance for Financial Inclusion 2010; Mas and Radcliffe 2011). In September 2008, they surveyed over 3,000 users regarding their satisfaction with M-Pesa. In addition, financial inclusion surveys ('FinAccess' surveys) were regularly conducted to monitor any changes in the number of Kenyans having access to financial services (Alliance for Financial Inclusion 2010; Mas and Radcliffe 2011; Muthiora 2015).

As the number of users of M-Pesa increased, traditional banks, branchless banking service competitors and other stakeholders, including parts of the government, lobbied to stop M-Pesa, arguing that the service was not safe, did not meet risk management requirements, and that the absence of regulations was anti-competitive (Buku and Meredith 2013; Hayes and Westrup 2012). In 2008, telecommunications company, Zain (now Airtel), aimed to launch their branchless service, Zap!, but the Central Bank of Kenya initially withheld the introduction as it found that Zap! did not meet expected safety requirements, which M-Pesa was meeting (Hayes and Westrup 2012).[45] The pressure on the Central Bank of Kenya increased further when Kenyan media started to report on the objections and concerns of traditional banks, competitors and other stakeholders (Alliance for Financial Inclusion 2010).

As a response, the Kenyan Ministry of Finance commissioned the Central Bank of Kenya and the National Central Bank to conduct an audit of M-Pesa regarding its safety and risk assessment (Buku and Meredith 2013; Mas and Radcliffe 2011; Muthiora 2015). In early 2009, this audit concluded that M-Pesa was meeting safety and risk assessment criteria, and that the service was being appropriately overseen by the Central Bank of Kenya. Safaricom's internal anti-money laundering and risk assessment policies helped demonstrate that M-Pesa was safe (Buku and Meredith 2013; Mas and Radcliffe 2011; Muthiora 2015).

While the audit in 2009 helped to demonstrate that M-Pesa is safe, concerns regarding its anti-competitiveness remained and are still present today (INT06). Already at the time M-Pesa was launched in Kenya, Safaricom and Vodacom were leaders in the country's mobile phone provider market, and the Central Bank of Kenya's cooperation with the providers when launching M-Pesa probably helped maintain their dominance (Buku and Meredith 2013). In 2016, Kenya's Communications Authority (CA) commissioned UK-based consultants, Analysys Mason, to analyse the competition in the telecommunication sector. Analysys Mason highlighted Safaricom's dominance on the market and initially recommended separating M-Pesa from Safaricom to allow for more competition. However, they later took back this recommendation, as it 'could

44 I.e. procedures agents have to follow to verify a customer's identity when they register for M-Pesa or undertake cash transactions (Buku and Meredith 2013).

45 Zap! was eventually launched in February 2009, and was followed by other similar products in 2009 and 2010. By the end of 2010, six branchless mobile banking services were available on the Kenyan market, all of which had to meet the same requirements as set out for M-Pesa prior to its launch (Muthiora 2015, 13).

be seen as disproportionate and constraining the CA's discretion to act' (Kubania 2018), and instead recommended that Safaricom stops offering discounts and individually tailored loyalty schemes to M-Pesa users who are also Safaricom clients (Dahir 2018; Kubania 2018).

The Central Bank of Kenya used the oversight approach for several years. Based on what has been learnt from this approach, the Kenyan Government eventually passed the *National Payment System Act* (2011), which incorporated regulations for all payment service providers, i.e. traditional banks, but also branchless banking providers such as Safaricom and Vodacom. The Act also gave the Central Bank of Kenya the authority to oversee all payment service providers (Buku and Meredith 2013). In 2014, the Act was complemented by the *National Payment System Regulations* (2014), which incorporate lessons learnt from the M-Pesa case, as well as issues such as requirements for agents, maintenance of records, safety and risk management, privacy and protection of consumers, governance, interoperability, and bank oversight and audit (Muthiora 2015).

2.5.4. How effective was the oversight?

The approach taken by the Central Bank of Kenya contributed to a significant growth in M-Pesa user numbers: in July 2007 – four months after the service's launch – M-Pesa had 268,499 registered users; in October 2007, it passed the 1-million-user mark; and in July 2009, more than 7 million Kenyans had registered (Kimenyi and Ndung'u 2009). As of July 2018, there are 20 million active users in Kenya, and the proportion of Kenyans having access to banking services increased from 26.4 per cent in 2006 to 66.7 per cent in 2013 (Fick and Miriri 2018; Muthiora 2015). More importantly, it provided access to banking services to the large rural population in Kenya (Buku and Meredith 2013; INT1), including to more women, who usually had less access than men (Buku and Meredith 2013). It has been reported that M-Pesa also helped lift approximately two per cent of Kenya's population out of poverty, as more people could securely store their savings, receive income via the service and send money to others, e.g. family members (Suri and Jack 2016). The numbers showing an increase in citizens' access to banking services – which were also confirmed in FinAccess surveys – indicates that M-Pesa helped to achieve the Kenyan government's aim to decrease the financial access imbalance. Moreover, the results of the Central Bank of Kenya's survey of 3,000 users in 2008 showed that M-Pesa users had more trust in M-Pesa than in other financial services: 89 per cent of users were satisfied with the service and 84 per cent indicated that losing access to M-Pesa would have a significant, negative impact on their lives (Mas and Radcliffe 2011).

M-Pesa's relatively rapid increase in users, which was facilitated by the oversight approach taken (instead of formally regulating the service), also had an impact on the Kenyan economy and job market: in 2009, there were 12,300 M-Pesa agents; this number almost tripled to more than 35,500 agents by 2011. By the end of 2011, M-Pesa had two million transactions per day (i.e. 70 per cent of all non-cash transactions in Kenya), and almost US$5 billion were transferred per year (i.e. 17 per cent of Kenya's GDP) (Kimenyi and Ndung'u 2009; Buku and Meredith 2013; Hayes and Westrup 2012).

Moreover, M-Pesa's success may have had spill-over effects: since its launch, a growth in digital entrepreneurship has been observed in Kenya, including the launch of several innovation hubs and technology start-ups, which make use of mobile banking services (Muthiora 2015). In addition, M-Pesa is seen to

have had an impact on Kenyans' occupational choices: women, especially, often changed from agricultural occupations to businesses (Suri and Jack 2016).

Despite initial concerns of traditional banks, M-Pesa has not replaced them, but many of them later entered into official partnerships with Safaricom and are now offering M-Pesa (Buku and Meredith 2013; INT2). However, the service had an impact on other 'traditional' money transfer services, such as Western Union and MoneyGram, which experienced declines in profits after M-Pesa's introduction; the services also had to lower their prices to be able to compete with M-Pesa (Mbiti and Weil 2011).

M-Pesa's success did not stop at the Kenyan borders: only one year after launch, the service was introduced in Tanzania, and ten years later it was available in several countries in Africa (e.g. Democratic Republic of Congo, Egypt, Ghana, Kenya, Lesotho, Mozambique, Tanzania), Europe (Albania, Romania) and Asia (India) (Omwansa 2009; Vodafone 2017). Compared to other mobile banking services, M-Pesa spread more quickly and soon became one of the most successful and widely used branchless mobile banking services in developing countries (Jack and Suri 2011). Some other countries took a similar regulatory approach as Kenya: in Tanzania, for instance, the *Bank of Tanzania Act* was amended to enable the Central Bank of Tanzania to oversee non-bank financial services and allow such services to follow a 'test and learn' approach – where the service was allowed to be launched outside of banking regulations under monitoring (Di Castri and Gidvani 2014). In South Africa, by contrast, where M-Pesa was introduced in 2010 but later ceased due to lack of success, mobile banking services were regulated by stricter banking law provisions than in Kenya and Tanzania. It is assumed that this is one main reason why M-Pesa failed in South Africa (FinMark Trust 2017; Iraki 2016).

The results of the 2009 audit on M-Pesa's safety also demonstrated the effectiveness of the oversight approach adopted, as the safety of M-Pesa and appropriateness of risk approaches could be validated (Buku and Meredith 2013; Mas and Radcliffe 2011; Muthiora 2015). The literature reviewed for this case vignette, as well as interviewees, did not identify any negative outcomes directly related to the oversight approach taken (INT05, INT06).

2.5.5. What lessons can be learnt from this example?

Within a few years of its launch, the co-operation between the private companies Safaricom and Vodacom, and the governmental Central Bank of Kenya, was considered to be a key example of a successful public-private partnership.

Key to M-Pesa's successful launch in Kenya were characteristics of the Kenyan population in the early 2000s, such as the low proportion of Kenyans having access to banking services and the increase in people using mobile phones, as well as the high literacy rate of 85 per cent (Buku and Meredith 2013; Kimenyi and Ndung'u 2009; Mas and Radcliffe 2011; Vaughan, Fengler and Joseph 2012). In the mid-2000s, there was also no relevant competing service in Kenya and there was a demand for alternatives to traditional banking. In addition, Safaricom and Vodacom were market leaders in Kenya, covering 80 per cent of the mobile phone provider market, which supported M-Pesa's spread (Buku and Meredith 2013).

The key actors in the partnership around M-Pesa – Safaricom, Vodacom and the Central Bank of Kenya, but also others such UK's DfID and the London-based Vodafone

team – saw the opportunities that M-Pesa could bring to the Kenyan society. Enabling more people to use banking services would not only be a revenue stream for the commercial telecommunications providers, but also potentially lead to more equality in the society, as well as have wider impacts on the Kenyan economy (Buku and Meredith 2013; Kimenyi and Ndung'u 2009; Mas and Radcliffe 2011). The innovation-friendly attitude of the Central Bank of Kenya when choosing the oversight approach over applying strict banking regulations on M-Pesa can be seen as a key driver of M-Pesa's success, while at the same time ensuring that safety is guaranteed. Moreover, it allowed Safaricom and Vodacom to develop a service tailored to the needs of the Kenyan population, which may not have been possible if formal banking law provisions had been applied (INT05).

The approach taken by the Central Bank of Kenya helped M-Pesa to grow within a short period of time and helped contribute to providing millions of Kenyans access to banking services. Moreover, M-Pesa's rapid spread across the country created a large number of jobs, increased the number and amount of non-cash transactions in Kenya, and is also associated with some spill-over effects (Buku and Meredith 2013; Hayes and Westrup 2012; Kimenyi and Ndung'u 2009; Muthiora 2015). As Muthiora (2015) has put it, the case of M-Pesa showed that 'regulators can be agents of change for financial inclusion', and also exemplified how businesses can benefit from early engagement with regulators (Muthiora 2015). The approach taken by the Central Bank of Kenya arguably contributed to the successful rollout of M-Pesa's, which might not have been possible (although this cannot be confirmed) if banking law provisions had been applied from the outset (Buku and Meredith 2013; Hayes and Westrup 2012; Kimenyi and Ndung'u 2009; Muthiora 2015).

Although M-Pesa is seen as a successful example of a public-private partnership, stakeholders also faced a number of challenges. As outlined above, traditional banks and other external stakeholders had objections and concerns when the service launched, in particular regarding safety and anti-competitiveness – the latter continue to this day. The Central Bank of Kenya had to demonstrate in an audit that M-Pesa meets all safety and risk assessment requirements; Safaricom and Vodacom's risk assessment and safety procedures and policies – which were a requirement set out by the Central Bank of Kenya prior to launch – as well as the electronic audit trails, which Safaricom and Vodacom had to provide as part of the regulatory agreement, helped demonstrate this (Buku and Meredith 2013; Mas and Radcliffe 2011; Muthiora 2015). The formal *National Payment System Act* (2011) and the *National Payment System Regulations* (2014), which build on oversight and regulatory lessons learnt from M-Pesa, have helped overcome some of these challenges by covering all payment service providers (including branchless banking providers), as well as by formalising requirements around safety, risks, governance, oversight, etc. (Muthiora 2015).

The example of M-Pesa has exemplified that a participatory oversight approach can be conducive to the emergence and spread of innovations. When selecting oversight approaches, however, the contextual factors cannot be underestimated and must be taken into account. The case of M-Pesa also showed that having clear strategies and oversight policies which specify risk and safety requirements, is key, as this can help build trust among users and diminish concerns.

2.6. Case vignette 6
DAMD: The Danish General Practitioners Database

Summary: This case vignette discusses the development of the Danish General Practitioners Database in the 2000s to help capture, store and analyse healthcare data from patients associated with GPs in Denmark.

From the late 1990s onwards, European countries began to promote digitalisation in healthcare systems. As part of this agenda, the digitalisation of patient data had the potential to dramatically improve the healthcare provision and the analysis of healthcare systems. Against this backdrop, from 2003 onwards, Danish GPs worked together with regional health authorities to develop a system that would automatically and continually capture and store the data collected by the ICT systems used by GPs.

2.6.1. Background and context

Healthcare systems have the potential to create large amounts of data by collecting patient health information during each appointment and following every test. Collecting these data together and producing reports can help promote quality improvement, as well as provide data for further research on the healthcare system – which could contribute to improving healthcare systems (Christiansen and Rudkjøbing n.d.).

During the 1990s, European countries were making efforts to incorporate digitalisation into healthcare. For example, in 1998, the UK launched NHS Direct, a nurse-led telephone information service that provided health advice 24 hours a day (NHS Direct 2010). NHS Direct also offered a website which allowed patients to introduce their symptoms and receive advice or get directed to another NHS service. In the early 2000s, the Norwegian Ministry of Health and Social Affairs developed an action plan for IT development in the health and social sector, which included electronic interaction within health and social services, telemedicine, and provision of quality-assured information on public health and social services (Bergrtom and Stromer 2003).[46]

In the 1990s, a group of General Practitioners (GPs) in Denmark led an effort to standardise information registration through the development of a Danish version of the International Classification of Primary Health Care (Wadmann and Hoeyer 2018). The idea was to code patient contacts in a uniform manner to enable GPs to retrieve data from the electronic medical record and combine them with additional data sources, such as laboratories. This system would allow comparisons between patients and the patient population, with the aim of improving quality of care. A pilot run in the late 1990s revealed that GPs spent an entire day every three months to produce statistical reports for just one patient. Therefore, GPs started to explore less time-consuming approaches. In 2003, a group of GPs in Denmark developed a data capture module to automatically and continually

46 At the time, most Norwegian hospitals were in the process of digitising their x-ray division, preparing their systems for digital storage, and communication of x-ray images.

capture data from IT systems used by GPs, called 'Sentinel', and a database for these data to be stored in, the Danish General Practitioners Database (DAMD)[47]. The technology was aimed at collecting and analysing healthcare data from patients associated with GPs, and to be processed into quality reports with patient and population overviews, as well as decision-making information, such as the most appropriate treatment to give a specific patient (Aaen 2018). DAMD aimed to contribute to data standardisation that would enable patient comparisons as well as patient population comparisons.

2.6.2. Why was oversight required?

Collecting patient data automatically from GP databases came with a number of advantages[48]: it provided GPs with the opportunity to see their patients as a stratified population according to specific diagnoses; it allowed GPs to monitor the treatment status of individual patients; it enabled GPs to identify their own weak points by benchmarking against national averages; and it required no additional effort from GPs (Wadmann and Hoeyer 2018). However, setting up a national database with patient health data came with additional risks related to new interests in the data by different stakeholders (INT07). One of the main risks was that of privacy and the possibility of identifying patients from the data, despite the data being anonymised (Anderson 2012). Additionally, the possibility of identifying patients could lead to breaches in doctor-patient confidentiality, affecting doctor-patient relationships and, as a consequence, delivery of care. Although these data could be used to improve the quality of care delivered to patients, it could also be used by private companies or other stakeholders in non-beneficial ways for the patient (e.g. employee recruitment, health insurance, etc.). As a consequence of these benefits and risks, and given the complex structure of the Danish healthcare system which makes integrated care a challenge (Andersen et al. 2011), DAMD needed to be closely monitored.

2.6.3. How was the oversight carried out?

The Danish healthcare system is overseen by the Danish Ministry of Health (Pedersen, Andersen, and Søndergaard 2012) but is the responsibility of the Danish regions (Pedersen, Andersen and Søndergaard 2012). There are five regional authorities that are politically and administratively responsible for the delivery of healthcare. Healthcare services are free at the point of care for all citizens and are paid for mainly through taxes. Citizens register with a GP, who will refer them to specialised healthcare services if required. GPs are self-employed, but most of their income comes from the regional healthcare authority with which they contract through collective agreements.

In 2003, a group of GPs supported through a collective agreement between the General Practitioner's Organisation (PLO) and the regional authorities of the South Denmark Region, began developing the DAMD information infrastructure (consisting of the data capture module Sentinel and the database itself) to create connections and relations across multiple entities of the Danish primary healthcare sector (Langhoff et al. 2018). The DAMD database was operated by the Danish

47 From the Danish 'Dansk Almen Medicinsk Database'.

48 Many of these points still hold true today with regard to automatic patient data collection.

Quality Unit of General Practice (DAK-E),[49] which was governed and financed through collective agreements between the regional authorities and the PLO) (Aaen 2018). Once developed, the Sentinel was voluntarily piloted by a group of GPs (Aaen 2018).

The Sentinel originally collected data on four diseases (Type 2 diabetes, chronic pulmonary disease (COPD), congestive heart failure, and depression) into four databases, in accordance with Danish regulation, which stated that 'Clinical Quality Databases' must have a well-defined purpose, and that information gathered on each of these diseases be stored in four different databases (Lippert, Kousgaard, and Bjerrum 2014; Aaen 2018). This allowed DAMD to be classified as a 'Clinical Quality Database', which meant it was exempt from the legal requirement of patient consent (INT07). The data collected was processed into quality reports and provided to local GPs.

Following the pilot project in 2003, in 2006 Danish regional authorities and the PLO reached a collective agreement to roll out implementation of Sentinel and DAMD across the country. This meant that DAMD would receive nationwide funding, as, for a database of this type to obtain government approval and public funding it needs to cover at least 90 per cent of patients with a disease in the Danish

49 DAK-E is responsible for coordinating quality development in general practice in Denmark and is owned by a fund managed between the Danish Regions and the PLO (DSAM n.d.).

hospital system. The agreement also expanded the functionality of DAMD, allowing the data to be used for cross-sectorial quality monitoring and delivery of data to research projects, in addition to its original purposes (Aaen 2018). Between 2006 and 2009, data collection increased from the initial four diagnoses to include approximately 700 International Classification of Primary Care diagnoses (Aaen 2018).

In 2010, the Danish Regions and PLO saw the potential that DAMD, as a national quality database, could be used to inform the Health Managers in the Danish Regions on the performance of general practice in the different regions (INT07). A new collective agreement was reached which made it mandatory for all GPs to install Sentinel Data Capture for data collection and transmission to DAMD. By 2013, over 96 per cent of Danish GPs were registered users of the database (Paulsen and Thomsen 2013). The Danish Regions and PLO also saw the opportunity for patient empowerment, as DAMD has access to information on almost every patient in Denmark. The 2010 collective agreement therefore also required the data collected in DAMD to be published on a web portal (sundhed.dk), enabling citizens to access their own health data online, as well as other health professional when relevant for a given treatment (Wadmann and Hoeyer 2018).[50]

In 2013, DAMD was discussed at a GP conference in Denmark (INT07). GPs raised concerns on the amount of data being collected from medical records and what the data was being used for. They claimed that the expansion of the infrastructure and the exact flow of the data had not been clear and transparent (Wadmann and Hoeyer 2018). The GPs engaged in conversations with IT providers, made freedom of information requests and read policy documents, which made the digital infrastructure more comprehensible to them. Fearing breaches in patient-doctor confidentiality (INT07), GPs began researching the legal basis for the data activities and found there was a new collective agreement being developed by the Danish Regions that would force GPs to report certain data to DAMD and made them subject to fines if they did not, breaking with the tradition of consensus-based regulation through collective agreements (Nexøe 2013) (Wadmann and Hoeyer 2018). In 2014, the Ministry of Health was to release a new Healthcare Act, which would give Health Managers in the Danish Regions access to DAMD for planning, quality assurance and financial control (Aaen 2018). This was strongly opposed by the developers of DAMD and by PLO, who stated that GPs would report less data as they would not report data that could risk compromising their position (for example, if they were not strictly following guidelines). In response, two GPs began a movement against DAMD (Wadmann and Hoeyer 2018) (INT07). The day before the new legislation was to enter into force, the two GPs organised a social media event for them and 70 colleagues to uninstall the Sentinel data capture system (Wadmann and Hoeyer 2018). Media attention was given to the movement, and the legality of DAMD was brought to question nationwide in regards to comprehensive collection and reuse of data without patient consent (Wadmann and Hoeyer 2018; Aaen 2018). Citizens began to demand their data be deleted and over 20,000 patients asked to opt out (Wadmann and Hoeyer 2018).

50 The process of transferring data onto sundhed.dk was overseen by a taskforce comprising the DAMD Steering Committee, MedCom (who operate sundhed.dk), PLO and the Danish Regions. This taskforce was responsible for overseeing the technical, legal and operative aspects of the process (Aaen 2018).

Data collection for DAMD was suspended in the autumn of 2014 due to an investigation commissioned by DAK-E and conducted by the Statens Serum Institut (SSI), which concluded that the comprehensive use of DAMD lacked legal basis (Statens Serum Institut 2014). The investigation deemed that DAMD did not meet the legal requirements for clinical databases, which in Denmark is limited to disease-specific registers (OECD 2016). Additionally, it was considered that DAMD did not collect data in accordance to the European Data Protective Directive 95/46 (i.e. for specified, explicit and legitimate purposes). DAMD was therefore closed down.

2.6.4. How effective was the oversight?

The investigation that led to the collapse of DAMD revealed how the accountability of the database had been complicated by intertwined stakeholder interests and an excess of functionalities. Over the years of DAMD's existence, different stakeholders became involved and additional functions were added, yet the legal framework was not updated accordingly. This led to lack of transparency and accountability, and ultimately the suspension of DAMD. The legality of DAMD was limited to its four original diseases, as per the collective agreement between the Danish Regions and PLO in 2003. The expansion of DAMD to include mandatory participation among GPs raised concerns among GPs on privacy and patient-doctor confidentiality. Additionally, with the involvement of other healthcare professionals, as well as national, regional and local government, came concerns on how new functions in data input could harm the validity of data collection and whether there was sufficient legal basis for the project.

Despite the conclusion that data was illegally obtained for DAMD, the Ministry of Health announced that the Danish National Archives considered DAMD a unique database which should be preserved at the National Archives (Lund 2015). This was enabled by the Data Protection Act, which has an exemption that allows personal data to be transferred to the Danish National Archive without consent (INT07). However, given the national debate on DAMD before the data was transferred to the National Archives, patients were given the option to have their data deleted (INT07).

2.6.5. What lessons can be learnt from this example?

The DAMD case vignette is an example of a data-driven health technology that was perhaps a victim of its own success, and could potentially serve as a 'warning' for those seeking to take advantage of the opportunities provided by new technologies to do so in a contained and considered manner, and ensuring transparency in the system (INT07). DAMD expanded rapidly without the legal framework being adapted, leading to lack of transparency on the ownership and accountability of DAMD and communication, and ultimately the suspension of DAMD (INT07) (OECD 2016).

The collapse of DAMD is attributed to two challenges common to data-related projects: function creep and stakeholder creep. These terms refer to an increase of functions and stakeholders, respectively, beyond the original scope of a data-driven project. Data does not expire nor necessarily deteriorate, which means it can be reused, leading to continual expansion of uses for the data. As new uses for the data were explored, new stakeholders became involved. In the case of DAMD, stakeholders involved included regulatory authorities with a potential conflict of interest, leading to unclear organisational boundaries and a lack of accountability (INT07). The Ministry of Health was likely to benefit from the use of DAMD for health planning and management.

The addition of functions in data intensive projects can lead to issues related to privacy, legality and performance due to changes in the purpose of technology. For example, in the case of DAMD, function creep resulted in 'invasion of privacy beyond what was originally understood and considered socially, ethically, and legally acceptable' (Dahl and Sætnan, n.d.). Although function and stakeholder creep is a risk of all data-driven projects, it was particularly an issue for DAMD given its usage of patient health data (INT07). DAMD was originally developed with two[51] functions. In 2014, seven[52] additional functions had been added to the database, and there was an increase in the number of stakeholders involved (from three[53] to 11[54]).

In 2016, the Organisation for Economic Cooperation and Development (OECD) urged Denmark to bring back DAMD, or a version of DAMD (OECD 2016). This was prompted because, following the collapse of DAMD in 2014, Denmark became one of the few countries in the OECD with no means of monitoring primary care performance (OECD 2017). The review by the OECD outlined the reasons for the failure of DAMD and provided recommendations on how to reinstate the database, focusing on greater transparency (OECD 2016). The OECD provided policy recommendations to solve the suspension of DAMD through changes to Danish law, removing the requirement for disease-specific registers and allowing patient-based data collection. Restoration of DAMD was negotiated in the Danish parliament with input from doctor and patient groups. The new DAMD would ensure patients own their own data and would limit the use of personally identifiable data (Sundheds- og Ældreministeriet 2017). As of November 2018, DAMD has not been reinstated.

51 Collect patient data on four ICPC diagnoses and produce quality reports.

52 Export data to clinical registries; delivery data to research projects; data collection on approximately 700 ICPC diagnoses; export patient data to sundhed.dk; commodification of data; export data to other healthcare professionals; export data to regions and municipalities for management purposes.

53 GPs, Danish Regions Health Authorities and PLO.

54 GPs, Danish Regions Health Authorities, PLO, Steering Committee for the data project, Quality and Research Committee, RKKP, patients, SSI, medical industry, healthcare professionals, and national/regional/local government.

2.7. Case vignette 7 The Global System for Mobile Communications

Summary: This case vignette discusses the development of the Global System for Mobile Communications standard in Europe in the 1980s.

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 European Union, national governments and private stakeholders worked together to develop a pan-European standard for 2G cellular networks – the Global System for Mobile Communications (GSM).

2.7.1. Background and context

Digital mobile cellular technology was the second generation of mobile communications technology (2G), following and largely replacing first generation analogue systems (1G).[55] The development of 2G wireless technology during the 1980s and early 1990s offered three key advantages over its predecessors. First, transmitting digital signals consumed less battery power, which helped increase the run time of mobile devices. Second, 2G digital coding exhibited a higher spectral efficiency – the information rate that can be transmitted over a given bandwidth – than 1G analogue coding and offered increased call quality. And third, transmissions made over 2G could be digitally encrypted, enhancing the privacy and security of calls made over mobile networks. Data services – such as the short message service (SMS) – were introduced for the first time with 2G.

By the early 1980s, most Western European countries had analogue (1G) cellular networks in place. These networks, however, were based on a patchwork of different standards. While the United Kingdom, France and Austria used an adapted version of the US Advanced Mobile Phone System (AMPS) standard, other countries, particularly in Scandinavia, based their networks on a Nordic Mobile Telephony (NMT) standard. France, Germany and Italy, meanwhile, opted for their own national systems (Hillebrand 2013). In most cases, national telecommunication markets were controlled by commercial monopolies (Pelkmans 2001).

2.7.2. Why was oversight required?

With new digital mobile cellular technology on the horizon, there was a possibility that proprietary and incompatible 2G systems would be developed across European nations. Continued fragmentation had a number of potential drawbacks. It would lead to consumers potentially being stuck with

55 Analogue systems send signals that can take a smooth and continuous range of values, while digital systems send discrete signals that may only be drawn from a finite set of values. Most commonly digital signals are binary – they can take two values of either zero or a non-zero (usually large) number.

a failing technology or facing high switching costs; poor economies of scale for network operators and equipment producers; and poor roaming capabilities (Bekkers, Verspagen and Smits 2002). Because demand within individual European states was too low to reach 'critical mass' – the point at which the rate of adoption becomes self-sustaining and creates further growth – there was also a risk that network operators would not be able to afford the investment in the expensive equipment (such as new base stations and handsets) required for 2G (Pelkmans 2001).[56] A standardised pan-European system, however, would enable operators to make these infrastructural investments with economies of scale. Furthermore, European standards would allow for cross-border roaming. Roaming – particularly for business purposes – was deemed to be an important factor in the wider adoption of mobile communications (Pelkmans 2001). Beyond its commercial and technical rationale, the concept of a European network also chimed with prevailing political and economic imperatives in the European Union, including the drive for market liberalisation and increased competition (INT08).

Even by the mid-1970s, the availability of frequencies for mobile communication had become a major challenge. The range of frequencies over which data could be transmitted was limited and most frequencies had already been allocated (for example for military use, TV broadcasting and aeronautical navigation). The 900 MHz spectral band provided a frequency that could be used for a common European standard.[57] If action was not taken quickly, however, the opportunity would be lost. At the Conférence des Administrations Européennes des Postes et Telecommunications (CEPT) meeting in 1982, it was noted that if operators were allowed to use the 900 MHz band for incompatible systems, a pan-European system would not be feasible within the 20th century (Hillebrand 2013; Dupuis 2007)[58] The prospect of missing out on the opportunities at hand offered a strong incentive for cooperation between European actors.

2.7.3. How was the oversight carried out?

In light of the considerations outlined above, the prospect of a harmonised pan-European mobile communication system became a priority matter for the CEPT during the 1980s. The subject was first raised during a presentation at the 1982 CEPT meeting (Hillebrand 2013; Dupuis 2007). By the end of the year, the Groupe Spécial Mobile (GSM) had been formed to oversee the development of the new standard. As a working group of the CEPT, the GSM comprised of representatives of national European telecommunications administrations, together with a number of European mobile network operators.[59] At the first GSM meeting in Stockholm, there were 31 representatives from 11 European countries (Karlsson and Lugn 2016). At the time of the GSM's formation, digital mobile cellular technology was at a pre-commitment and pre-competitive stage. No actor had made a

56 At the time, many network operators had also made recent and large-scale investments into other areas of network development, such as digital switches for fixed (landline) telephone networks (INT01).

57 A spectral *band* is a section of the radio *spectrum frequencies* in which channels are usually used or set aside for one purpose.

58 More information about this meeting and its significance in the context of this case vignette is included in the next section.

59 Notably, at this stage no equipment manufacturers were members of the GSM (Pelkmans 2001).

commitment to any particular technology and the technology was not sufficiently advanced for commercialisation (Pelkmans 2001). Notably, the time-division multiple access (TDMA) technology (enabling multiple users to share the same frequency channel), that was to become a core feature of the eventual standard, was not confirmed until 1987 (Pelkmans 2001). During its early phases, the GSM, therefore, witnessed debate concerning whether or not the new standard would be digital, or whether it would be based on an existing analogue standard (Temple 2010).[60] The question of whether the new standard should support hand portables was also the subject of much deliberation (Hillebrand 2013).

The specifications of the proposed pan-European standard were developed by the GSM between 1984 and 1987, with plenary meetings supported by subgroups established to work intensively on specific aspects of the standard. Areas of focus included: the standardisation of the security architecture, including authentication and encryption; the use of smart cards as Subscriber Identity Modules (SIM); concepts for international roaming; and arrangements for the licensing of mobile stations. The most critical issue, however, was the selection of radio transmission technologies. While the GSM moved towards agreement that the standard should use digital radio transmission technology, the question of which access technology should be used was less straightforward. Following debate during a GSM plenary meeting in Madeira in 1987, it agreed that further technical work would proceed on the assumption that a narrow band TDMA solution would be used (Hillebrand 2013). This period of intensive development was marked by intensive cooperation between public and private stakeholders. GSM groups were opened to participation of manufacturers as well as operators (Hillebrand 2013; Temple 2010).

By 1987, the basic parameters for the Global System for Mobile Communication standard (the GSM Standard) were agreed. To ensure the standard would be widely adopted in a timely fashion, a memorandum of understanding was signed by stakeholders[61] from 13 countries[62] (Temple 2010). Under the memorandum, commercial operators accepted commercial risks and responsibilities, and governments committed to supportive actions, such as establishing conducive administrative and regulatory frameworks (Signatories 1987). The memorandum cemented the public-private partnership that had characterised the GSM debates and served to capitalise on the political direction by aggregating the purchasing power of mobile operators across Europe (Temple 2010). In the same year, following a recommendation from CEPT, the European Council issued a Directive (87/372/EEC) requiring member states to ensure spectral frequencies around 900 MHz be reserved for purpose public pan-European cellular digital communications service (Council of the European Union 1987). The Council Directive did not compel industry actors to follow any particular course of action. Rather, network operators were offered access to a new

60 The UK government, for example, felt that digital technology needed to prove its commercial viability over existing analogue systems (Temple 2010).

61 The idea of the MoU was to cement the high level collaborative agreement into an action plan involving commercial entities. The MoU could be signed by 'any telecommunications administration and/or any public telecommunications operator within CEPT authorised in his country to provide public digital cellular mobile telecommunications services' (Signatories 1987).

62 The Memorandum of Understanding was signed by stakeholders from the following countries: Germany, Belgium, Denmark, Spain, Finland, France, Ireland, Italy, Norway, Netherlands, Portugal, the United Kingdom and Sweden.

part of the spectrum with certain conditions attached[63] in order to promote the broad goal of a harmonised pan-European system (Temple 2010). In 1991, the former Finnish prime minister, Harri Holkeri, made the world's first GSM call (Fonearena 2011).

In 1989, the Groupe Spécial Mobile was transferred from CEPT to the newly formed European Telecommunications Standards Institute (ETSI), which took over responsibility for managing the GSM standard. ETSI was open to all interested parties (such as equipment manufacturers, network operators, administrators, users and research bodies) within Europe. In 1992, it was also opened to international stakeholders. The inclusion of international stakeholders was motivated, in part at least, by the desire of European (and national) authorities to open up the European telecommunications market to international competition (Temple 2010). Telstra Australia was the first non-European network operator to join. Another organisation quick to participate was the US-based company, Motorola (Temple 2010). The opening up of ETSI was a key driver of the global expansion of the GSM standard (see below). In 1995, the GSM Association (GSMA) was also formed to support and promote the GSM standard across the world.

During the design of the GSM standard, care was taken to avoid a situation where one intellectual property right (IPR) holder could control or block development of the standard (Bekkers, Verspagen and Smits

63 Specifically the frequency band was "reserved exclusively for a public pan-European cellular digital mobile communication service [introduced] by 1 January 1991" (Council of the European Union 1987).

2002). Instead, the standard contained 140 essential patents held by 14 firms – though four companies (Motorola, Nokia, Alcatel, and Philips) held over half of these (Bekkers, Verspagen, and Smits 2002). To mitigate IPR risks, a group of network operators drafted a contract describing procurement rules whereby suppliers had to offer free worldwide licences that were essential to the GSM standard, and manufacturers had to indemnify operators against patent infringements. However, this procurement contract ultimately failed due to some suppliers refusing to sign, resulting in licences being negotiated on an individual basis. As discussed below, this would ultimately have important implications for the structure of the telecommunications market (Bekkers, Verspagen and Smits 2002).

2.7.4. How effective was the oversight?

The GSM standard is widely considered to have been a successful piece of industrial policy (Pelkmans 2001; Haug 2002; Hillebrand 2013). First, it resulted in the replacement of the analogue mobile cellular network with a digital network, which has subsequently been improved through several higher generation and more advanced digital technologies (3G, 4G and, imminently, 5G). While digital technology has tended to replace analogue (for example in computation, information storage, and cinematography) it has not done so for landline communication and so was not a given for mobile cellular technology (Temple 2010). The technological advance was not hindered by regulation, but rather accelerated by it. Second, the memorandum of understanding regarding the GSM standard ensured that while operators would remain national, they were connected into a pan-European network (Temple 2010). Mobile networks prior to GSM had been national endeavours, with the exception of the NMT cooperation (Haug 2002). Finally, before the GSM standard, mobile phones were expensive, luxury devices predominantly used for business purposes (Agar 2013; Gustke 2017). The economies of scale offered by wide adoption of the standard resulted in handset devices becoming cheaper and the market switching to being driven by demand (Pelkmans 2001).

Another measure of the effectiveness of the GSM standard was its spread beyond Europe. The ambition for a pan-European mobile system was exceeded, with the GSM becoming the dominant worldwide standard for over a decade. In 1994, the Chinese government decided that GSM should be used as a national standard. Shortly afterwards, the country's first GSM networks went into operation (Hillebrand, 2013).[64] In the United States, an adaption of the GSM standard using the 1900 MHz band was developed in 1995 (Hillebrand, 2013). As GSM offered a complete standard for mobile communication (as opposed to describing only one element), it was attractive to countries with little existing mobile communication infrastructure. Due to the open stance taken by the ETSI, non-European countries and their network operators could join and rapidly implement the standard. In 2008, the GSMA announced that GSM networks served more than 700 mobile operators across 218 countries and territories, covering over 3 billion people (GSMA 2008). GSM-based networks have been a major driving force behind the rise of worldwide mobile phone users to five billion worldwide in 2018 (GSMA Intelligence 2018). The staying power of the GSM standard has also been impressive. 2G networks fostered by

64 China's GSM also had additional requirements, including a new SMS alphabet and more network nodes than required in European countries (Hillebrand, 2013).

the GSM standard have only recently started to be decommissioned (for example in Australia and Singapore, though more are planned for shut-down in the near future) due to being superseded by 3G and 4G networks.

The public in Europe benefitted from having the ability to use their mobile devices while travelling abroad, as they were guaranteed to be compatible with networks in other countries under tariff arrangements that had been made between the network providers. However, while roaming was possible, it was costly, with a call costing up to ten times more while roaming than on a home network (Sutherland 2001). High roaming charges have remained an issue since, prompting several waves of EU regulation to tackle the problem (European Commission 2018) Due to the prevalence of the GSM standard, mobile phones using this standard were often ahead of the competition, as businesses focused resources on improving devices that catered to the largest market. As such, the public in Europe (and other regions that adopted the GSM standard) had access to the cutting-edge of mobile consumer devices (Temple 2010).

The United States took a different approach to Europe and let market competition proceed without public oversight. During the decade of GSM implementation in Europe, three competing digital standards emerged in the United States: IS-136 describing the digital advanced mobile phone service (D-AMPS); IS-95 describing code division multiple access (CDMA) technology developed; and an adaption of the GSM standard PCS-1900 (Hardy, Malleus and Mereur 2013). Network operators in the United States were free to use any of these standards. While the US model did eventually deliver broad coverage by digital cellular networks, its progress was significantly slower than that which occurred in Europe. By 1993, there were over one million users of the GSM standard in Europe, and every European country had at least one GSM operator by 1995. At this time, the US Federal Communications Commission (FCC) had not yet completed assigning spectral frequencies for 2G networks (Gandal, Salant and Waverman 2003).

One negative implication of the GSM standard was its bearing on the structure of the telecommunications market, specifically its detrimental impact for small and medium sized manufacturers. As noted above, the GSM standard contained a number of intellectual property patents for digital technologies – so-called 'essential IPRs' – controlled by a relatively small number of firms. After rejecting operators' attempts to ensure non-discriminative worldwide licenses to these patents, certain patent-holding manufacturers opted for a strategy in which IPRs were typically only made available via cross-licenses with other companies which themselves had patent licences to offer in return. This strategy reduced market risks for patent-holding operators, but created significant barriers to market entry for smaller firms without patents. During the late 1990s, as much as 85 per cent of the GSM market in Europe was controlled by only five firms (INT08) (Pelkmans 2001; Bekkers, Duysters and Verspagen 2002).

Another area where oversight was perhaps lacking was in managing the risk of electromagnetic interference with existing systems. In 1989, two years after the GSM standard had incorporated TDMA technology, it was discovered that this feature caused significant interference with certain types of hearing aids, which manifested as a buzzing sound at a distance of up to 40 meters (ETSI 1997). The extent of interference varied from distracting to painful, depending on the hearing aid model (Skopec 1998; Temple 2010).

2.7.5. What lessons can be learnt from this example?

There are several important reasons why the GSM standard was successful. First, it was essential that industry actors were involved from the outset with the development and implementation of the standard. There was industry interest in digital mobile technology, as, despite the small user base of the preceding 1G approach, it had expanded rapidly, indicating the potential for a large market served with modern technology. Due to the promise of substantial revenue growth, industry actors were willing to make financial commitments to the development of standards and technology. Second, these industry actors were by and large network operator monopolists within European nations; they did not expect to suffer from competition with other network operators, and indeed did not do so until the later stages of GSM implementation. Having monopoly powers within nations, network operators had an incentive to support a pan-European network and to realise the future opportunity of setting profitable roaming charges. Finally, the scale of the project was enormous and required the support of European governing bodies. This support was given through actions such as the directive to reserve spectral ranges for a pan-European system, and the involvement of European Institutions such as CEPT and ETSI.

Standards and intellectual property rights can be at tension with one another, with standards describing a common set of rules and IPR serving to enable a firm to exploit an advantage (Bekkers, Verspagen and Smits 2002). Providing IPR holders are willing to licence out for reasonable fees to any interested party, the two concepts can co-exist without conflict. In the case of the GSM, some IPR holders made general declarations regarding the fair and reasonable licencing of their patents, but others would not agree to do so – including Motorola, who held the largest number of essential patents. Motorola's insistence on cross-licensing may have benefitted other companies who held patents essential to the GSM standard or otherwise valuable to Motorola, but, as noted above, acted as a barrier to entry for other firms for many years (Bekkers, Verspagen and Smits 2002; Bekkers, Duysters and Verspagen 2002). Prior to GSM, European telecommunications patents that were essential to a standard were either open or available for use upon payment of a reasonable royalty. The manoeuvring around essential IPR from companies primarily based in the United States changed the environment to one where IPR was used to leverage market advantage. This has resulted in a significant proportion of handset costs being attributable to IPR royalties (Armstrong, Mueller and Syrett 2014; Galetovic 2018). Therefore, one learning point concerns how standardisation, as a form of oversight, can interact with IPRs to shape market structures, with potential unintended consequences for both industry actors and the public.

Oversight approaches must be chosen in the context of the wider environment. In the United States, market forces prevailed and dominant firms were allowed to emerge (for instance, Microsoft in the field of software). The respective choices to let market forces determine standards in the United States and regulation determine standards in Europe were arguably appropriate for the two environments. In the case of the GSM standard, regulation was employed at an appropriate time in a swift and decisive fashion, such that it stimulated technological progress and overcame the significant barriers posed to the development of 2G by siloed national networks and markets. While there was a risk of prematurely locking in to a sub-optimal technology, the early and deep involvement of industry actors helped mitigate and avoid this risk.

2.8. Case vignette 8 The NIH Recombinant DNA Advisory Committee in the United States

Summary: This case vignette discusses the development of the NIH Recombinant DNA Advisory Committee in the United States to help discuss and debate issues surrounding the use of recombinant DNA technology.

Recombinant DNA (rDNA) technology began to emerge in the late 1960s with the development of techniques to splice DNA molecules. Recombinant DNA technology offered a range of possibilities for molecular biological research, including gene therapy and genetic modifications. Recognising both the potential applications of rDNA, but also its multifaceted risks, the scientific community sought to develop fora in which the uses of rDNA could be discussed. In the United States, these efforts led to the formation, in 1973, of the National Institutes of Health (NIH) Recombinant DNA Advisory Committee.

2.8.1. Background and context

Following the discovery of the structure of DNA in the early 1950s, molecular biology took off as a subject of study. In 1957, Arthur Kornberg became the first person to synthesize DNA in a test tube (US National Library of Medicine n.d.). This was followed by the deciphering of the genetic code over five years between 1961 and 1966 (Nirenberg 2004), and the first DNA sequencing in 1968 (Hutchison 2007). Deciphering the genetic code gave way to plans for genetic engineering – the direct manipulation of an organism's genes and DNA.

Recombinant DNA (rDNA) are DNA molecules formed from two other different pieces of DNA to create a sequence that would not be found naturally (Smith 2018). rDNA technology began to emerge in the late 1960s, when biochemist Paul Berg of Stanford University first developed techniques to splice (cut and join) DNA molecules. In 1971, Berg proposed an experiment to splice genes into the virus SV40,[65] and concerns began to arise within the scientific community regarding the potential biohazards associated with this process (Wivel 2014; Lenzi et al. 2014). The experiment was temporarily postponed in response to these concerns, but was carried out later that year to produce the first piece of rDNA ever created.

2.8.2. Why was oversight required?

Recombinant DNA technology offered a wide range of possibilities for new molecular biology research (Khan et al. 2016). Recombinant technology provided the ability to put genes of interest in bacteria and replicate them and their protein products.[66] This meant that a wide range of genes and proteins could be investigated to identify their function. It

65 SV40 is a virus that occurs naturally in monkeys and was introduced to humans through contaminated poliovirus vaccines between 1955 and 1963 (Martini et al. 2007).

66 Synthetic human insulin, for example, was the first commercial health care product to be produced using this technology (Johnson 1983).

also opened up the possibility of gene therapy and genetic modifications (Khan et al. 2016). Oversight was required to facilitate research in these areas and to ensure that these potential benefits were realised.

On the other hand, scientists recognised the potential for rDNA technology to have serious adverse safety effects. In the case of Berg's experiment with SV40, for example, American biologist Robert Pollack highlighted the potential human cancer risk that might result from splicing a small animal tumour virus with a bacteriophage that naturally lives in humans (Wolf, Gupta and Kohlhepp 2009; Swazey, Sorenson, and Wong 1977). Others were concerned about potential environmental consequences (Wolf, Gupta and Kohlhepp 2009), as the risk of ecosystem disruption caused by the accidental or intentional introduction of rDNA into the environment is much the same as that caused by the introduction of exotic species (Patra and Andrew 2015), which had been observed with many introduced plants and animals worldwide (IUCN 1967). In the run up to the introduction of the first genetically modified crops in the early 1990s, scientists expressed concern about the potential for these introduced organisms to displace native species, particularly microbial species (Tiedje et al. 1989). This might occur as a result of, for example, the interaction between genetically modified plants and the soil microbial community changing microbial biodiversity and affecting ecosystem functioning (Dunfield and Germida 2004). rDNA was also associated with a number of ethical issues that contributed to the need for oversight. Religious organisations began to call for formal legislative measures as early as 1980 (Wivel 2014), and religious and moral objections to the manipulation of life through genetic modification have continued throughout the history of rDNA (Kuzma and Tanji 2010). More recently, others have voiced additional ethical considerations, such the need for access to the technology to be equitable, and the need to establish an appropriate balance between the technology's potential benefits and risks for both individuals and communities (Kuzma and Tanji 2010).

2.8.3. How was the oversight carried out?

Oversight of rDNA technology was initiated by the scientific community. Peer exchange of views began after Berg responded to Pollack's objections and postponed his DNA splicing experiment, and in January 1973 a conference to discuss the potential hazards posed by rDNA research took place in Asilomar, California (the first Asilomar conference). One of the conference outputs was a letter published in Science by Berg and colleagues, discussing the lack of knowledge about rDNA technology and its associated risks (Berg et al. 1974). Responding to these concerns in 1974, the National Academy of Sciences created a committee to investigate rDNA technology, bringing the issue into the public and media consciousness (Wivel 2014). In 1975, the scientific community organised a second Asilomar conference to debate the dangers of rDNA experimentation, at which about 150 molecular biologists from around the world agreed to a voluntary moratorium on particular types of experiments until their hazards could be properly assessed (Wivel 2014). The experiments that were identified at this conference as carrying some degree of risk were those involving putting toxin genes, drug-resistant genes and cancer genes into E. coli, which is a bacteria found in the human gut, among other places (Berg n.d.). The same group of scientists subsequently published a letter calling on 'scientists throughout the world' to adopt the same voluntary moratorium (Berg n.d.). The day after the second Asilomar conference, then director

of the National Institutes of Health (NIH) Dr Donald Fredrickson began formation of the NIH Recombinant DNA Advisory Committee (RAC), which was created to provide oversight of the field of rDNA (Wivel 2014).

The original RAC was dominated by bacterial geneticists, and there were no non-scientific 'public' members on the committee (Wivel 2014). The RAC's first task was to develop a set of guidelines for research involving rDNA molecules, which was published in June 1976. The NIH Guidelines began with a statement of four general principles that were consistent with the general conclusions reported from the second Asilomar conference (Singer 1977). These guidelines were: that some experiments were potentially so hazardous that they should not be attempted until further research into their risks could be conducted; that there were several feasible experiments posing less or no potential hazard that could be conducted under certain conditions; that experiments posing more serious potential hazards should employ more rigorous safeguards to ensure the containment of potentially hazardous agents; and that the guidelines should be reviewed at least annually in order to incorporate new knowledge (Singer 1977). Because they were guidelines and not regulations, they could be reviewed annually and amended easily and frequently (Wivel 2014). However, a specific provision in the guidelines called for the suspension, limitation or termination of NIH research grants if the guidelines were violated by an NIH-funded project, or by any project conducted at an institution receiving NIH funding for projects involving rDNA techniques (NIH 2016). Some legal scholars have argued that this provision allowed the guidelines the status of de facto regulations (Wivel 2014). This clause is still present within the current NIH Guidelines. All projects involving rDNA techniques conducted within the United States fall within the scope of the NIH Guidelines, however they are funded, and are therefore obligated to comply with its requirements. For example, the obligation for all research falling within the remit of the Guidelines to comply with its provisions is written into the National Science Foundation's post-award requirements (NSF 2018). The NIH Guidelines, thus, provide justification for other funders to withdraw funding in the case of non-compliance, but do not explicitly call for this. It is the NIH that is responsible for reviewing and updating the NIH Guidelines, but the RAC continues to offer guidance to inform this process (INT09).

The role of the RAC was and remains to make recommendations on research involving recombinant or synthetic molecules, including rDNA (Department of Health & Human Services 2017). In the early days of the RAC, the committee reviewed all research protocols involving rDNA and related technologies, and offered advice and recommendations regarding their conduct. Over time, as rDNA research continued and evidence was accumulated demonstrating that initial concerns about the risks to human safety were unwarranted, the RAC moved to only reviewing a subset of protocols it deemed to be novel and/or presenting particular legal, moral or ethical concerns (INT09). The full RAC now holds open public meetings four times a year to discuss such protocols, and is obligated to give notice of these meetings to the public to enable them to attend (Department of Health & Human Services 2017). According to the RAC meeting minutes, public attendance at the open meetings held in 2015 and 2016 ranged between ten and thirty public attendees per meeting (National Institutes of Health

2016).[67] The recommendations offered by the RAC at these meetings are not binding, but Food and Drug Administration (FDA) officials always attend and can later choose to impose these suggestions as part of their own review process (Wivel 2014).

There were no non-scientific members included in the first RAC, but in 1978 the US Secretary of Health, Education and Welfare, Joseph Califano, introduced a requirement for the committee to include non-scientific members: at the time, the composition was 2/3rd scientists and 1/3rd non-scientists (Wivel 2014). The Committee is still required to have a majority of members knowledgeable in relevant scientific fields, such as molecular biology, but also at least four members knowledgeable in related areas such as public health, ethics, law and public attitudes (Department of Health & Human Services 2017). Public concern and even alarm about rDNA research had been mounting during the 1970s (Institute of Medicine 2014), and having non-scientist members on scientific oversight bodies makes research more accountable to the public and ensures that community values, views and norms, as well as the interests of human research subjects, are represented on the Committee (Allison, Abbott and Wichman 2008).

67 The majority of the attendants at these meetings are representatives of biotechnology/pharmaceutical companies (National Institutes of Health 2016).

NIH oversight also occurred at a local level among individual institutions, including academic medical centres. Each institution had, and continues to have, two committees: the Institutional Review Board (IRB), an ethics and scientific panel that focused on protecting the welfare and rights of research participants – for example, monitoring processes to attain informed consent; and the Institutional Biosafety Committee (IBC), which concentrated on reviewing the potential biohazards presented by the scientific protocols (Wivel 2014). The IBCs and IRBs adhered to certain requirements, which were written into an appendix of the NIH guidelines in 1985, and modified continuously thereafter. These requirements currently include for each committee to be comprised of at least five members, representing a diversity of backgrounds and areas of expertise, at least one of whom (two for an IBC) should not be otherwise affiliated with the institution (US Food and Drug Administration 2018; National Institutes for Health, n.d.). The IRBs and IBCs issued provisional approvals, and the RAC determined a final recommendation forwarded to the Director of NIH after a period of public comment. As noted above, this was not binding and could be rejected by the NIH director; but, for the most part, RAC recommendations were taken seriously and accepted (INT09). An example of an occasion on which the RAC was bypassed and a protocol was approved without RAC approval was in the case of a 51-year-old woman who was dying of brain cancer, and for whom, in December 1992, oncologists wished to try a therapy that not previously been tested in humans (Thompson 1993). There was insufficient time available for the established review procedure to be carried out and the RAC expressed concerns about allowing expedited review for such a novel procedure. However, in the same month, the NIH director and FDA commissioner granted a compassionate plea exemption and approved the procedure (Wivel 2014).

In 1980, public opinion on rDNA technology started to reach a head. The general secretaries of the national Protestant, Catholic and Jewish bodies wrote a joint letter to President Jimmy Carter expressing their concern about threats to the nature of human life and the dignity of the individual human being posed by genetic engineering (Wivel 2014). In the same year, a prominent US scientist was found to have attempted gene therapy in Israel and Italy, so as to avoid RAC oversight, following a protocol that had been disapproved (Institute of Medicine 2014). In 1982, President Carter formed a presidential commission – a quasi-judicial task force that includes public hearings in its research into a specific issue – to examine the ethical questions raised by rDNA technology (Wivel 2014). The commission concluded that using human DNA posed no fundamentally novel ethical issues, but recommended extensive public scrutiny over future developments. The NIH RAC formed a Human Gene Therapy Subcommittee (HGTS) in 1984 to create guidelines for reviewing human gene therapy protocols in particular. Gene therapy is the introduction of genes into cells to replace missing or defective genes and correct genetic disorders. These guidelines were published after two iterations with public comments in 1985. From this point, the RAC conducted its review of human gene therapy research in tandem with the FDA, which determined in 1984 that it would be responsible for the regulation of gene therapy products (Wolf, Gupta and Kohlhepp 2009; Lenzi et al. 2014). After reviewing several protocols, the HGTS soon extended the range of its oversight to also cover gene transfer (the movement of genetic material between organisms other than by natural reproduction). After the requisite protocols were approved, human gene

therapy clinical research involving participants began in 1990 (Lenzi et al. 2014; Wivel 2014).

The next major phase of the RAC saw the streamlining of oversight procedures, as evidence had been accumulated to demonstrate that rDNA technology would not pose severe hazards. The HGTS was disbanded and its committee merged with the RAC in 1992, due to the dual review system being rendered redundant by increasing confidence in the safety of gene therapy research (Wivel 2014). In 1996, driven by similar concerns that requiring consent from the NIH and FDA represented a redundancy in the protocol approval system, and following a review of the RAC which suggested eliminating the overlapping roles between the NIH and the FDA, the NIH director announced the abolition of the RAC and its replacement with a smaller group of scientists and ethicists who would meet ad hoc (Wivel 2014). However, there was public resistance favouring the retention of the RAC; therefore, the director instead reduced the membership of the RAC and emphasised its status as an advisory body offering guidance to the formal FDA authority (Institute of Medicine 2014). It was at this point that the RAC began reviewing only the protocols that proposed novel research at it's open public meetings (Wivel 2014). Researchers were still required to submit all gene therapy protocols to both the RAC and the FDA, as well as to report unexpected serious adverse events during clinical trials directly to the RAC (Wolf, Gupta and Kohlhepp 2009). In these circumstances, the RAC would assess the adverse events in the context of the study protocol, offer non-binding recommendations regarding continuation of the experiment, and – as with all of its work – engage in discussion with, and make its findings available to, the public (Wivel 2014; Wolf, Gupta and Kohlhepp 2009). These roles have remained unchanged up to the present time.

In 1999, Jesse Gelsinger, an 18-year-old male with a rare genetic disorder – that was at the time controlled by diet and medicine – died due to his participation in a gene therapy experiment (Nature 2016). Gelsinger suffered a massive immune response to the viral vector that was used to carry a corrected gene to his cells, which led to multiple organ failure. He was the first person publicly identified as having died in a clinical trial for gene therapy. Following this tragedy, the acting director of the NIH expanded the advisory role of the RAC in 2000, so that it could thereafter determine which protocols it should be required to review at public meetings (King 2002). The acting director also increased RAC membership from 15 to up to 21, to add new relevant expertise in areas such as public policy and statistics (Advisory Committee to the Director 2000). Reporting requirements of serious adverse events were also revised to ensure easy communication between the FDA and RAC, and two new entities – the Gene Transfer Safety Advisory Board and the Genetic Modification Clinical Research Information System – were established to facilitate information sharing between the RAC, researchers, industry representatives and the public (King 2002). There have been few further changes to the RAC since this period, but, in 2018, the NIH director and FDA commissioner proposed eliminating the RAC's role in reviewing human gene therapy protocols, again due to concerns about the redundancy of the dual approval process (Adelman et al. 2018; Collins and Gottlieb 2018). If these proposed changes were to take place, responsibility for reviewing the hazards and ethics of research protocols would pass to local IBCs and IRBs (Adelman et al. 2018), and the RAC's focus would become emerging biotechnology issues (Collins and Gottlieb 2018).

2.8.4. How effective was the oversight?

The lack of legislative action in rDNA technology can be used as a proxy to indicate the effectiveness of the NIH RAC. The NIH is not a regulatory agency and therefore had no formal authority to regulate; nevertheless, government officials viewed formal legislation as unnecessary in this area due to the track record of the RAC (Wivel 2014; Wolf Gupta, and Kohlhepp 2009). It was seen as more important that the RAC be viewed as a credible advisory body commanding respect from researchers, and being able to use the bully pulpit authority has been enough to influence research practice in the field (INT09). In this respect, this method of oversight has been relatively effective, in that in the United States the Guidelines have been adhered to while maintaining their easily adaptable form.

Some contend that the RAC's policy of conducting reviews of research protocols in an open forum, in contrast to the closed reviews of the FDA due to legal reasons, helped allay public fears and generally increase clarity (Wivel 2014; King 2002). This process of open public meetings and debate is beneficial to both the public and to those involved in the field, as the enhanced accountability of associated researchers and regulatory bodies to the public improves public confidence in the field, resulting in fewer public objections and greater ability for the field to progress and translate research into practical benefits. In addition to this, the RAC's open meetings and wider public engagement also offered important educational opportunities for the RAC itself to learn from the public (INT09). This was the case even though public meetings inevitably attracted only a selection of the public, some of who were very vocal and had to be responded to by everyone (INT09). It should be noted, however, that having to respond to public challenges also offered important learning for researchers and regulatory bodies (INT09). To inform and educate the public is an important role of any oversight body, and some have said that the RAC could perhaps have made more effective use of this opportunity for mutual learning by conducting even more public education than it did (INT09).

The RAC's oversight has, however, been associated with some serious failings (Wolf, Gupta and Kohlhepp 2009). Congressional investigations into the death of Jesse Gelsinger, for example, concluded that there was confusion as to the need for reporting adverse events to the RAC, and that there appeared to be under-reporting of adverse events in many gene therapy trials, fuelling concern over the federal oversight of gene therapy (Wilson 2009). There had also been communication failings between the FDA and RAC, with the FDA not informing the RAC that it had authorised a change to the original protocol regarding administration of the viral vector (Wolf, Gupta and Kohlhepp 2009).

2.8.5. What lessons can be learnt from this example?

The effectiveness of the NIH RAC can be attributed largely to the nature of the guidelines; since they were not formal legislation, and rather a 'living' document, they were much more easily amended than regulations (Wivel 2014; Wolf, Gupta and Kohlhepp 2009). This arrangement allowed for the stance taken at the beginning of oversight to evolve as the technology was re-evaluated; in this case, many of the early concerns about safety did not materialise and review procedures eased accordingly. The absence of congressional involvement also insulated the research from political changes. Some argue that stem cell and cloning research could use a similar arrangement in the US, as both technologies pose comparable risks

and benefits (Wivel 2014; Wolf, Gupta, and Kohlhepp 2009).

The death of Gelsinger due to his involvement in gene therapy research has been attributed to a lack of public oversight, communication failings between the FDA and the RAC, and the FDA's provision of protection for proprietary information, which states that the authority will treat all non-public information as confidential (Wolf, Gupta and Kohlhepp 2009). The investigation into Gelsinger's death revealed that the FDA had not communicated its authorisation of a study protocol change to the RAC, which was particularly significant in this case as it involved a change to the administration of the viral vector to which Gelsinger suffered an autoimmune response. This investigation also identified several previous trials in which serious adverse events (SAEs) had been reported to the FDA and not the RAC, in part due to the FDA's protection of confidentiality – meaning that such events were not being made available for public review (Wolf, Gupta and Kohlhepp 2009). Failure to report SAEs to the RAC also occurred due to misunderstandings about the different roles of the RAC and FDA, and the need to report SAEs to both. According to Malcolm Brenner, director of the Baylor College of Medicine's Center for Gene Therapy, there was widespread belief that only SAEs associated with the gene therapy itself, rather than other aspects of study participation such as staff failures, should be reported to the RAC (Finn 2000). Greater harmonisation of roles between the FDA and NIH occurred in response to the investigation's findings, and there were subsequent efforts to increase public involvement in recombinant DNA oversight (Wolf, Gupta and Kohlhepp 2009). The NIH and FDA also sponsored a series of conferences discussing gene transfer safety, which were scheduled to take place quarterly (Finn 2000) and aimed to improve patient safety through discussion of principles such as quality control, informed consent and good clinical practice (Finn 2000). There are lessons to be learnt here regarding the need for adequate communication between oversight bodies, clarity surrounding their respective roles, clear policies regarding the requirements for scientists to engage with them, and the role of oversight bodies in educating both scientists and doctors regarding safe and ethical practice.

An area that will require further reflection is the oversight of private research. Since the RAC only had authority over research that was either federally funded or conducted at institutions receiving federal research funding, and the FDA was restricted to oversight of private research aiming to develop a product marketed in the United States, a share of private research escaped assessment (Wolf, Gupta and Kohlhepp 2009). Although some private researchers voluntarily submitted protocols for review (Wolf, Gupta and Kohlhepp 2009), more measures will likely be needed to ensure a balance between corporate confidentiality due to proprietary interests and the public interest.

2.9. Case vignette 9
The Human Fertilisation and Embryology Act in the UK

Summary: This case vignette discusses oversight developments in the UK surrounding the legal, social and ethical issues in relation to human fertility research and treatment.

Responding to public and parliamentary concerns regarding the legal, social and ethical issues associated with developments in human fertility research and treatment, in 1990 the UK adopted the Human Fertilisation and Embryology Act. The Act regulated the licensing of clinics to ensure patient protection and established measures enabling scientific research to progress in a responsible manner. A key component was the creation of an independent regulatory body – the Human Fertilisation and Embryology Authority (HFEA) – to oversee assisted reproductive technologies.

2.9.1. Background and context

Assisted reproductive technology (ART) is the use of laboratory or clinical technology to achieve pregnancy. Around one in seven UK couples may have difficulty conceiving naturally (NHS 2017), and ART supports these couples by offering them an alternative. ART methods include in vitro fertilisation (IVF), surrogacy, donor insemination (DI) and intracytoplasmic sperm injection (ICSI), among others. Since their original development, these technologies have enabled millions of families to have children (Kamphuis et al. 2014). The birth of the world's first IVF baby, Louise Brown, at a Greater Manchester hospital in 1978, marked the moment when IVF first entered the public consciousness and the beginning of widespread demand for, and subsequent development of, ART (Heitman 1999). By the 1980s, ART was viewed as a desirable solution to infertility (Levitt 2009), with live births following IVF occurring in Australia in 1980, the United States in 1981 and both Sweden and France in 1982 (Cohen et al. 2005).

2.9.2. Why was oversight required?

A review of the psychological aspects of infertility conducted in the early 1980s highlighted that infertility is frequently a source of emotional trauma for both individuals and couples (Rosenfeld and Mitchell 1979), causing considerable relationship stress (Seibel and Taymor 1982). Although by the dawn of ART it had become more socially acceptable to be a childless couple in the UK, many infertile couples continued to feel what they described as social pressure to become parents (Seibel and Taymor 1982). The psychological impact of involuntary childlessness was conceptualised in the 1980s as the 'crisis of infertility', which is an emotional state characterised by feelings of loss of health, loss of self-esteem, mourning, depression, guilt and frustration (Bresnick 1981). The potential for ART to relieve couples of this suffering offered very real benefits. These potential benefits have been quantified through a survey-based willingness-to-pay (WTP) evaluation conducted in Israel, which found that the mean WTP for technological advances in ART was US$3116.9 among IVF patients and US$2284.4 among the general

public (Gonen 2016). Even the social benefit of ART, as defined by the general public's WTP for its improvement, is substantial. This assertion is supported by a study employing a health investment model to assess the impact of a singleton birth following IVF on UK tax contributions (Connolly et al. 2009). The model found that, based on the average cost invested into a successful IVF singleton birth and the projected net tax contributions of the resulting child over their lifetime, IVF offers an 8.5 fold return on investment for society (Connolly et al. 2009). This finding is particularly pertinent given concerns about the potential economic and social impacts of falling fertility rates and an ageing population (Harper 2014). The popularity of ART contributed to the field's rapid development, and new knowledge was integrated into daily practice more quickly than in any other field of medicine (Kamel 2013). Oversight was therefore required to manage and regulate the industry's rapid expansion, while avoiding excessive restriction of a field offering clear benefits.

ART is also associated with several important ethical issues that made governance necessary. Two of the most contentious ethical debates centred around the status of the human embryo – whether it requires the same moral status as a mature adult – and the extent to which fertility is a fundamental right to be addressed by the state (Montgomery 1991). Regarding the first of these, oversight was required to regulate the use of human embryos in research, which was the most debated issue concerning the ethics of IVF at the time (Cavaliere 2017). In reference to the second, it is important to note here that research and clinical provision of ART are expensive, and therefore costly to research and innovation funding bodies (and the NHS in the UK). There is, of course, an opportunity cost associated with public spending on ART research and provision, which links back to the question of whether fertility is a fundamental right that should be paid for by the state (Montgomery 1991). Oversight was required to put limits on the use of ART and to direct which technologies were to be used by which individuals and when, since individual patients and physicians might be motivated to try whatever they perceive as having potential value to them (Gonen 2016). Another frequently-raised ethical concern questioned how one could prevent the extension of ART via a 'slippery slope' towards cross-species fertilisation, eugenics[68] or other similar practices (Walton 1990; Levitt 2009), an issue that required oversight to ensure that research remained within the bounds of what is broadly acceptable according to societal values. The development of ART also required regulation to prevent clinical malpractice; for example, the transfer of more than two eggs or embryos during a single cycle of fertility treatment for women under the age of 40, or more than three in women aged 40 and over (Mayor 2004). Patients and doctors have pressured regulatory bodies to allow the transfer of more embryos in order to increase the likelihood of a successful implantation (INT10), although there is evidence that pregnancies of more than one baby are more dangerous, for both the babies and the mothers (Mayor 2004). Regulatory oversight prevents such risky procedures from being carried out even when they might be desirable to patients, who are not fully aware of the associated hazards (INT10). Without formal oversight, the only option available for patients in cases of malpractice is litigation, which can be an inadequate instrument when the effects of ART are life altering or

68 Eugenics is the pseudoscientific philosophy and practice of attempting to 'improve' a population's genetic makeup, typically through a process of selective breeding (Matsumoto 2009).

threatening; for example, a clinic donating eggs without the consent of the donor, or selling the biological products of a donor with HIV without informing the patient (Deech 1999; Letterie 2017).[69]

2.9.3. How was the oversight carried out?

The events that led to the establishment of the Human Fertilisation and Embryology (HFE) Act began in the early 1980s, and took place in direct response to the birth of Louise Brown in 1978. In 1981, the UK Secretary of State for Social Services responded to public and parliamentary concerns regarding the legal, social and ethical issues associated with developments in human fertility research and treatment, and announced the establishment of a Committee of Inquiry into Human Fertilisation and Embryology (Janforum 1985). This diverse 16-member committee was led by philosopher May Warnock, and included theologians, social workers, attorneys and scientists chosen to represent professional, scientific, religious, legal and lay viewpoints ('A Welcome Report' 1984). In 1984, the committee published the Warnock report, which set out much of the conceptual foundations for the eventual Human Fertilisation and Embryology (HFE) Act.

Parliamentary legislation typically takes a few years to be developed and implemented (INT10), so in 1985, the Medical Research Council and the Royal College of Obstetricians and Gynaecologists established the Voluntary (later Interim) Licensing Authority (VLA) to provide temporary oversight for ART. The VLA aimed to establish principles to govern fertility treatment and human embryo research, as well as to ensure that clinics operated accordingly while statutory legislation was pending. It faced criticism, however, for its inability to place adequate pressure on practitioners to follow guidelines (Montgomery 1991; Human Fertilisation & Embryology Authority 2018).

In 1987, the government, published a White Paper titled, 'Human Fertilisation and Embryology: A Framework for Legislation', which was followed three years later by the 1990 Human Fertilisation and Embryology Act. The Act regulated the licensing of clinics to ensure patient protection and established measures enabling scientific research to progress in a responsible manner. Among the regulations to reform research practices, the HFE Act placed a time limit for how long human embryos could be kept intact in vitro – 14 days – a rule that has been widely adopted in other legislations around the world (Lovell-Badge 2008). A key component of this Act was the creation of an independent regulatory body to oversee ART – the Human Fertilisation and Embryology Authority (HFEA) – which replaced the Interim Licensing Authority. The HFEA includes non-scientific 'public' members and, by law, the chairperson cannot be a scientist (INT10). The HFE Act thus employed a principles-based regulatory approach, which for the most part established high-level, broadly-stated guiding principles to grant a certain amount of flexibility, as opposed to detailed prescriptive rules (Devaney 2011). While some of the provisions enshrined in the Act did offer fixed regulations about issues on which there was broad societal consensus, the Act included a provision that permitted future licensing of techniques in human embryo research (Montgomery 1991). The establishment of the HFEA as a statutory licensing authority thus created a forum in which ethical issues could be continually debated alongside the evolution

69 A case in which four embryos were transferred instead of two, for example, resulted in a quadruplet pregnancy in which the patient delivered four premature infants, only three of which survived (Letterie 2017).

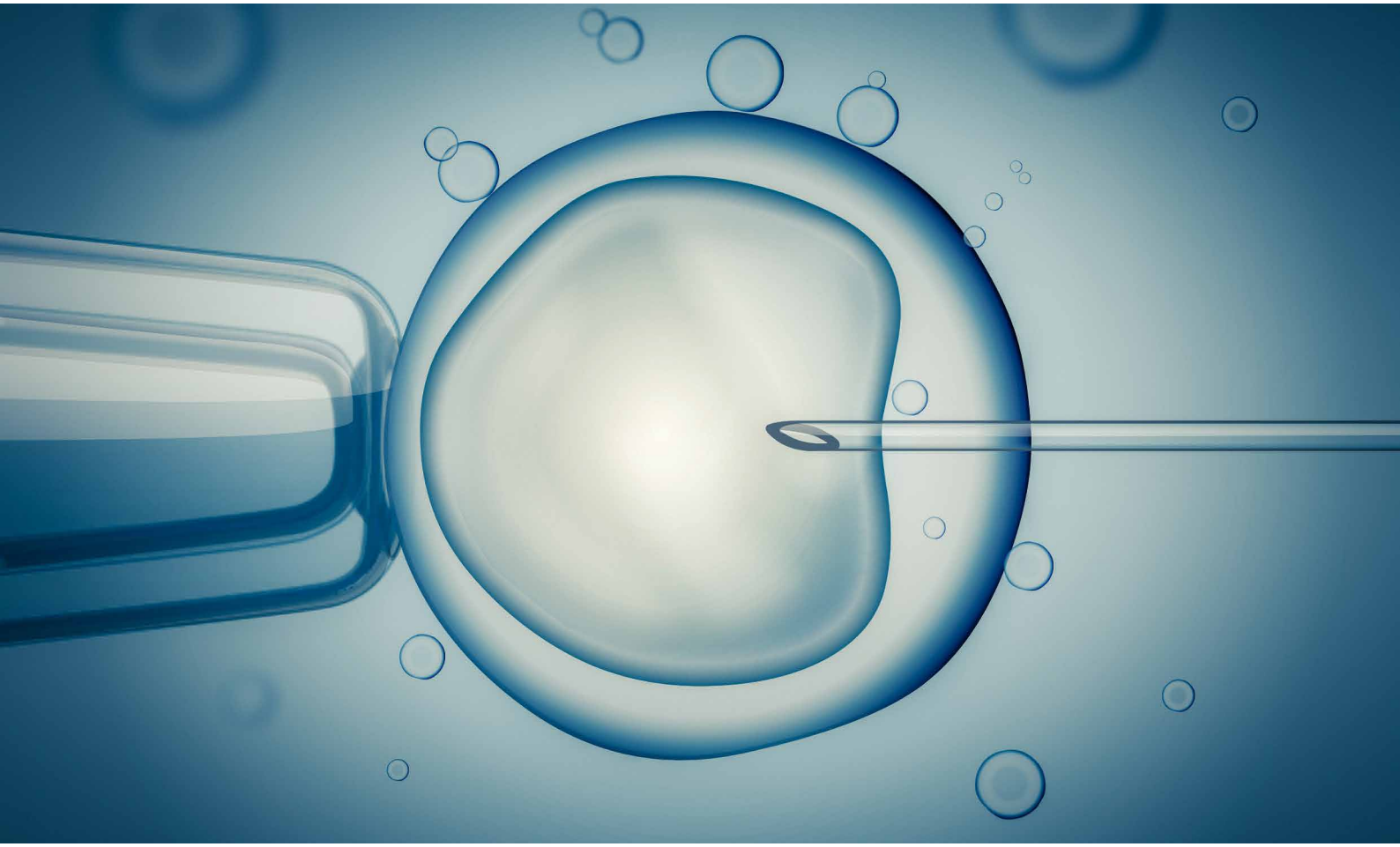
of scientific research and public attitudes, and enabled licenses for research projects to be granted on a case-by-case basis (Hauskeller 2004). Over time, this forum became increasingly open and transparent in response to growing demands for public bodies to open themselves up to scrutiny, and the HFEA began to make the minutes of its meetings publicly available and to hold open public meetings (Leather 2005).

Another important feature of the HFE Act was the flexibility it offered with respect to the licensing of clinics, which took place at the institutional level. The Act permitted the HFEA to grant three different types of license, each of which permitted the licensed institution to conduct an activity that was otherwise prohibited: 1. Offer ART treatment; 2. Store embryos and reproductive cells; and 3. Conduct human embryo research (Brazier 1999). Individual research centres and clinics still apply to the HFEA for a new license or renewal of an existing one (new licenses are granted for two years and renewals can be granted for up to four), and the HFEA can also modify or revoke a license if it has concerns about an institution's performance (HFEA n.d.). This format of legislating at the institutional level created an enabling environment for institutions rather than one that applied prescriptive rules.

Over the years, some amendments have been necessary to accommodate evolving scientific developments and social change. Since the 1990 Act did not address the ability to obtain cells from an early embryo that can grow in vitro indefinitely (human embryonic stem cells), the government commissioned an independent enquiry to determine how to best regulate this area (Lovell-Badge 2008). The enquiry was led by the Chief Medical Officer – Sir Liam Donaldson – and was asked to assess the benefits, risks and possible alternatives of new developments in human embryo research (UK Department of Health 2000). The resulting 'Donaldson Report' was published in 2000, and in 2001, the Human Fertilisation and Embryology (Research Purposes) Regulations extended the permitted use of embryo research to include 'increasing knowledge about the development of embryos', 'increasing knowledge about serious disease', and 'enabling any such knowledge to be applied in developing treatments for serious disease' (House of Commons 2007; Lovell-Badge 2008). These regulations established codes of practice for the use of human embryonic stem cells and helped create the UK Stem Cell Bank, which must store samples of all human embryonic stem cell lines derived in the UK for medical research and treatment (Lovell-Badge 2008).

There was another minor amendment to the Act in 2003 – the HFE (Deceased Fathers) Act 2003 – for which the most significant change was to allow a man to be listed on birth certificates as the father of a child conceived after his death (Sheldon 2005). This amendment came about when Diane Blood – a widow who had lost her husband to meningitis soon after they had decided to try to start a family – successfully convinced the Government and High Court that not allowing her children's father to be named on their birth certificates because they were conceived after his death was a breach of her children's human rights (Sheldon 2005).

In 2004, the Parliamentary Under-Secretary for Public Health announced that the 1990 Act would be reviewed by way of public consultation conducted by the Department of Health (Knight and Smith 2013). Following three years of public and parliamentary debate, a major review and update of the Act was passed in 2008. The key legislative changes can be grouped into four broad categories (Knight and Smith 2013). The first of these dealt with fertility treatment and the family,



and removed heteronormative clauses in line with the changing nature of familial relationships in modern society. The new Act recognised same-sex couples as legal parents and replaced the phrase 'need for a father' with 'need for supportive parenting'. The other categories of changes related to the HFEA's data collection policies (altering previous restrictions to facilitate follow-up research), limiting the use of reproductive technologies to select characteristics in future offspring, and defining the limits of embryo research (Knight and Smith 2013). One of the most controversial issues included in the HFE Act 2008 was that it allowed the creation of admixed embryos containing human and animal material (Dyer 2008; Lovell-Badge 2008).

In 2015, the HFE Act was further amended to legalise mitochondrial donation in the UK – The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 – enabling women with mitochondrial disease to have a healthy child who is related to both them and their partner (Craven et al. 2016). This followed seventeen years of discussion and debate on the topic. Responsibility for developing a licensing framework and overseeing the field going forward in the UK was awarded to the HFEA (Craven et al. 2016). The UK was the first to pass regulation on mitochondrial donation and is the only country that allows it, although progress towards legalising its clinical use has recently been

made in both Australia (Nogrady 2018) and Singapore (Ong 2018).

Discussions about possible changes to the HFE Act are ongoing, in particular covering areas thought to not have enough sufficient regulation, such as surrogacy and legal parenthood.[70] There have also been discussions around whether IVF still requires its own oversight body, as it is now a more established science, with some individuals raising concerns that the existence of the HFEA can act as a deterrent for academic activity in the field of IVF research (Winston 2018).[71]

2.9.4. How effective was the oversight?

The HFE Act and HFEA were created to oversee human embryo research and the provision of infertility treatments, and to make oversight decisions based on an understanding of both the underlying science and the associated ethics. With respect to its role engaging with the ethics of ART, the HFE Act and Authority can be judged to have been largely effective, as reflected in their success in retaining public confidence in the field; however, with respect to managerial issues the HFEA has demonstrated some shortcomings (Morgan 2004). According to one legal academic, HFEA staff conducted a deficient level of oversight at times, resulting in a lack of inspection of clinics and the under-reporting by clinics of treatment cycles (Morgan 2004). A report by the government official in charge of reviewing the quality of public financial reporting, Sir John Bourne, found that in the 2001–2002 financial year, the HFEA only visited 11 of the 119 licensed fertility centres, and that 5 of these 11 had under-reported their treatment cycles (Morgan 2004). Although this finding has not been linked to any threat to public safety, and the HFE Act has been relatively effective in its oversight of safe ART provision, this represented an important managerial inefficiency.

The principles-based oversight approach employed in the HFE Act has 'stood the test of time' (INT10) and appears to have been largely successful, as the ongoing debate that it allowed has meant that few legal amendments have been required (Lovell-Badge 2008). As a result of having this principles-based regulatory structure in place very early on in the development of ART, the UK was ready to cope with and respond to technological developments as they came along, decreasing potential delays to research (INT10). Some suggest that the overall success of the HFE Act, with respect to its oversight of HFE research, can be viewed through international comparison of developments in the field; a 2008 analysis of publications shows that the UK over-performs in terms of its production of human embryonic stem cell research articles relative to other countries, including the United States, which the author attributes to its permissive policy environment (Levine 2008).

It has been argued, however, that legislative delays could have been further reduced and that the HFE Act has in fact encountered some operational challenges (Morgan 2004). Legislative delays in the amendment process

70 For example, a government enquiry (the Brazier Committee) recommended the creation of a Code of Practice for non-profit surrogacy agencies, and legislation setting out the scope of reasonable 'payment' (compensation for expenses) that might be provided to surrogate mothers (Horsey 2016).

71 In 2010, the HFEA came close to being abolished when the UK Government, wishing to reduce the budget deficit, identified 192 public bodies that could be abolished, including the HFEA (Davies et al. 2013). However, there was significant objection to the HFEA's proposed abolition (English 2013; Dyer 2011; Davies et al. 2013), and the government subsequently decided to keep the authority.

are considered by some to have been a barrier to scientific innovation in the derivation of human embryonic stem cell lines (Lovell-Badge 2008). This delay occurred despite the fact that the original Act included a provision allowing Parliament to add additional purposes for the use of embryos in research as they became available (Lovell-Badge 2008).[72] The HFEA itself is also said to have experienced management issues, both structurally and in terms of performance. Some described the HFEA as slow, bureaucratic and hindered by the high turn-over of members and staff that contributed to a lack of institutional memory (Devaney 2011; Morgan 2004).

2.9.5. What lessons can be learnt from this example?

The HFE Act offers a valuable lesson regarding the regulation of issues concerning incompatible ethical positions around which society is deeply divided (Montgomery 1991). The majority of provisions enshrined in the Act do not attempt to finalise debates but, rather, the principles-based regulatory approach and establishment of a new statutory licensing authority (the HFEA) created a forum in which ethical issues could be continually discussed. The balance between competing views with respect to ethical questions was left to be determined by the HFEA, rather than being established by Parliament itself (Montgomery 1991), and the case-by-case basis for handling projects or requests helped resolve ethical questions in a manner acceptable to multiple stakeholders. This approach is facilitated by the diversity of backgrounds and perspectives offered by the HFEA's members, whose areas of expertise include, but are not limited to, gynaecology, genetics, counselling, law and finance (HFEA 2018b). The membership also includes multiple individuals who have personal experience with fertility problems (HFEA 2018b), although campaign group, CORE (Comment on Reproductive Ethics), has criticised the HFEA for not including any individuals who are critical of the principle of ART (Morgan 2004). These factors offer important lessons for the future oversight of similarly contentious issues around emerging science and technology.

Other elements of the HFE Act and HFEA that represent successes include how early the UK put in place a decent regulatory structure. When Dolly the sheep was born, the HFE Act was ready to permit development of stem cells from cloned embryos and to engage with the public in order to manage public concern (INT10). The Act has proved capable of adapting to newly emerging areas of research and practice, as amendments can be made without having to re-write the whole Act. In this respect, the HFE Act offers a valuable lesson as to how proactive oversight and legislation can facilitate technological advancement, rather than being a barrier to it. The example is widely perceived as having successfully struck a balance between legislation designed to reduce societal risk while not stifling innovation.

The Act also benefits from its simplicity, including a simple framework surrounding the oversight body; the HFEA is positioned very close to the Department Health, facilitating dialogue regarding regulatory recommendations (INT10). The HFEA is strengthened by its flexible structure, with lots of subcommittees listening to requests, but consideration of the HFEA's role relative to bodies regulating related areas highlights the potential to gather together legislative authorities to eliminate inefficiencies in the

72 The first human embryonic stem cell lines were derived in the United States five years prior to the UK (Lovell-Badge 2008).

oversight of emerging science and technology (INT10). Finally, the HFEA has access to expert advisors but does not leave decisions up to them, avoiding any potential conflict of interest (INT10). As noted above, the HFEA includes non-scientific 'public' members, and the chair cannot be a scientist, improving public confidence in the regulatory body. A key part of the HFEA chairperson's role is to keep the public on board with regulatory developments (INT10).; public education is vital and represents another important lesson for successful oversight of emerging science and technology. In pursuit of this aim, the HFEA has fostered meaningful two-way engagement with the public, both educating the public about its work and actively seeking public engagement and feedback on the decisions that it takes. The HFEA's extensive stakeholder engagement includes professional stakeholder meetings, policy workshops, service user engagement with the testing and developing new services, and an annual conference (HFEA 2018a).

One area in which the HFE Act could potentially be improved might be to devise mechanisms for avoiding further hindrances to scientific progress, as is said to have occurred with human embryonic stem cell lines. Though the HFE Act included a provision to account for areas in which the original Act showed insufficient foresight regarding technological developments, a lengthy legislative procedure was still required to make the necessary amendments. One expert in healthcare law suggests including more flexible regulatory features such as sunset provisions[73] to facilitate speedier passage of amendments (Devaney 2011). As for the managerial issues facing the HFEA, while some of the structural complaints are common among governmental bodies, it has been suggested that easing the legal requirements on enforcement officers and using more unannounced inspections would improve performance (Devaney 2011). This insight could apply to several areas of emerging science and technology requiring oversight.

73 A sunset provision is a clause written into legislation that gives it an expiry date; the bill, or part of it, will become null after the specified date, unless the law is extended via additional legislative action (UK Parliament, n.d.).

2.10. Case vignette 10 The first crypto-war: Public key cryptography in the United States

Summary: This case vignette discusses oversight developments in the United States in relation to public key cryptography technology.

The invention of 'public key cryptography', in the mid-1970s, enabled two individuals to exchange encrypted messages between them. It therefore made it possible to incorporate complex encryption into everyday communication formats, such as phone and email-based networks, as these markets began to grow. Concerned about the impact of public encryption on their ability to monitor communications, agencies of the US Government sought to restrict public access to this technology. From the early 1990s onwards, they pushed programmes that would provide 'backdoors' into encryption systems. Meanwhile, a broad coalition of non-state actors – including cryptographers, privacy advocates and industrial interests – fought against the government's agenda. Driven by a range of interests, from the protection of civil liberties to concerns about industrial competitiveness, these groups tried to protect widespread, unmediated access to encryption systems.

2.10.1. Background and context

Cryptography is a method by which two or more parties can communicate securely through shared access to a mechanism for the encryption and decryption of information passed between them ('What Is Cryptography?' n.d.). Historically, all forms of cryptography relied on a shared knowledge of the 'code' according to which the information had been encrypted. During the 1970s, however, 'public key cryptography' was developed. Public key cryptography enabled two individuals to exchange encrypted messages without the need for any prior communication between them. The crucial invention, in this regard, was the introduction of a public-private key interface. Every user would possess both a 'public key' and a corresponding 'private key'. A message could be encrypted by anyone with access to the public key, but could only be decrypted by the individual holding the private key. A hidden mathematical connection between public and private keys made this possible and a user's private key could not be derived from knowledge of their public key (Diffie 1988).

The invention of public key cryptography was announced by cryptographers at Stanford University, in 1976 (Diffie and Hellman 1976). By 1977, MIT researchers had already developed the first public key-based encryption system (Diffie 1988). The growth of personal computing, e-mail and mobile telephony during the 1980s expanded the potential applications of public key cryptography.[74] As the computer and mobile 'revolutions' gathered pace, demand for public key cryptographic solutions capable of ensuring secure communications

74 This, of course, was not coincidental. The growth of modern communication networks had been a key driver of cryptographers' efforts to create new forms of encryption technology capable of preserving the ability to communicate securely and privately in a computer-based society.

soon began to 'explode', particularly within the United States (Kehl, Wilson, and Bankston 2015).

2.10.2. Why was oversight required?

In the two decades that followed the invention of public key cryptography, a wide range of stakeholders tried to shape the pathway of the technology within society. These stakeholders often possessed quite different ideas about the benefits, opportunities, risks and drawbacks of public key cryptography for society at large. As such, they differed in their understanding of why 'oversight' was required.

For the US government, and more specifically its security and intelligence agencies, the technological innovation of public key cryptography represented a potential threat to national security (Pednekar-Magal and Shields 2003; Kehl, Wilson and Bankston 2015). Stressing the need for the government to be able to monitor communications in the interests of addressing risks to public safety and security, agencies such as the Federal Bureau of Investigation (FBI), the National Security Agency (NSA) and the Central Intelligence Agency (CIA) argued that the proliferation of robust, publically-accessible cryptography solutions would cut the intelligence services out of communication networks, providing secure channels in which drug traffickers, terrorists and other criminals could interact free from government surveillance (Pednekar-Magal and Shields 2003; Kehl Wilson, and Bankston 2015). From the perspective of these agencies, a way had to be found to mediate public key cryptography and preserve the ability of officials to monitor communications (Pednekar-Magal and Shields 2003; Kehl, Wilson and Bankston 2015).

A second group of stakeholders – a diverse, yet broadly aligned, coalition of cryptographers, privacy rights activists and hacker groups – held a different view. For this group, the principal benefit of public key cryptography was precisely its capacity to secure individuals' right to communicate free from the interference of government. By removing the state's monopoly over sophisticated encryption techniques, public key encryption would provide citizens with secure channels that were essential to the preservation of privacy, freedom of expression and democracy in the Internet age. The principal aim of these stakeholders was therefore to ensure that these multifaceted benefits of public key cryptography were not undermined (Kehl, Wilson and Bankston 2015; Pednekar-Magal and Shields 2003; Seifert 2000).

It is also possible to identify a third key stakeholder grouping in the form of industrial interests. Many computer and telecommunications companies, including large corporations like Apple, AT&T, Hewlett-Packard, IBM and Microsoft, also took an active interest in public key encryption (Kehl, Wilson and Bankston 2015). For them, the privacy provided by public key encryption represented an important selling point for new computer and telephone devices, and for the growth of the Internet more generally (Froomkin 1996). To this extent, these companies shared the view of other stakeholder groups concerning the importance of widespread access to encryption (Kehl, Wilson and Bankston 2015).

2.10.3. How was the oversight carried out?

Driven by their opposing views on the benefits and drawbacks of public key cryptography, different stakeholders tried to influence the technology's development in a way that reflected their own particular concerns. The first major attempt to do so came from the US government in 1993, in the form of the 'Clipper chip', a state-of-the-art

microchip developed by government engineers (The White House Press Secretary 1993). Installed into a device, it provided strong public key encryption to users while also providing government agencies with the ability, if required, to open a 'backdoor' into encrypted communications.[75] Led by the NSA, the Clipper programme was supported by other executive agencies including the FBI, the CIA, the Department of Justice, the Department of Commerce and the National Security Council. In April 1993, the programme was officially announced by the White House (Levy 1994; Froomkin 1996; Kehl, Wilson and Bankston 2015; Pednekar-Magal and Shields 2003).[76]

The programme's aim was to encourage the widespread adoption of the Clipper chip by companies active in the sale of encryption-enabled devices. Programme leaders opted for a non-legislative strategy (Froomkin 1996; Pednekar-Magal and Shields 2003). Rather than seeking to make the chip a legal requirement, the NSA and its allies tried to wield the government's market power as a major consumer of encrypted devices to push industry in the direction of the Clipper (Froomkin 1996; Pednekar-Magal and Shields 2003).[77]

Opposition to the Clipper programme served to unite those largely unconnected stakeholder groups who, for their own different reasons, emphasised the benefits of widespread access to public key cryptography over its risks.[78] From 1993 onwards, these groups lobbied against the programme. A body called the Computer Professionals for Social Responsibility (CPSR) played an important role in coordinating these efforts (Kehl, Wilson and Bankston 2015). With a membership consisting of many leading figures from the field of public cryptography, the CPSR issued statements and organised online petitions against the chip. Online petitions and information dissemination campaigns were also undertaken by 'Cybherpunks', a computer hackers group (Kehl, Wilson and Bankston 2015). Meanwhile, the Digital Privacy and Security Working Group (DPSWG), a coalition of privacy advocates and industrial interests, including leading computer companies such as Apple, AT&T, Hewlett-Packard, IBM and Microsoft, also mobilised against the Clipper.[79] When, as required by law, the US government conducted a public consultation on the programme, these various groups combined to ensure that 318 of the 320 responses received by the consultation did not support the backdoor programme (Kehl, Wilson and Bankston 2015).

In February 1994, when the White House endorsed the Clipper chip as a government-approved standard, public resistance against the programme increased further (Seifert

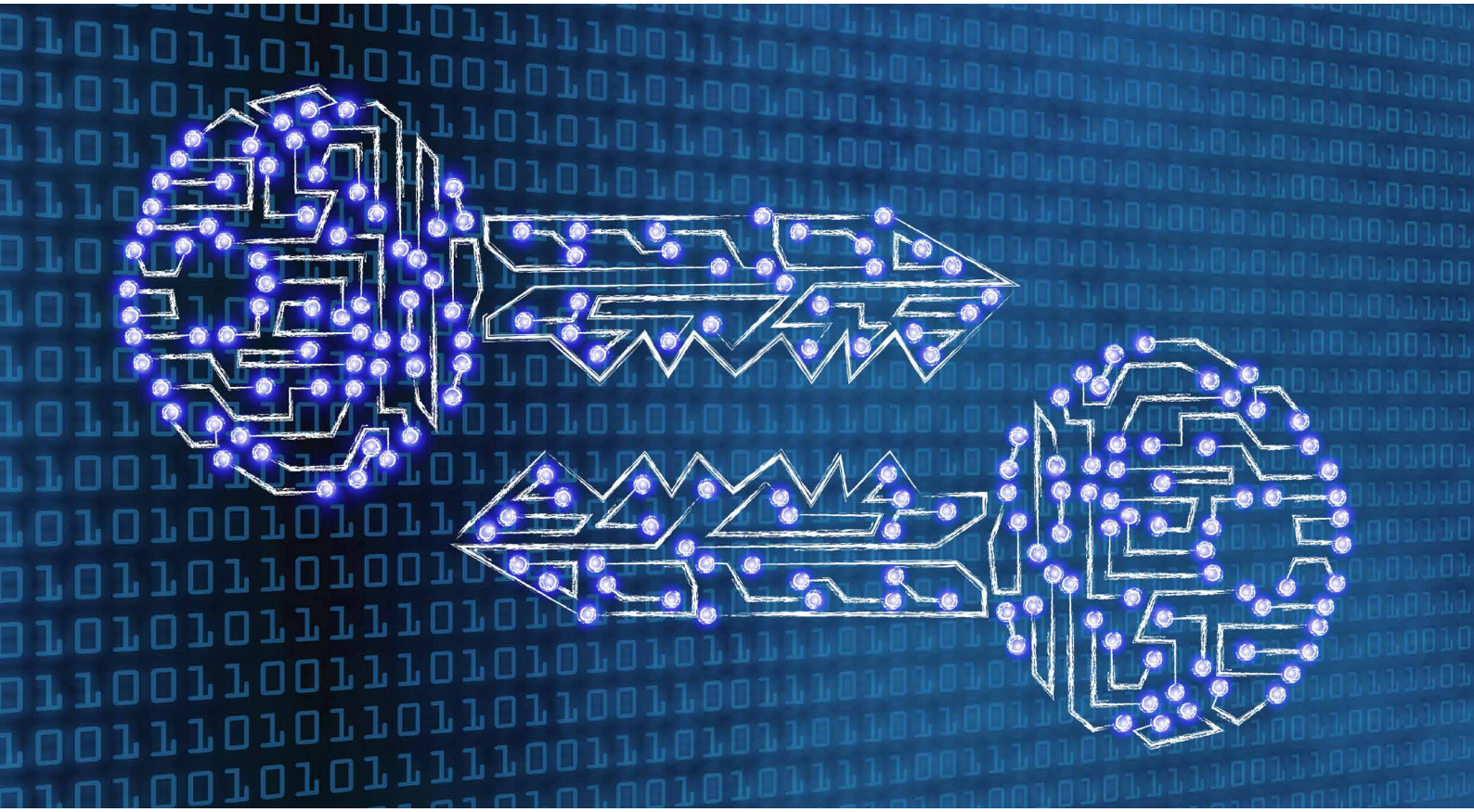
75 The proposed 'backdoor' relied on a system of 'key escrow', under which a copy of each chip's private encryption key would be stored by the government.

76 The authorisation came shortly after the election of Bill Clinton as the new President.

77 In practice, this policy took the form of using guaranteed government purchases of mobile and computer devices to incentivise companies to use the Clipper Chip. In 1992, the US government successfully persuaded AT&T to use the Clipper chip in its phones using this approach (Pednekar-Magal and Shields 2003).

78 Proponents of public access to public key encryption tended to see its principal benefit as its capacity to secure the right of individuals to secure communication channels, therefore protecting rights such as privacy and freedom of expression in an increasingly computer- and phone-based society.

79 The DPSWG wrote to the White House expressing concern that the proposed programme contravened 'fundamental privacy and other constitutional rights'. Industrial interests also lobbied through the Computer and Business Equipment Manufacturers Association, a trade association comprising 26 of America's largest companies. The group issued statements and submitted comments to the Department of Commerce's Computer System Security and Privacy Advisory Board (Kehl, Wilson and Bankston 2015).



2000).[80] Public mobilisations included further petitions, media campaigns, industry statements and boycotts of companies following the government standard. Several companies formally announced that they would be using an alternative encryption mechanism. Meanwhile, a CPSR petition against the Clipper programme received over 50,000 signatures (Pednekar-Magal and Shields 2003). Then, in June 1994, a computer scientist from AT&T exposed a serious security flaw in the Clipper chip, casting doubt over whether the chip could actually guarantee a backdoor into public key encryption communication (Kehl, Wilson and Bankston 2015). This revelation, when combined with mounting public pressure, forced the Clinton Administration to rollback on the Clipper programme (Kehl, Wilson and Bankston 2015).

From 1995 onwards, the US government revamped its campaign to limit access to public key cryptography. The renewed campaign proceeded on two fronts. First, the government introduced an alternative proposal to the Clipper programme, referred to as 'commercial key escrow' (CKE), in which the 'spare keys' enabling government access to encrypted communications would not

80 Though 'voluntary' for the private sector, the clear intention was to make the standard the commercial norm for encryption more broadly.

be maintained by the government itself.[81] Alongside this, the government tried to incentivise participation in CKE by offering companies that participated exemptions from export controls on encryption-enabled products. These export controls had existed since the 1970s, when the US government had classified encryption algorithms as munitions for export control purposes, and had been a source of considerable frustration to many telephone and computer companies, as they were seen as undermining their competitiveness in overseas markets (Froomkin 1996; Kehl, Wilson and Bankston 2015). Now, the government tried to use their removal as a 'carrot' to facilitate cooperation (Froomkin 1996; Kehl, Wilson and Bankston 2015).

Ultimately, however, these new initiatives experienced much the same fate as the Clipper programme. Opposition to the revised programmes comprised not only those same groups that had opposed the Clipper, but also international organisations. During the 1990s, the Organization for Economic Cooperation and Development and the European Commission rejected the US government's attempts to encourage the adoption of key escrow systems internationally (Kehl, Wilson, and Bankston 2015).[82] Amid persistent arguments about the economic drawbacks of restrictions on the domestic and international sale of public key cryptography, in 1999 the Clinton Administration announced the elimination of most controls on the export of encryption systems (Kehl, Wilson and Bankston 2015).[83]

2.10.4. How effective was the oversight?

In this case, observations can be made about the effectiveness of two types of oversight: that conducted by the government and that conducted by non-state actors. The US government's attempts to oversee the development of public key cryptography were ultimately unsuccessful. In the interests of national security, executive agencies tried to restrict (or more accurately mediate) access to the technology. In doing so, however, they failed to generate widespread support for these efforts. Government programmes, such as the Clipper chip, were strongly opposed by a broad coalition of stakeholders, which on numerous occasions forced the government to roll back on its plans.

Compared to the government, the oversight of non-state stakeholders was more successful in shaping the trajectory of public key cryptography. Key interest groups, including computer professionals, privacy groups and industrial interests, built a consensus viewpoint regarding the benefits of public key cryptography and undertook coordinated action that saw this vision eventually realised in public policy. The oversight of non-state actors paved the way for unmediated access to public key cryptography.

81 This policy went through a number of iterations. While the first proposal was for the 'spare keys' to be held by a trusted third party, this was later replaced by a recommendation that industry itself take the lead in constructing a 'global key management infrastructure' accessible by the government (Pednekar-Magal and Shields 2003; Kehl, Wilson and Bankston 2015).

82 While the UK and France were receptive to the US government's arguments concerning the need for commercial key escrow, most governments within the EU and the OECD opted for a stance that prioritised consumer choice (Baker 1997; Kehl, Wilson and Bankston 2015).

83 Some restrictions on the export of non-militarised encryption products still remain in place. Administered by the Department of Commerce's Bureau of Industry and Security, areas of restriction include the export of encryption systems exceeding 64-bits and the export of products to 'rogue states' (U.S. Department of Commerce. n.d.).

The protection of unmediated access to public key cryptography had a number of positive effects. Most notably, it contributed to the enormous growth in the market for Internet services during the 1990s, both within the United States and beyond. While it is difficult to be precise about the extent of public key cryptography's contribution, or to say what might have been different had enterprises such as the Clipper become a reality, commentators have argued that unmediated public key cryptography played an important role in the emergence of services such as electronic banking, secure electronic record keeping, private messaging and improved cybersecurity (Kehl, Wilson and Bankston 2015). The benefits of these services have not only been economic, but also rights-based, including the ability to protect individual civil liberties such as privacy and freedom of expression (Kehl, Wilson and Bankston 2015).

At the same time, some have argued that non-state actors' rejection of any government attempts to mediate public key encryption had detrimental effects too. Intelligence agencies have maintained that certain threats to national security and public safety would be reduced by government access to encrypted communications (Timberg and Miller 2014). From this perspective, although public access to robust encryption has protected the right to privacy, it has also potentially eroded the state's ability to enforce laws designed to protect other human rights.[84] Proponents of this argument have drawn on new concerns about the threat of global terrorism to justify their claim (Sanger and Perlroth 2015), prompting claims that we are about to see a reiteration of the encryption regulation debate – a 'second crypto-war' ('The Second Crypto War and the Future of the Internet | HuffPost' n.d.).

2.10.5. What lessons can be learnt from this example?

The encryption debates of the 1990s – what some, in anticipation, refer to as the 'first crypto-war' – provide two major lessons for technology oversight. First, the case illuminates the pitfalls likely to be faced by governments seeking to oversee the path of a technology without parliamentary oversight and meaningful public engagement. The NSA and its allies pursued a non-legislative strategy (Froomkin 1996; Pednekar-Magal and Shields 2003). For those against both the Clipper chip and the CKE, however, the fact that these programmes had no mandate from Congress undermined their legitimacy considerably (Froomkin 1996). The failure of executive agencies to engage meaningfully with public consultations contributed further to the belief that the government was not interested in broader societal concerns. While it may not have changed protestors' opinions on the Clipper chip itself, a programme sanctioned by legislative authority, with a more engaged consultation process, may have been less susceptible to claims that it was merely the agenda of a narrow segment of the executive. In this sense, it may have opened the door to a more meaningful government-stakeholder debate about how public key cryptography's risks and benefits might be balanced. As it happened, however, the government's approach gave rise to a polemic debate between two diametrically opposed points of view.

84 A common argument here is that the tendency of pro-encryption stakeholders to see privacy as an 'absolute' value, rather than one that exists in relation to other constitutional rights, has prevented them from engaging in a more nuanced discussion about how these legitimate concerns of security and intelligence agencies could be met (Singhal 1995).

The case also highlights the potential for the oversight of non-state actors to play a central role in shaping the pathway of new technologies within society.[85] While agencies of the US government had clear plans for how public key cryptography should be controlled and managed, actors beyond the state ensured that these plans did not come to fruition. Through their combined efforts, a broad coalition of stakeholders forced numerous shifts in government policy on public key encryption. There are also lessons here concerning the ways in which non-state actors are able to successfully exert influence over public policy. In particular, the campaign against the Clipper chip was marked by a considerable degree of coordination between diverse stakeholder groups and the use of multiple forms of protest (including online petitions, lobbying, boycotting, campaigning and technical sabotage). The deployment of a compelling economic case against the planned approach, supported by large-scale industrial interests, also appears to have been an important factor in influencing the government's stance.

85 There is also a subsidiary lesson here: the strength of public resistance against the Clipper and CKE could, at least in part, be seen as a consequence of the absence of formal participative mechanisms used by the government in its attempts to oversee public key encryption.

3 Learning from past and present oversight efforts

Summary of lessons learnt from the examples of emerging science and technology oversight

1. **Balanced:** It is important that oversight approaches aim to balance the conflicting benefits and risks associated with the emerging science or technology, as well as the needs of the different stakeholders.
2. **Diverse and contextual:** There is no 'one-size-fits-all' approach to emerging science and technology oversight – it is vital to take into account the context within which the science or technology is developing.
3. **Takes the initiative:** Stakeholders that take the initiative to put in place oversight structures in a timely manner can take advantage of the opportunities provided by the emerging science or technology, and also help identify the risks.
4. **Anticipatory:** It is helpful to anticipate the different potential paths an emerging science or technology could take as it evolves over time, as well as the ensuing impacts.
5. **Adaptable:** For an oversight approach to be effective, it helps to build in flexibility so that it can respond to changes and be adjusted over time as the science or technology evolves.
6. **Collaborative:** Adopting an inclusive and participatory approach to science and technology oversight helps build accountability and confidence.
7. **Embraces communication:** Effective communication between the main actors involved in the oversight process facilitates transparency and clarity of roles and responsibilities.
8. **Engaged with the public:** Harnessing the role of the public can help build accountability and trust, and also engage with the public about the benefits and risks associated with the science or technology.

In this chapter, we reflect on the case vignettes presented in Chapter 2 and articulate a set of lessons across the vignettes. The vignettes offer a real-life illustration of how oversight has been carried out in practice in different contexts. To draw out common themes from the examples – and specifically, lessons that can be learnt – we undertook a comparative analysis of the ten vignettes (primarily using a workshop as described in Annex A). The learning we present in this chapter is based both on what has worked well and not so well (and the reasons for this), in relation to the oversight approaches adopted in ten diverse examples. In particular, we have sought to better understand what we can learn from a historical review of the variety, progression, and achievements – positive and negative – of different oversight methods.

These lessons can be regarded as a set of guiding principles to help stakeholders think about effective, efficient and ethical ways in which to provide oversight of emerging science and technology. We envisage that the lessons may be of interest to national and local government policymakers, industry, innovators, funders and academia, but also more broadly to anyone – including the public – interested in the development and adoption of new and emerging science and technology. As the examples we have considered in this study are diverse and span a range of oversight methods, science and technology areas, countries, sectors and time periods, the lessons are wide-ranging and cover a spectrum of topics. Furthermore, they are meant to stimulate discussion and debate about how oversight strategies could encourage and shape the

advent of emerging science and technology – both in terms of businesses and industry that might develop over time, as well as the potential benefits reaching people swiftly and effectively. The lessons we present have been articulated to be generalisable for science and technology. As such, they could be applied in different current or future contexts where oversight strategies might be required to leverage the anticipated benefits of emerging science and technology, while safeguarding against the potential risks and uncertainties. It is this delicate balance between the often conflicting benefits and risks associated with emerging science and technology as they develop over time that the lessons we present aim to address.

3.1. What are some of the lessons that can be learnt?

In rest of the chapter, we discuss the lessons we have drawn out from the case vignettes. In each case we describe the lesson and then highlight two to three of the examples that highlight aspects of this lesson.[86]

3.1.1. Balanced

Key lesson 1: ***It is important that oversight approaches aim to balance the conflicting benefits and risks associated with the emerging science or technology, as well as the needs of the different stakeholders***

Emerging science and technology brings numerous benefits as well as problems, and oversight can help to address these issues.

At a high level, the different approaches to oversight demonstrated in the case vignettes have reinforced the fundamental significance of recognising the need to balance the often-conflicting benefits and risks (both real and perceived) associated with emerging science and technology. In other words, it is important that oversight approaches try and ensure that they promote the growth of science/technology (for example, by various means of support for innovators and industry driving the innovations), while at the same time minimising public health and safety risks as the science/technology develops over time. The case vignettes have highlighted that while it is important to harness the benefits of emerging science and technology, it is equally vital that stakeholders involved in the oversight process are able to recognise and respond to challenges and risks associated with the science/technology. This theme is linked to the themes on anticipation (key lesson 4), adaptability (key lesson 5) and public engagement (lesson 8).

Examples illustrating this lesson:

- **Balancing the often-conflicting and sometimes-uncertain benefits and risks associated with emerging science and technology**: Fintech regulatory sandboxes allow emerging financial technology to be tested while also providing safeguards for consumers. The Human Fertilisation and Embryology Act and Agency has, since its development in 1990, managed to strike a balance between reducing societal and ethical risks while also enabling the UK to be one of the leaders in the scientific and technological developments.
- **Balancing the needs and expectations of the different stakeholders:** The

86 For some lessons, all examples could be used to highlight the lesson. In these cases, we have chosen a few examples we think best illustrate the lesson.

Cartagena Protocol on biosafety illustrates the balancing act of oversight at an international level. The Protocol attempts to balance the potential risks of GMOs to health, safety and the environment, with the benefits of innovation and trade, while also trying to provide both international harmonisation and national sovereignty in decision making. The protocol began being negotiated in 1995, started to be ratified in 2003, and, to this day, continues to be negotiated in order to take into account scientific developments.

3.1.2. Diverse and contextual

Key lesson 2: ***There is no 'one-size-fits-all' approach to emerging science and technology oversight – it is vital to take into account the context within which the science or technology is developing***

Across the ten vignettes, there are numerous mechanisms and instruments of oversight, ranging from legislative acts, governance and regulations, to non-regulatory standards, agreements and civil society movements. Clearly there is no single 'best' approach to science and technology oversight that is suitable for all circumstances. When it comes to deciding on how to oversee an emerging science or technology, it is vital to carefully consider the contextual factors within which the science or technology is emerging. In other words, it is important to take into account the circumstances – e.g. cultural, political, economic – within which the science/technology is developing (and consequently within which the oversight process is carried out). An oversight approach for a specific technology that is effective, for example, in one country may be less effective in other countries due to cultural or socio-economic dissimilarities. Furthermore, since contexts can vary significantly, it is important to be able to have a choice of oversight models to implement. As we have seen across vignettes, different oversight models exist which involve, to varying degrees, one or more stakeholders. For example, the role of the central government in supporting or leading the oversight process comes across as a noteworthy lesson (see key lesson 3); however, it is important to acknowledge that there are other models too that could potentially be as effective as government-led oversight of science and technology (e.g. public-private partnerships; governments playing a facilitating/coordinating role in the oversight as opposed to leading).

Examples illustrating this lesson:

- **National context**: In the Estonia digital society and Kenya M-Pesa examples, overall the respective governments were successful at introducing new technologies. It is worth noting that the governments were starting from a reasonably clean slate, as in both cases the technologies that were being brought in were relatively new to the countries. In both cases the technologies also largely aligned with the needs of citizens, providing them services they may not have had before.
- **International context:** Two of the case vignettes cover oversight beyond the national level: the GSM standard and the Cartagena Protocol on biosafety. The former is generally seen as a success, while the later has seen more criticism. One difference between them is the benefit that each stakeholder involved obtained by 'signing up' to the oversight approach. In the case of GSM, public and private stakeholders in different countries were all brought together by being able to see the benefit each of them was likely to obtain by working together, which they would not have been able to achieve if they were

working in isolation. On the other hand, in the case of the Cartagena Protocol, as some countries are net importers of GMOs and some are net exporters of GMOs, countries did not necessarily have a shared vision of the benefit of the Protocol.

- **Variety of oversight models:** The case vignettes highlight the variety of oversight models that exist. There is variety in terms of who carries out the oversight: for example, the Green Revolution in India and the development of a digital society in Estonia were both primarily government-led approaches; while the development of M-Pesa in Kenya operated as a public-private partnership. There is variety also in the structures put in place: for example, while the Human Fertilisation and Embryology Authority's decisions are legally binding, the NIH Recombinant DNA Advisory Committee is only an advisory body (although the FDA can enforce their decisions). There is also variety in the level at which the oversight approaches are implemented: while most of the examples show national level approaches, the GSM standard and the Cartagena Principle are both international approaches.

3.1.3. Takes the initiative

Key lesson 3: ***Stakeholders that take the initiative to put in place oversight structures in a timely manner can take advantage of the opportunities provided by the emerging science or technology, and also help identify the risks***

Across a number of the case vignettes, one of the main drivers behind the oversight process has been that the main stakeholders involved have taken the initiative to solve a specific 'problem' or address an issue. When a new science or technology emerges and the key stakeholders choose to oversee its development, it is important that (appropriate) oversight structures and systems are implemented as early as possible. Not only does this ensure that the various benefits and opportunities of the science/technology can be potentially exploited, but also that the main associated risks and uncertainties can potentially be identified early. This proactive approach can be exhibited by all stakeholders (to varying degrees) to help develop and progress the science/technology in such a way that it benefits everyone. Furthermore, a proactive and progressive approach to oversight can be exhibited at different levels and by different stakeholders involved in the oversight process. This theme is linked to the themes on anticipation (key lesson 4) and adaptability (key lesson 5).

Examples illustrating this lesson:

- **Proactive cross-national and cross-stakeholder collaboration:** The GSM standard is an example of public and private bodies coming together, across country divides, to develop a standard at a specific time when that was still possible. The stakeholders involved anticipated the benefits for all of them on working together on this endeavour, as well as the time limitation (in that they needed to agree on it when a spectral band was still available). Their proactivity enabled Europe to have a more advanced mobile communications market, compared to many other countries, and to lead the way in establishing a global standard.
- **Proactive governments:** The Green Revolution in India, the introduction of M-Pesa into Kenya, and the development of Estonia into a digital society are all examples of governments selecting a particular path they saw as bringing significant societal and economic benefits,

and following through to ensure that the technology was widely adopted. All countries were effective at having the technology adopted and reaped the benefits the governments had hoped for (to varying degrees), although, as is noted in Chapter 2, there were unintended consequences of these actions.

- **Proactive research community:** The Human Fertilisation and Embryology Act and the NIH Recombinant DNA Advisory Committee examples illustrate the role of scientists in identifying new science that poses risks and controlling its use. In both cases, scientists set in place their own bodies to monitor and control how the newly developed science was used before governments could put their own structures in place.

3.1.4. Anticipatory

Key lesson 4: ***It is helpful to anticipate the different potential paths an emerging science or technology could take as it evolves over time, as well as the ensuing impacts***

While it is difficult, if not impossible, to forecast the exact path a science or technology will take, it is important to anticipate how it might develop over time, as well as the potential impacts. The vignettes have illustrated the significance of being able to develop an oversight system or structure that could foresee the potential implications (for example, on society or the environment) of the evolution and wider adoption of the science/technology. Notably, at least to some extent, this highlights the need for a means by which the unintended (negative) medium- to long-term consequences of the rollout of the science/technology can be projected – and therefore planned for. In other words, it is beneficial if the oversight approach is able to identify (and respond to) both ongoing as well as future challenges, although of course not everything can be foreseen. As we have seen across the case vignettes, unintended consequences could relate to environmental, economic, legal, ethical, privacy and security issues. This theme is indirectly linked to the theme on adaptability of the oversight approach (key lesson 5) and taking the initiative (key lesson 3).

Examples illustrating this lesson:

- **Anticipating the impacts of the science or technology:** The Estonia example illustrates a government anticipating some impacts, while not anticipating others. The government anticipated the possible social consequences early on, and throughout its oversight approach took a number of measures to avoid the risk of social exclusion through the use of education programmes. However, it did not perhaps necessarily anticipate the risk of cyber-attacks that could result from reliance on ICT systems, which made Estonia vulnerable to a subsequent serious cyber-attack. While Estonia quickly learnt from this lesson, the threat perhaps could have been anticipated. The Green Revolution example demonstrates that some long-term negative impacts – for example, in this case, negative environmental consequences – of new agricultural technologies were not anticipated adequately.
- **Anticipating the future development of the science or technology:** The Human Fertilisation and Embryology Act and Authority and the NIH Recombinant DNA Advisory Committee are examples of structures put in place with the acknowledgement that science/technology will develop over time and, therefore, while an oversight body is needed immediately,

the precise 'rules' that should be followed may need to be adapted over time. These bodies were able to alter their advice, and therefore what was permitted, as scientific evidence as to the true risks and benefits of the science/technology developed.

3.1.5. Adaptable

Key lesson 5: ***For an oversight approach to be effective, it helps to build in flexibility so that it can respond to changes and be adjusted over time as the science or technology evolves***

The case vignettes have demonstrated the significance of oversight processes being flexible in their approach so that they can respond to changes or feedback as the science or technology evolves over time. Rigid oversight frameworks will generally find it very challenging to keep up with the pace at which science and technology often evolves. Therefore, it is important to have an oversight approach that is in itself evolving and adaptable as the science/technology and/or as public opinion develops. In addition, it is important to incorporate strategies or mechanisms within the oversight framework by means of which potential failures can be dealt with – this is vital to ensure that trust in the oversight process is not completely eroded in the event of a failure of expected oversight.

This theme is related to the theme on anticipation (key lesson 4) and highlights the need to be able to keep a 'watchful eye' on how the science/technology is developing in practice and, if necessary, having the flexibility to adjust the oversight process over time. At a higher level, it also highlights the importance of having sufficient checks in place in the oversight process to ensure that the science or technology is deployed in an innovative, safe and ethical manner. Thus, it is helpful to have the capability to respond and react to challenges encountered – some of these unexpected – as the oversight process develops over time. It is worth acknowledging that the nature and scope of the changes required will depend on the complexity of the oversight approach; generally, the more wide-ranging the changes are, the more time it will take for them to mature and, consequently, for the oversight approach to adapt. This theme is also indirectly related to taking the initiative (key lesson 3).

Examples illustrating this lesson:

- **'Test and learn' approaches:** Both the M-Pesa and the Fintech regulatory sandboxes vignettes illustrate the benefits of industry and regulators working together to understand the benefits and risks of an emerging technology and hence the appropriate regulatory structures that need to be put in place for that technology. These 'test and learn' approaches allowed a technology to be launched separate from formal regulatory structures, therefore enabling industry to test and adapt products early, and for regulators to see how the technology was developing early on and learn from it. In the learning from the launch of M-Pesa, without a fixed regulatory structure but with heavy scrutiny, was used to develop regulations for branchless mobile banking services. In the UK, the regulatory sandbox has not yet led to new regulations; however, companies that have been through it have adapted their products to make them more compatible with the market. Of course this approach is only suitable for selected technologies where the risk of allowing the technology to be used is sufficiently low. In the sandboxes, testing is carried out under restricted conditions (i.e. only a restricted aspect of the product, deemed to be the

least risky, is tested); while in the example of M-Pesa there were few restrictions placed, although it was the only product of its type being tested (where as sandboxes cover multiple products) and it was carefully monitored. While the products tested in these vignettes have not led to any disasters, this approach is not risk free.

- **Flexible expert bodies/frameworks:** The Human Fertilisation and Embryology Authority and the NIH Recombinant DNA Advisory Committee are both expert bodies that, through a range of means, decide what should and should not be allowed in their areas of focus (human fertility research and treatment and rDNA technology, respectively). While they started with a set of broad guidelines, as the science/technology has developed they have been able to alter their guidelines, both for what should be permitted – for example, as there is more known about the risks of the technologies – and also to cover new aspects of the science as they have arisen. The Cartagena Protocol on biosafety is an example that exhibits the creation of a basic broad oversight framework (for biosafety) that allowed countries that had signed up to the Protocol to establish their own national standards (within a set structure). Due to the number of countries involved in negotiations, the process for adapting the overall Protocol is slow.

3.1.6. Collaborative

Key lesson 6: ***Adopting an inclusive and participatory approach to science and technology oversight helps build accountability and confidence***

The vignettes illustrate the value of collaborative or participatory approaches to oversight that engage with and involve a variety of stakeholders. Participatory approaches, particularly involving multi-stakeholder or multi-agency collaborations, can help stimulate discussion and debate across stakeholders. The variety of perspectives and expertise offered by different actors in the oversight process can contribute to a more diverse (key lesson 2) and balanced (key lesson 1) approach. Involving all interested stakeholders in the oversight processes can help to promote understanding about the benefits and risks associated with the science/technology. This inclusivity can, in turn, help to foster accountability, shared responsibility and buy-in for the science/technology. Ultimately, this can contribute to the building of trust and confidence between the stakeholders involved, and in the science/technology itself. A key stakeholder group that is often at the centre of science/technology oversight efforts is the public (we discuss some of the important lessons in relation to the public in key lesson 8). This theme is also linked to the theme on communication (key lesson 7).

Examples illustrating this lesson:

- **Cross-national and cross-stakeholder collaboration:** The GSM standard is an example of public and private stakeholders in countries working together with a shared objective to achieve benefits for all those involved. This was enabled by the stakeholders having a shared goal and vision about what the technology could offer.
- **International cooperation:** The Cartagena Protocol on biosafety is an example of a collaborative international agreement that was negotiated between more than 100 countries and has been ratified in over 170 countries. Despite the number of challenges encountered to date, the Cartagena Protocol highlights the case of a large number of countries coming together

to address potential complex issues surrounding the impacts and implications of an emerging technology.

- **Collaboration between different actors (e.g. industry and regulators, other non-state actors):** Fintech regulatory sandboxes in the UK and the introduction of M-Pesa in Kenya both illustrate the benefits of collaboration between industry and regulatory bodies, allowing both to learn from the other. The crypto-war example in the United States demonstrates how a diverse coalition of non-state actors (e.g. privacy rights activists, cryptographers, industry) all came together to effectively influence the trajectory of public key cryptography in the United States.

3.1.7. Embraces communication

Key lesson 7: ***Effective communication between the main actors involved in the oversight process facilitates transparency and clarity of roles and responsibilities***

As observed in the case vignettes, effective and clear communication between the different stakeholders involved in the oversight process is key to ensuring that the oversight process unfolds in an effective, efficient and timely manner. Some oversight models can be very complex, consisting of a 'package' of oversight instruments, and often involving a number of stakeholders, each with divergent perceptions and expectations about the science/technology. To ensure that the oversight process proceeds smoothly, it is important that the different stakeholders communicate with each other effectively. It also helps to have a clear understanding and demarcation of the roles and responsibilities of the different actors. In addition, transparency is an important factor to consider in this regard: having a transparent approach enables clarity in understanding who is doing what; furthermore, ensuring transparency in the oversight approach can be a crucial factor in building and achieving confidence in and awareness of the science/technology. Communication about the benefits and risks associated with the science/technology, with wider stakeholders – notably with the public – is an important consideration during the oversight process (this is covered in more detail in the theme on public engagement (key lesson 8)). This theme is also linked to the theme on collaboration (key lesson 6).

Examples illustrating this lesson:

- **Clarity about roles and responsibilities:** As recombinant DNA technology progressed, the NIH Recombinant DNA Advisory Committee also evolved, with better harmonisation of the roles and responsibilities between the FDA and the NIH Recombinant DNA Advisory Committee.
- **Open approach:** In the GSM example, the creation of ETSI over the course of the development of the standard opened up the system to numerous interested parties within Europe and beyond. The inclusion of international stakeholders (outside of Europe) in the standard development process by the opening up of ETSI was a key driver of the global expansion of the GSM.
- **A system lacking transparency:** DAMD provides an example of a technology that had the potential to provide extensive benefits to stakeholders that had access to it, and for which there was no clear accountable ownership. Over time, the uses of the data collected from GP surgeries evolved and changed, but, until it was raised by GPs, no-one went back and checked that as functionalities were added

DAMD was still operating within legal bounds.

- **Lack of communication:** In the crypto-war example, the benefits and risks of encryption technology were seen in a very different light by the two stakeholder groups (the US government on the one side and an alliance of cryptographers, privacy rights activists, 'hacker' groups and, to some extent, industry on the other side). There was limited dialogue between the groups and they continued to hold opposing views. In the end, one side 'won' over the other, rather than reaching a compromise that suited both sides.

3.1.8. Engaged with the public

Key lesson 8: ***Harnessing the role of the public can help build accountability and trust, and also engage with the public about the benefits and risks associated with the science or technology***

The role of the public in discussions and debates about emerging science and technology cannot be overestimated. While it might be helpful to try and educate the public about understanding the science/technology itself, it is more important to engage with them and build understanding about the potential benefits and risks associated with emerging science and technology. Engagement with the public during the oversight process helps to promote accountability and buy-in. In turn, this could lead to an increase in confidence, which could potentially result in a swifter and more effective uptake of the science/technology. Across the vignettes there are different levels of engagement with the public. This includes public demonstrations, where the value of adopting a technology is explained; public education, where a technology and its risks and benefits are explained; and public discussion, where the public also gets the opportunity to feedback their views. This theme links to the themes on collaboration (key lesson 6) and communication (key lesson 7).

Examples illustrating this lesson:

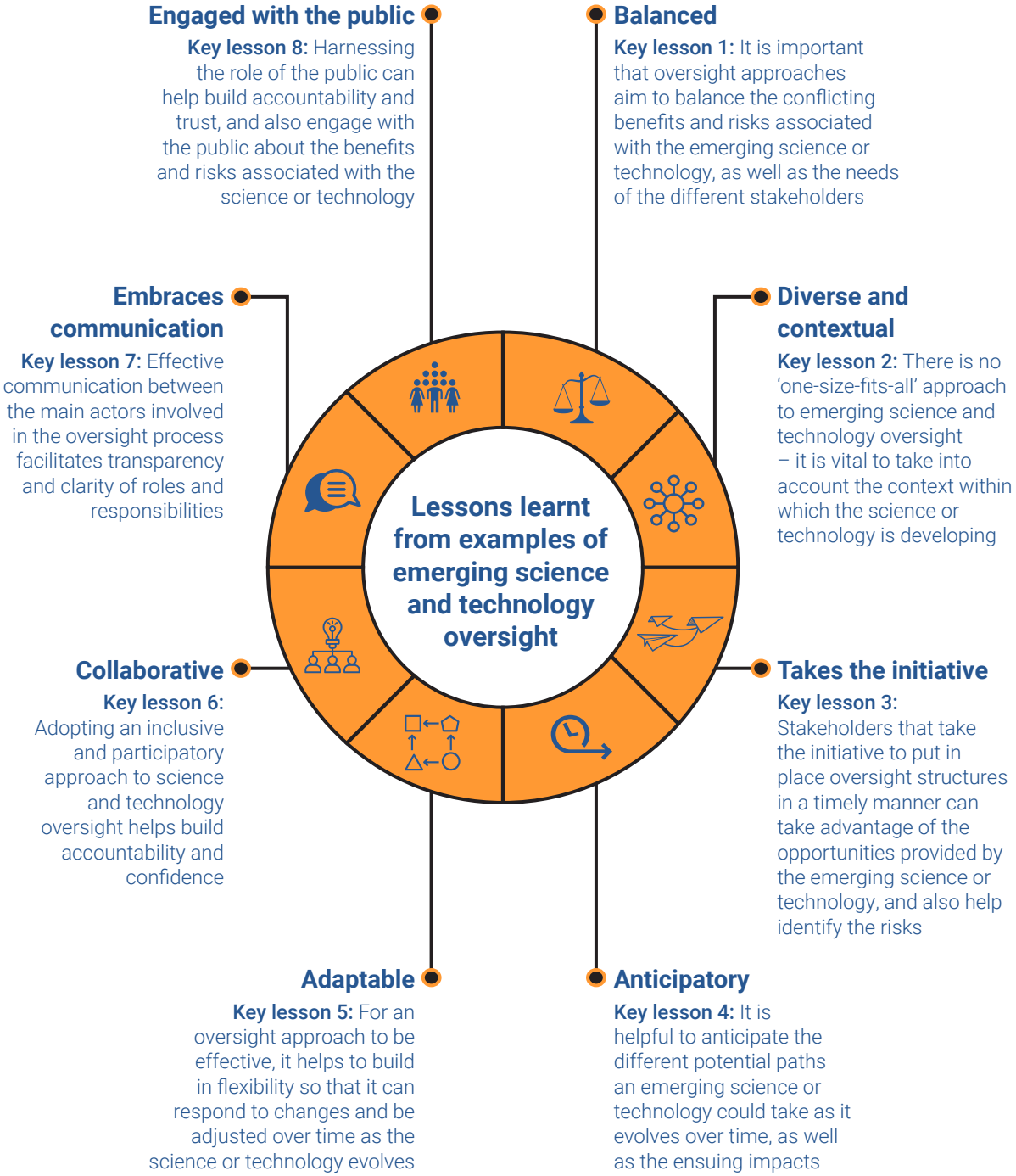
- **Public demonstrations of the benefits of a technology can help to encourage adoption:** The government of India engaged in active encouragement of the take-up of HYVs through large-scale public information campaigns. The government of Estonia, in order to build confidence in its digital society programme, provided a digital log showing citizens which administrations had accessed their personal data.
- **Public meetings can help to educate the public as well as allowing for public discourse:** The Human Fertilisation and Embryology Authority and the NIH Recombinant DNA Advisory Committee both hold public meetings and make minutes publicly available. These meetings have two goals: first, to educate the public on the technology and its risks and benefits; and second, they serve as a forum for discussion with the public of the risks of the technology, particularly ethical issues.
- **Feedback from the public can be used to help develop effective technology:** In its oversight strategy of M-Pesa, the Central Bank of Kenya employed user surveys as one of its measures to monitor the development of M-Pesa – specifically, to assess the experience users were having with the service and whether they found it trustworthy. Additionally, financial inclusion surveys were conducted to monitor changes in the number of Kenyans having access to financial services.

3.2. Concluding thoughts

Ultimately, the oversight of emerging areas of science and technology seeks to achieve a balance between taking advantage of the numerous opportunities offered by the science/technology and mitigating against or addressing the potential risks that might develop as the science/technology matures. This relates to the tension that often exists when a science or technology emerges between the economic growth of businesses and wider industry on the one hand, and the health, safety and environmental risks to the public. As illustrated in this study, there is an entire spectrum of oversight approaches and the actual mechanism of oversight that is adopted in practice can take on different forms, involve a variety of stakeholders, and is greatly dependent on contextual factors. As we have observed in the vignettes, oversight mechanisms need to be tailored to these specific contexts: there are no simple and straightforward recipes for 'success'. A common aim across the different oversight mechanisms is to establish enabling conditions and structures within which science and technology can be nurtured and developed for the benefit of society. However, it is important to acknowledge that oversight is not always effective and there is much that can also be learnt from those instances when the implications and wider outcomes of the oversight approach – in the short-term and long-term – might not have unfolded as originally desired. Indeed, as we have seen across a number of the examples in this report, there are often unintended consequences of overseeing the development of science and technology.

The lessons we have articulated (summarised in Figure 2) are intertwined with each other and share some common aspects; they are not intended to be a 'silver bullet' or solution for emerging science and technology oversight. Rather, we offer them as key themes derived from historical and current examples that could be associated with the effective, efficient and ethical delivery of science and technology oversight. It is also worth noting that it is not necessarily possible for an oversight approach to use all of the different lessons at once. For example, being adaptable and taking initiative while also being collaborative and engaging the public can be difficult because of the challenges in acting quickly and decisively while also taking in views across the public and other stakeholders. It is necessary to consider the importance of the different lessons to the situation at hand, and trade-off between them to establish an oversight approach that works in a particular context. In addition, it is important to acknowledge that the effectiveness of oversight approaches depends on the benefits and risks of the technology to which they are applied. Developing a better understanding of what has happened in the past – both in terms of the oversight being effective and not so effective – can help inform decisions about science and technology oversight in the future. It is hoped that the analysis we have undertaken provides some important insights and learning about science and technology oversight that could potentially be applicable in future contexts.

Figure 2: Summary of lessons learnt from the examples of emerging science and technology oversight



References

'A Welcome Report.' 1984. *British Medical Journal* 289 (6439).

Adelman, Zach N., Lorraine M. Albritton, Kathleen Boris-Lawrie, Michael J. Buchmeier, Paula Cannon, Mildred Cho, David DiGiusto, et al. 2018. 'Protect NIH's DNA Advisory Committee.' *Science* 362 (6413): 409–10. As of 16 December 2018: https://doi.org/10.1126/science.aav2483

Adenle, Ademola A., E. Jane Morris, Denis J. Murphy, Peter W. B. Phillips, Eduardo Trigo, Peter Kearns, Yun-He Li, Hector Quemada, José Falck-Zepeda, and John Komen. 2018. 'Rationalizing Governance of Genetically Modified Products in Developing Countries.' *Nature Biotechnology* 36 (February): 137–39. As of 16 December 2018: https://doi.org/10.1038/nbt.4069

Advisory Committee to the Director, Working Group on NIH Oversight of Clinical Gene Transfer Research. 2000. 'Enhancing the Protection of Human Subjects in Gene Transfer Research at the National Institutes of Health.'

Agar, J. 2013. *Constant Touch: A Global History of the Mobile Phone*. Revolutions in Science. Icon Books Limited. As of 16 December 2018: https://books.google.co.uk/books?id=sBNfZNqcOzoC

Agarwal, Khushboo. 2018. 'Playing in the Regulatory Sandbox.' *NYU Journal of Law & Business*. As of 16 December 2018: https://www.nyujlb.org/single-post/2018/01/08/Playing-in-the-Regulatory-Sandbox

Aaen, Jon, and Jeppe Agger Nielsen. 2018. "The Dark Side of Data Intensive Projects: Function Creep and Stakeholder Creep." *Twenty-Sixth European Conference on Information Systems (ECIS2018)*.

Alliance for Financial Inclusion. 2010. 'Enabling Mobile Money Transfer. The Central Bank of Kenya's Treatment of M-Pesa.' Bangkok: Alliance for Financial Inclusion. As of 16 December 2018: https://www.gsma.com/mobilefordevelopment/wp-content/uploads/2013/09/enablingmobilemoneytransfer92.pdf

Allison, Robert D., Lura J. Abbott, and Alison Wichman. 2008. 'Roles and Experiences of Non-Scientist Institutional Review Board Members at the National Institutes of Health.' *IRB* 30 (5): 8–13.

Andersen, Tariq, Pernille Bjørn, Finn Kensing, and Jonas Moll. 2011. 'Designing for Collaborative Interpretation in Telemonitoring: Re-Introducing Patients as Diagnostic Agents.' *International Journal of Medical Informatics*, Special Issue: Supporting Collaboration in Healthcare Settings: The Role of Informatics, 80 (8): e112–26. As of 16 December 2018: https://doi.org/10.1016/j.ijmedinf.2010.09.010

Anderson, Ross. 2012. 'The Privacy of Our Medical Records Is Being Sold off | Ross Anderson.' *The Guardian*, August 28, 2012, sec. Opinion. As of 16 December 2018: https://www.theguardian.com/commentisfree/2012/aug/28/code-practice-medical-data-vulnerable

Armstrong, Ann, Joseph Mueller, and Tim Syrett. 2014. 'The Smartphone Royalty Stack: Surveying Royalty Demands for the Components Within Modern Smartphones.' SSRN.

Arner, Douglas W., Janos Barberis, and Ross P. Buckley. 2017. 'FinTech, RegTech, and the Reconceptualization of Financial Regulation.' *Northwestern Journal of International Law & Business*, 371.

Athwal, D. S. 1971. 'Semidwarf Rice and Wheat in Global Food Needs.' *The Quarterly Review of Biology* 46 (1): 1–34.

Baker, Stewart A. 1997. 'Decoding OECD Guidelines for Cryptography Policy.' *International Lawyer (ABA)* 31: 729–56.

Bekkers, Rudi, Geert Duysters, and Bart Verspagen. 2002. 'Intellectual Property Rights, Strategic Technology Agreements and Market Structure: The Case of GSM.' *Research Policy* 31 (7): 1141–61. As of 16 December 2018: https://doi.org/10.1016/S0048-7333(01)00189-5

Bekkers, Rudi, Bart Verspagen, and Jan Smits. 2002. 'Intellectual Property Rights and Standardization: The Case of GSM.' *Telecommunications Policy* 26: 171–88.

Berg, Paul. n.d. 'The moratorium letter regarding risky experiments.' As of 16 December 2018: https://www.dnalc.org/view/15021-The-moratorium-letter-regarding-risky-experiments-Paul-Berg.html

Berg, Paul, David Baltimore, Herbert W. Boyer, Stanley H. Cohen, Ronald W. Davis, David S. Hogness, Daniel Nathans, et al. 1974. 'Potential Biohazards of Recombinant DNA Molecules.' *Science* 185 (4148): 303.

Bergrtom and Stromer. 2003. 'Norway Advances toward Fully Digital Healthcare | Diagnostic Imaging.' Diagnostic Imaging. As of 16 December 2018: http://www.diagnosticimaging.com/pacs-and-informatics/norway-advances-toward-fully-digital-healthcare

Biosafety Unit. 2013. 'Text of the Cartagena Protocol on Biosafety.' The Biosafety Clearing-House (BCH). 2013. As of 16 December 2018: http://bch.cbd.int/protocol/text/

———. 2018. 'The Cartagena Protocol on Biosafety.' The Biosafety Clearing-House (BCH). October 11, 2018. As of 16 December 2018: https://bch.cbd.int/protocol

Biswas, Soutik. 2018. 'Delhi Smog: Foul Air Came from India's Farming Revolution.' *BBC News* (blog). October 23, 2018. https://www.bbc.com/news/world-asia-india-45890916

Björklund, Fredrika. 2016. 'E-Government and Moral Citizenship: The Case of Estonia.' *Citizenship Studies* 20 (6–7): 914–31.

Borlaug, Norman. 2000. 'The Green Revolution Revisited and The Road Ahead.' Special 30th Anniversary Lecture, The Norwegian Nobel Institute, Oslo.

Bourreau, Marc, and Tommaso Valletti. 2015. 'Enabling Digital Financial Inclusion through Improvements in Competition and Interoperability: What Works and What Doesn't?' 065. CGD Policy Paper. Washington, D.C.: Center for Global Development. As of 16 December 2018: https://www.cgdev.org/sites/default/files/CGD-Policy-Paper-65-Bourreau-Valletti-Mobile-Banking.pdf

Brazier, Margaret. 1999. 'Regulating the Reproduction Business?' *Medical Law Review* 7: 166–93.

Bresnick, Ellen R. 1981. 'A Holistic Approach to the Treatment of the Crisis of Infertility.' *Journal of Marital and Family Therapy* 7 (2): 181–88. As of 16 December 2018: https://doi.org/10.1111/j.1752-0606.1981.tb01368.x

Bromberg, Lev, Andrew Godwin, and Ian Ramsay. 2017. 'Fintech Sandboxes: Achieving a Balance between Regulation and Innovation.' *Journal of Banking and Finance Law and Practice* 28 (4): 314–336.

Buku, Mercy W., and Michael W. Meredith. 2013. 'Safaricom and M-PESA in Kenya: Financial Inclusion and Financial Integrity.' *Washington Journal of Law, Technology & Arts* 8 (3): 375–400.

Cambridge Centre for Alternative Finance. 2018. 'Guide to Promoting Financial & Regulatory Innovation.' As of 16 December 2018: https://www.jbs.cam.ac.uk/fileadmin/user_upload/research/centres/alternative-finance/downloads/2018-06-ccaf-whitepaper-guide-to-promoting-financial-regulation-innovation.pdf

Cardash, Sharon L, and Frank J Cilluffo. 2013. 'Estonia's Cyber Defence League: A Model for the United States?' *Studies in Conflict & Terrorism* 36 (9): 777–87.

Cavaliere, Giulia. 2017. 'A 14-Day Limit for Bioethics: The Debate over Human Embryo Research.' *BMC Medical Ethics* 18 (1): 38. As of 16 December 2018: https://doi.org/10.1186/s12910-017-0198-5

Central Statistical Bureau of Latvia. 2017. 'Internet Usage Habits of Latvian Population in 2017.' As of 16 December 2018: https://www.csb.gov.lv/en/statistics/statistics-by-theme/science-ict/computers-internet/search-in-theme/2207-internet-usage-habits-latvian

Centre for Public Impact. 2016. 'Mobile Currency in Kenya: The M-Pesa.' As of 16 December 2018: https://www.centreforpublicimpact.org/case-study/m-currency-in-kenya/

Christiansen, Terkel, and Andreas Rudkjøbing. n.d. 'Deletion of the Danish General Practice Database (DAMD).' As of 16 December 2018: https://www.hspm.org/countries/denmark27012013/livinghit.aspx?Section=2.7%20Health%20information%20management&Type=Section

Cohen, Jean, Alan Trounson, Karen Dawson, Howard Jones, Johan Hazekamp, Karl-Gösta Nygren, and Lars Hamberger. 2005. 'The Early Days of IVF Outside the UK.' *Human Reproduction Update* 11 (5): 439–59. As of 16 December 2018: https://doi.org/10.1093/humupd/dmi016

Collins, Francis S., and Scott Gottlieb. 2018. 'The Next Phase of Human Gene-Therapy Oversight.' *New England Journal of Medicine* 379 (15): 1393–95. As of 16 December 2018: https://doi.org/10.1056/NEJMp1810628

Connolly, M., F. Gallo, S. Hoorens, and W. Ledger. 2009. 'Assessing Long-Run Economic Benefits Attributed to an IVF-Conceived Singleton Based on Projected Lifetime Net Tax Contributions in the UK.' *Human Reproduction (Oxford, England)* 24 (3): 626–32. As of 16 December 2018: https://doi.org/10.1093/humrep/den435

Convention on Biological Diversity. 2012. 'About the Protocol.' The Biosafety Clearing-House (BCH). May 29, 2012. As of 16 December 2018: http://bch.cbd.int/protocol/background/

———. 2015. '10th Anniversary of the Cartagena Protocol on Biosafety.' 2015. As of 16 December 2018: https://bch.cbd.int/protocol/10thAnniversary.shtml

———. 2018. 'Convention on Biological Diversity.' 2018. As of 16 December 2018: https://www.cbd.int/

Council of the European Union. 1987. 'On the Frequency Bands to Be Reserved for the Coordinated Introduction of Public Pan-European Cellular Digital Land-Based Mobile Communications in the Community.' Council Directive 87/372/EEC. Official Journal of the European Communities.

Craven, Lyndsey, Mary Herbert, Alison Murdoch, Julie Murphy, James Lawford Davies, and Doug M. Turnbull. 2016. 'Research into Policy: A Brief History of Mitochondrial Donation.' *STEM CELLS* 34 (2): 265–67. As of 16 December 2018: https://doi.org/10.1002/stem.2221

Czosseck, Christian, and Kenneth Geers. 2009. *The Virtual Battlefield: Perspectives on Cyber Warfare*. Cryptology and Information Security Series. Ios Press.

Dahir, Abdi Latif. 2018. 'Kenya Won't Force a Spin-off of the World's Leading Mobile Money Service after All.' Quartz Africa. February 22, 2018. As of 16 December 2018: https://qz.com/africa/1212396/kenya-safaricom-shouldnt-split-from-m-pesa-analysys-mason-says/

Dahl, Johanne, and Ann Sætnan. n.d. "It All Happened so Slowly' – On Controlling Function Creep in Forensic DNA Databases.' *International Journal of Law, Crime and Justice* 37 (3): 87–103.

Dalrymple, Dana G. 1974. 'Development and Spread of High-Yielding Varieties of Wheat and Rice in the Less Developed Nations.' 145638. Foreign Agricultural Economic Report (FAER). United States Department of Agriculture, Economic Research Service. As of 16 December 2018: https://ideas.repec.org/p/ags/uersfe/145638.html

Davies, Martin, Sophie Brannan, Eleanor Chrispin, Veronica English, Rebecca Mussell, and Julian C. Sheather. 2013. 'Ethics Briefing: Reprieve for Regulatory Bodies.' *J Med Ethics* 39: 413–14.

Deech, Ruth. 1999. 'Aims of the HFEA: Past and Future.' *Human Fertility* 2 (2): 118–21.

Deloitte. 2018. 'A Journey through the FCA Regulatory Sandbox: The Benefits, Challenges, and next Steps.' As of 16 December 2018: https://www2.deloitte.com/uk/en/pages/financial-services/articles/journey-through-financial-conduct-authority-regulatory-sandbox.html

Department of Health & Human Services. 2017. *Charter: Recombinant DNA Advisory Committee*.

Deshpande, Advait, Katherine Stewart, Louise Lepetit, and Salil Gunashekar. 2017. 'Understanding the Landscape of Distributed Ledger Technologies/Blockchain.' RR-2223-BSI. As of 16 December 2018: https://www.rand.org/pubs/research_reports/RR2223.html

DESI. 2018. 'Digital Public Services.' Digital Economy and Society Index Report 2018.

Devaney, Sarah. 2011. 'Regulate to Innovate: Principles-Based Regulation of Stem Cell Research.' *Medical Law International* 11: 53–68.

Di Castri, Simone, and Lara Gidvani. 2014. 'Enabling Mobile Money Policies in Tanzania. A 'Test and Learn' Approach to Enabling Market-Led Digital Financial Services.' London: GSMA.

Diffie, Whitfield. 1988. 'The First Ten Years of Public-Key Cryptography.' *Proceedings of the IEEE* 76 (5): 560–77.

Diffie, Whitfield, and Martin E Hellman. 1976. 'New Directions in Cryptography.' *IEEE Transactions on Information Theory* IT-22: 12.

DSAM. n.d. 'DAK-E - DSAM - Dansk Selskab for Almen Medicin.' As of 16 December 2018: https://www.dsam.dk/flx/english/quality_development/dak_e/

Dunfield, Kari E., and James J. Germida. 2004. 'Impact of Genetically Modified Crops on Soil- and Plant-Associated Microbial Communities.' *Journal of Environmental Quality* 33 (3): 806–15. As of 16 December 2018: https://doi.org/10.2134/jeq2004.0806

Dupuis, Philippe. 2007. 'Operators Cooperation in Early GSM Standardisation.' Lemesos, Cyprus, March.

Dyer, Clare. 2008. 'MPs Vote to Allow Creation of 'Admixed' Embryos.' *BMJ : British Medical Journal* 336 (7654): 1149. As of 16 December 2018: https://doi.org/10.1136/bmj.39588.463148.DB

———. 2011. 'New Life for the HFEA?' *BMJ* 342 (January): d439. As of 16 December 2018: https://doi.org/10.1136/bmj.d439

E-Estonia. 2018a 'ID Card.' E-Estonia. As of 16 December 2018: https://e-estonia.com/solutions/e-identity/id-card/

E-Estonia. 2018b 'I-Voting.' E-Estonia. As of 16 December 2018: https://e-estonia.com/solutions/e-governance/i-voting/

Eggers, William D., Mike Turley, and Pankaj Kishnani. 2018. 'The Future of Regulation.' As of 16 December 2018: https://www2.deloitte.com/insights/us/en/industry/public-sector/future-of-regulation/regulating-emerging-technology.html

English, Veronica. 2013. 'The Future of the Human Fertilisation and Embryology Authority.' *Reproductive BioMedicine Online* 26 (4): 305–6. As of 16 December 2018: https://doi.org/10.1016/j.rbmo.2013.01.002

Enterprise Estonia. 2018a 'E-Estonia — We Have Built a Digital Society and so Can You.' E-Estonia. As of 16 December 2018: https://e-estonia.com

———. 2018b 'E-Governance.' E-Estonia. As of 16 December 2018: https://e-estonia.com/solutions/e-governance/

———. 2018c 'E-Tax — e-Estonia.' E-Estonia. As of 16 December 2018: https://e-estonia.com/solutions/business-and-finance/e-tax

ETSI. 1997. 'GSM Electro Magnetic Compatibility (EMC) Considerations.' European Telecommunications Standards Institute.

Etzo, Sebastiana, and Guy Collender. 2010. 'The Mobile Phone 'Revolution' in Africa: Rhetoric or Reality?' *African Affairs* 109 (437): 659–68. As of 16 December 2018: https://doi.org/10.1093/afraf/adq045

European Commission. 2018. 'Roaming.' Digital Single Market. As of 16 December 2018: https://ec.europa.eu/digital-single-market/en/roaming

Evenson, R E, and D Gollin. 2003. 'Assessing the Impact of the Green Revolution, 1960 to 2000' 300: 6.

EY. 2017. 'As FinTech Evolves, Can Financial Services Innovation Be Compliant? The Emergence and Impact of Regulatory Sandboxes — in the UK and across Asia-Pacific.' As of 16 December 2018: https://www.ey.com/Publication/vwLUAssets/ey-the-emergence-and-impact-of-regulatory-sandboxes-in-uk-and-across-apac/$FILE/ey-the-emergence-and-impact-of-regulatory-sandboxes-in-uk-and-across-apac.pdf

Falck-Zepeda, Jose Benjamin, and Patricia Zambrano. 2011. 'Socio-Economic Considerations in Biosafety and Biotechnology Decision Making: The Cartagena Protocol and National Biosafety Frameworks.' *Review of Policy Research* 28 (2): 171–95. As of 16 December 2018: https://doi.org/10.1111/j.1541-1338.2011.00488.x

Fáykiss, Péter, Dániel Papp, and Ágnes Tőrös. 2018. 'Regulatory Tools to Encourage FinTech Innovations: The Innovation Hub and Regulatory Sandbox in International Practice.' *Financial and Economic Review* 17: 43–67.

FCA. 2015. 'Regulatory Sandbox.' As of 16 December 2018: https://www.fca.org.uk/publication/research/regulatory-sandbox.pdf

———. 2017. 'Regulatory Sandbox Lessons Learned Report.' As of 16 December 2018: https://www.fca.org.uk/publications/research/regulatory-sandbox-lessons-learned-report

Fick, Maggie, and Duncan Miriri. 2018. 'Exclusive: Kenya's Safaricom Taking M-Pesa to Ethiopia, Sources Say.' *Reuters*, July 17, 2018. As of 16 December 2018: https://www.reuters.com/article/us-safaricom-ethiopia-exclusive/exclusive-kenyas-safaricom-taking-m-pesa-to-ethiopia-sources-say-idUSKBN1K715H

FinMark Trust. 2017. 'Research Report on Mobile Money in South Africa.' Johannesburg: FinMark Trust. As of 16 December 2018: http://www.finmark.org.za/wp-content/uploads/2017/12/Final-Report-on-Mobile-Money-in-South-Africa-v11.1_clean_digital_CB.pdf

Finn, Robert. 2000. 'Why Were NIH Adverse Event Reporting Guidelines Misunderstood?' *JNCI: Journal of the National Cancer Institute* 92 (10): 784–86. As of 16 December 2018: https://doi.org/10.1093/jnci/92.10.784

Fonearena. 2011. 'World's First GSM Call Was Made 20 Years Ago.' 2011. As of 16 December 2018: https://www.fonearena.com/blog/40515/worlds-first-gsm-call-was-made-20-years-ago.html

Frankel, Francine R. 1974. *India's Green Revolution: Economic Gains and Political Costs*. Princeton: Princeton University Press.

Froomkin, A. 1996. 'It Came from Planet Clipper: The Battle Over Cryptographic Key 'Escrow." *University of Chicago Legal Forum*, no. 1. As of 16 December 2018: https://chicagounbound.uchicago.edu/uclf/vol1996/iss1/3

FSB. 2017. 'Financial Stability Implications from FinTech: Supervisory and Regulatory Issues That Merit Authorities' Attention.' As of 16 December 2018: http://www.fsb.org/2017/06/financial-stability-implications-from-fintech/

Galetovic, Alexander. 2018. 'An Estimate of the Average Cumulative Royalty Yield in the World Mobile Phone Industry: Theory, Measurement and Results.' *Telecommunications Policy* 42: 263–76.

Gandal, Neil, David Salant, and Leonard Waverman. 2003. 'Standards in Wireless Telephone Networks.' *Telecommunications Policy* 27: 325–32.

GO Science. 2015. 'FinTech Futures: The UK as a World Leader in Financial Technologies.' As of 16 December 2018: https://www.gov.uk/government/publications/fintech-blackett-review

Gonen, Limor Dina. 2016. 'Social and Private Benefits of Assisted Reproductive Technology: A National Survey-Based Evaluation in Israel.' *J Comp Eff Res* 5 (1): 49–63.

GSMA. 2008. '3 Billion GSM Connections On The Mobile Planet – Reports The GSMA.' *Newsroom* (blog). April 16, 2008. As of 16 December 2018: https://www.gsma.com/newsroom/press-release/3-billion-gsm-connections-on-the-mobile-planet-reports-the-gsma/

———. 2017. 'State of the Industry Report on Mobile Money. Decade Edition: 2006–2016.' London: GSMA. As of 16 December 2018: https://www.gsma.com/mobilefordevelopment/wp-content/uploads/2017/03/GSMA_State-of-the-Industry-Report-on-Mobile-Money_2016.pdf

GSMA Intelligence. 2018. 'The Mobile Economy 2018.' GSM Association.

Gupta, A. 2000. 'Governing Trade in Genetically Modified Organisms: The Cartagena Protocol on Biosafety.' *Environment: Science and Policy for Sustainable Development* 42 (4): 22–33. As of 16 December 2018: https://doi.org/10.1080/00139150009604881

Gupta, A., and R. Falkner. 2006. 'The Influence of the Cartagena Protocol on Biosafety: Comparing Mexico, China and South Africa..' *Global Environmental Politics* 6 (4): 23–55. As of 16 December 2018: https://doi.org/10.1162/glep.2006.6.4.23

Gustke, Jim. 2017. 'Cell Phone Cost Comparison Timeline.' *Industry Insights* (blog). August 22, 2017. As of 16 December 2018: https://www.ooma.com/blog/cell-phone-cost-comparison/

Hardy, D., G. Malleus, and J.N. Mereur, eds. 2013. *Networks: Internet · Telephony · Multimedia*. Springer Berlin Heidelberg. As of 16 December 2018: https://books.google.co.uk/books?id=GZPzCAAAQBAJ

Harper, Sarah. 2014. 'Economic and Social Implications of Aging Societies.' *Science* 346 (6209): 587–91. As of 16 December 2018: https://doi.org/10.1126/science.1254405

Haug, Thomas. 2002. 'A Commentary on Standardization Practices: Lessons from the NMT and GSM Mobile Telephone Standards Histories.' *Telecommunications Policy* 26 (3–4): 101–7.

Hauskeller, Christine. 2004. 'How Traditions of Ethical Reasoning and Institutional Processes Shape Stem Cell Research in Britain.' *Journal of Medicine and Philosophy* 29 (5): 509–32. As of 16 December 2018: https://doi.org/10.1080/03605310490518104

Hayes, Niall, and Chris Westrup. 2012. 'Context and the Processes of ICT for Development.' *Information and Organization* 22 (1): 23–36. As of 16 December 2018: https://doi.org/10.1016/j.infoandorg.2011.10.001

Heitman, Elizabeth. 1999. 'Social and Ethical Aspects of In Vitro Fertilization.' *International Journal of Technology Assessment in Health Care* 15 (1): 22–35.

HFEA. 2018a. 'Annual Report and Accounts 2017/18.' London: Human Fertilisation & Embryology Authority.

———. 2018b. 'Meet Our Authority Members.' Human Fertilisation and Embryology Authority. As of 16 December 2018: https://www.hfea.gov.uk/about-us/our-people/meet-our-authority-members/

———. n.d. 'How We Regulate.' Human Fertilisation & Embryology Authority. As of 16 December 2018: https://www.hfea.gov.uk/about-us/how-we-regulate/.

Hillebrand, Friedhelm. 2013. 'The Creation of Standards for Global Mobile Communication: GSM and UMTS Standardization from 1982 to 2000.' *IEEE Wireless Communications* 20 (5): 24–33. As of 16 December 2018: https://doi.org/10.1109/MWC.2013.6664470

HITSA. n.d. 'HITSA.' Accessed November 14, 2018. As of 16 December 2018: https://www.hitsa.ee/

HM Government. 2018. 'Projects Lay the Groundwork for a Future of Robolawyers and Flying Cars.' HM Government. As of 16 December 2018: https://www.gov.uk/government/news/projects-lay-the-groundwork-for-a-future-of-robolawyers-and-flying-cars

Horsey, Kirsty. 2016. 'Surrogacy in the United Kingdom: Present and Future Challenges.' In *Handbook of Gestational Surrogacy: International Clinical Practice and Policy Issues*. Cambridge University Press.

House of Commons. 2007. 'Science and Technology - Fifth Report.' As of 16 December 2018: https://publications.parliament.uk/pa/cm200607/cmselect/cmsctech/272/27205.htm

Human Fertilisation & Embryology Authority. 2018. 'IVF Regulation: Ensuring Safe and Ethical Treatment.' July 11, 2018. As of 16 December 2018: https://www.hfea.gov.uk/about-us/news-and-press-releases/2018-news-and-press-releases/ivf-regulation-ensuring-safe-and-ethical-treatment/

Hutchison, Clyde A. 2007. 'DNA Sequencing: Bench to Bedside and Beyond†.' *Nucleic Acids Research* 35 (18): 6227–37. As of 16 December 2018: https://doi.org/10.1093/nar/gkm688

Institute of Medicine. 2014. 'Oversight of Gene Transfer Research.' In *Oversight and Review of Clinical Gene Transfer Protocols: Assessing the Role of the Recombinant DNA Advisory Committee*. Washington, D.C.: The National Academies Press. As of 16 December 2018: https://www.ncbi.nlm.nih.gov/books/NBK195894/

Internal Revenue Service. 2017. 'Filing Season Statistics 2017.' As of 16 December 2018: https://www.irs.gov/newsroom/filing-season-statistics-for-week-ending-september-1-2017

International Monetary Fund. 2018. 'Report for Selected Countries and Subjects.' World Economic Outlook. As of 16 December 2018: https://www.imf.org/external/pubs/ft/weo/2018/02/weodata/weorept.aspx?sy=2016&ey=2023&scsm=1&ssd=1&sort=subject&ds=.&br=1&pr1.x=28&pr1.y=5&c=122%2C941%2C124%2C946%2C423%2C137%2C939%2C181%2C172%2C138%2C132%2C182%2C134%2C936%2C174%2C961%2C178%2C184%2C136&s=NGDPD&grp=0&a=#download

Iraki, X. N. 2016. 'Five Reasons M-Pesa Failed in South Africa.' The Standard. 2016. As of 16 December 2018: https://www.standardmedia.co.ke/article/2000201831/five-reasons-m-pesa-failed-in-south-africa

IUCN. 1967. 'Part III: Changes Due to Introduced Species.' In *Towards a New Relationship of Man and Nature in Temperate Lands*. Morges, Switzerland: International Union for Conservation of Nature and Natural Resources.

Jack, William, and Tavneet Suri. 2011. 'Mobile Money: The Economics of M-Pesa.' 16721. NBER Working Paper Series. Cambridge, MA: National Bureau of Economic Research. As of 16 December 2018: https://www.nber.org/papers/w16721.pdf

Jaffe, Gregory. 2005. 'Implementing the Cartagena Biosafety Protocol through National Biosafety Regulatory Systems: An Analysis of Key Unresolved Issues.' *Journal of Public Affairs* 5 (3–4): 299–311. As of 16 December 2018: https://doi.org/10.1002/pa.30

Janforum. 1985. 'The Warnock Report on Human Fertilization and Embryology.' *Journal of Advanced Nursing* 10 (July): 375–84.

Kalkun, Mari, and Tarmo Kalvet, eds. 2002. 'Digital Divide in Estonia and How to Bridge It.' Emor and PRAXIS Center for Policy Studies.

Kalvet, T. 2007. 'The Estonian Information Society Developments since the 1990s.' PRAXIS. As of 16 December 2018: https://books.google.co.uk/books?id=haGLYxkphtQC

Kamel, Remah Moustafa. 2013. 'Assisted Reproductive Technology after the Birth of Louise Brown.' *J Reprod Infertil* 14 (3): 96–109.

Kamphuis, Esme I., S. Bhattacharya, F. van der Veen, B. W. J. Mol, and A. Templeton. 2014. 'Are We Overusing IVF?' *BMJ* 348 (January): g252. As of 16 December 2018: https://doi.org/10.1136/bmj.g252

Kehl, Danielle, Andi Wilson, and Kevin Bankston. 2015. 'Doomed to Repeat History? Lessons from the Crypto Wars of the 1990s.' 2015. As of 16 December 2018: https://www.newamerica.org/cybersecurity-initiative/policy-papers/doomed-to-repeat-history-lessons-from-the-crypto-wars-of-the-1990s/

Kerem, Katri. 2003. 'Internet Banking in Estonia.' PRAXIS.

Khan, Suliman, Muhammad Wajid Ullah, Rabeea Siddique, Ghulam Nabi, Sehrish Manan, Muhammad Yousaf, and Hongwei Hou. 2016. 'Role of Recombinant DNA Technology to Improve Life.' *International Journal of Genomics* 2016. As of 16 December 2018: https://doi.org/10.1155/2016/2405954

Kimenyi, Mwangi S., and Njuguna S. Ndung'u. 2009. 'Expanding the Financial Services Frontier: Lessons From Mobile Phone Banking in Kenya.' As of 16 December 2018: http://www.www.w.gsma.com/mobilefordevelopment/wp-content/uploads/2012/06/1016_mobile_phone_kenya_kimenyi.pdf

Kinderlerer, Julian. 2008. 'The Cartagena Protocol on Biosafety.' *Collection of Biosafety Reviews* 4: 12–65.

King, Nancy M.P. 2002. 'RAC Oversight of Gene Transfer Research: A Model Worth Extending?' *Journal of Law, Medicine, and Ethics* 30: 381–89.

Kitsing, Meelis. 2010. 'An Evaluation of E-Government in Estonia.' In *Internet, Politics, and Policy 2010: An Impact Assessment Conference*, 20. Oxford University, UK.

———. 2011. 'Success Without Strategy: E-Government Development in Estonia.' *Policy & Internet* 3 (1): 1–21. As of 16 December 2018: https://doi.org/10.2202/1944-2866.1095

Knight, Christine, and Malcolm K. Smith. 2013. 'Editorial: The Human Fertilisation and Embryology Act 2008.' *New Genetics and Society* 32 (2): 107–18. As of 16 December 2018: https://doi.org/10.1080/14636778.2013.788354

Kohm, Katherine E. 2009. 'Shortcomings of the Cartagena Protocol: Resolving the Liability Loophole at an International Level Comment.' *UCLA Journal of Environmental Law and Policy* 27: 145–80.

Kubania, Jacqueline. 2018. 'Consultant Revises Position on Splitting Safaricom.' Business Daily. February 20, 2018. As of 16 December 2018: https://www.businessdailyafrica.com/corporate/companies/Analysys-Mason-Safaricom-M-Pesa-split-dominance/4003102-4312672-helh2lz/index.html

Kuzma, Jennifer. 2007. 'Moving Forward Responsibly: Oversight for the Nanotechnology-Biology Interface.' *Journal of Nanoparticle Research* 9 (1): 165–82. As of 16 December 2018: https://doi.org/10.1007/s11051-006-9151-0

Kuzma, Jennifer, and Susanna Priest. 2010. 'Nanotechnology, Risk, and Oversight: Learning Lessons from Related Emerging Technologies.' *Risk Analysis* 30 (11): 1688–98. As of 16 December 2018: https://doi.org/10.1111/j.1539-6924.2010.01471.x

Kuzma, Jennifer, and Todd Tanji. 2010. 'Unpackaging Synthetic Biology: Identification of Oversight Policy Problems and Options.' *Regulation & Governance* 4: 92–112.

Langhoff, Tue Odd, Mikkel Hvid Amstrup, Peter Mørck, and Pernille Bjørn. 2018. 'Infrastructures for Healthcare: From Synergy to Reverse Synergy.' *Health Informatics Journal* 24 (1): 43–53. As of 16 December 2018: https://doi.org/10.1177/1460458216654288

Leather, Suzi. 2005. 'The HFEA Then and Now.' *Human Fertility (Cambridge, England)* 8 (2): 63–64. As of 16 December 2018: https://doi.org/10.1080/14647270500030720

Lenzi, Rebecca N., Bruce M. Altevogt, Lawrence O. Gostin, Committee on the Independent Review and Assessment of the Activities of the NIH Recombinant DNA Advisory Committee, Board on Health Sciences Policy, and Institute of Medicine. 2014. *Historical and Policy Timelines for Recombinant DNA Technology*. National Academies Press (US). As of 16 December 2018: https://www.ncbi.nlm.nih.gov/books/NBK195888/

Letterie, Gerard. 2017. 'Outcomes of Medical Malpractice Claims in Assisted Reproductive Technology over a 10-Year Period from a Single Carrier.' *Journal of Assisted Reproduction and Genetics* 34 (4): 459–63. As of 16 December 2018: https://doi.org/10.1007/s10815-017-0889-3

Levine, Aaron D. 2008. 'Identifying Under- and Overperforming Countries in Research Related to Human Embryonic Stem Cells.' *Cell Stem Cell* 2 (6): 521–24. As of 16 December 2018: https://doi.org/10.1016/j.stem.2008.05.008

Levitt, Mairi. 2009. 'Assisted Reproduction: Managing an Unruly Technology.' *Health Care Analysis* 12 (1): 41–49.

Levy, Steven. 1994. 'Battle of the Clipper Chip.' *The New York Times*, June 12, 1994. As of 16 December 2018: https://www.nytimes.com/1994/06/12/magazine/battle-of-the-clipper-chip.html

Lippert, Maria Laura, Marius Brostrøm Kousgaard, and Lars Bjerrum. 2014. 'General Practitioners Uses and Perceptions of Voluntary Electronic Feedback on Treatment Outcomes – a Qualitative Study.' *BMC Family Practice* 15 (November). As of 16 December 2018: https://doi.org/10.1186/s12875-014-0193-6

Lovell-Badge, Robin. 2008. 'The Regulation of Human Embryo and Stem Cell Research in the United Kingdom.' *Nature* 9.

Lund, Jesper. 2015. 'Denmark Plans to Preserve Illegally Collected Medical Data.' *EDRi* (blog). March 25, 2015. As of 16 December 2018: https://edri.org/denmark-plans-preserve-illegally-collected-medical-data/

Marchant, Gary E., Braden R. Allenby, and Joseph R. Herkert. 2011. *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight: The Pacing Problem*. Springer Science & Business Media.

Marchant, Gary E., Douglas J. Sylvester, and Kenneth W. Abbott. 2009. 'What Does the History of Technology Regulation Teach Us about Nano Oversight?' *The Journal of Law, Medicine & Ethics* 37 (4): 724–31. As of 16 December 2018: https://doi.org/10.1111/j.1748-720X.2009.00443.x

Margetts, Helen, and Andre Naumann. 2017. 'Government as a Platform: What Can Estonia Show the World?' *Oxford Department of Politics and International Relations*, 1–41.

Mas, Ignacio, and Dan Radcliffe. 2011. 'Mobile Payments Go Viral. M-PESA in Kenya.' In *Yes Africa Can. Success Stories from a Dynamic Continent*, edited by Punam Chuhan-Pole and Manka Angwafo, 353–70. Washington, D.C.: The World Bank.

Matsumoto, David, ed. 2009. *The Cambridge Dictionary of Psychology*. Cambridge, UK: Cambridge University Press. As of 16 December 2018: https://www.cambridge.org/vi/academic/subjects/psychology/psychology-general-interest/cambridge-dictionary-psychology?format=PB

Mayor, Susan. 2004. 'UK Authority Sets Limit on Number of Embryos Transferred.' *BMJ : British Medical Journal* 328 (7431): 65.

Mbiti, Isaac, and David N. Weil. 2011. 'Mobile Banking: The Impact of M-Pesa in Kenya.' 17129. NBER Working Paper Series. Cambridge, MA: National Bureau of Economic Research. As of 16 December 2018: https://www.nber.org/papers/w17129.pdf

Montgomery, Jonathan. 1991. 'Rights, Restraints and Pragmatism: The Human Fertilisation and Embryology Act 1990.' *The Modern Law Review* 54 (4): 524–34.

Morgan, Derek. 2004. 'Ethics, Economics and the Exotic: The Early Career of the HFEA.' *Health Care Analysis* 12 (1): 7–26.

Muthiora, Brian. 2015. 'Enabling Mobile Money Policies in Kenya. Fostering a Digital Financial Revolution.' London: GSMA. As of 16 December 2018: http://t1.daumcdn.net/brunch/service/user/P5W/file/mxAyGPsEeNdS1FAkt9vWxBJVHSg.pdf

National Institutes for Health. n.d. 'Requirements for Institutional Biosafety Committees under the NIH Guidelines.'

National Institutes of Health. 2016. 'RAC Meetings.' *Office of Science Policy* (blog). 2016. As of 16 December 2018: https://osp.od.nih.gov/biotechnology/rac-meetings/

Nature, Editorial. 2016. 'Gene-Therapy Trials Must Proceed with Caution: The Perils of the Past Must Not Be Allowed to Happen Again.' *Nature News* 534 (7609): 590. As of 16 December 2018: https://doi.org/10.1038/534590a

Newell, Peter, and Ruth Mackenzie. 2000. 'The 2000 Cartagena Protocol on Biosafety: Legal and Political Dimensions.' *Global Environmental Change* 10 (4): 313–17. As of 16 December 2018: https://doi.org/10.1016/S0959-3780(00)00049-2

Nexøe, Jørgen. 2013. 'Developing Danish General Practice.' *Scandinavian Journal of Primary Health Care* 31 (3): 129–30. As of 16 December 2018: https://doi.org/10.3109/02813432.2013.815989

NHS. 2017. 'Infertility.' 2017. As of 16 December 2018: https://www.nhs.uk/conditions/infertility/

NHS Direct. 2010 'NHS Direct - What Is NHS Direct?' As of 16 December 2018: https://web.archive.org/web/20100710183704/http://www.nhsdirect.nhs.uk/About/WhatIsNHSDirect

NIH. 2016. 'NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.' Bethesda: National Institutes of Health.

Nirenberg, Marshall. 2004. 'Historical Review: Deciphering the Genetic Code – a Personal Account.' *Trends in Biochemical Sciences* 29 (1): 46–54. As of 16 December 2018: https://doi.org/10.1016/j.tibs.2003.11.009

Nogrady, Bianca. 2018. 'Australia Moves a Step Closer to 'Three-Person IVF." *Nature*, June. As of 16 December 2018: https://doi.org/10.1038/d41586-018-05451-z

NSF. 2018. 'Chapter XI - Other Post Award Requirements and Considerations.' National Science Foundation. As of 16 December 2018: https://www.nsf.gov/pubs/policydocs/pappg18_1/pappg_11.jsp

NSW Government. 2016. 'Regulatory Sandboxes.' Text. Innovation NSW. As of 16 December 2018: https://www.innovation.nsw.gov.au/regulatorysandboxes

OECD. 2016. 'Primary Care Review of Denmark.'

———. 2017. 'Primary Care in Denmark, OECD Reviews of Health Systems.' As of 16 December 2018: http://www.oecd.org/els/primary-care-in-denmark-9789264269453-en.htm

Ofgem. 2018. 'The Innovation Link.' Ofgem. As of 16 December 2018: https://www.ofgem.gov.uk/about-us/how-we-engage/innovation-link

Omwansa, Tonny. 2009. 'M-PESA: Progress and Prospects.' In *Innovations/Mobile World Congress 2009*, 107–23. As of 16 December 2018: https://profiles.uonbi.ac.ke/tomwansa/files/innov-gsma-omwansa.pdf

Ong, Sandy. 2018. 'Singapore Could Become the Second Country to Legalize Mitochondrial Replacement Therapy.' *Science | AAAS*, As of 16 December 2018: https://www.sciencemag.org/news/2018/06/singapore-could-become-second-country-legalize-mitochondrial-replacement-therapy

ONS. 2018. 'Internet Users, UK: 2018.' Office for National Statistics.

Ott, Arvo. 2014. 'E-Estonia – EGovernance Roadmap and Frameworks.' As of 16 December 2018: https://www.nbr.co.nz/sites/default/files/estonia%202.%20arvo%20ott_interoperability.pdf

Paddock, William C. 1970. 'How Green Is the Green Revolution?' *BioScience* 20 (16): 897–902. As of 16 December 2018: https://doi.org/10.2307/1295581

Parayil, Govindan. 1992. 'The Green Revolution in India: A Case Study of Technological Change.' *Technology and Culture* 33 (4): 737–56. As of 16 December 2018: https://doi.org/10.2307/3106588

———. 2003. 'Mapping Technological Trajectories of the Green Revolution and the Gene Revolution from Modernization to Globalization.' *Research Policy* 32 (6): 971–90. As of 16 December 2018: https://doi.org/10.1016/S0048-7333(02)00106-3

Patra, Satyajit, and Araromi Adewale Andrew. 2015. 'Human, Social, and Environmental Impacts of Human Genetic Engineering.' *Journal of Biomedical Sciences* 4 (4). As of 16 December 2018: https://doi.org/10.4172/2254-609X.100014

Paulsen, MS, and JL Thomsen. 2013. 'Data Til Kvalitetsudviklings -Og Forskningsprojekter Fra Dansk AlmenMedicinsj Database (DAMD).' *Practicus* 216: 8.

Pearse, Andrew. 1980. *Seeds of Plenty, Seeds of Want: Social and Economic Implications of the Green Revolution*. New York: Clarendon Press. As of 16 December 2018: https://www.amazon.co.uk/Seeds-Plenty-Want-Implications-Revolution/dp/0198771509

Pednekar-Magal, Vandana, and Peter Shields. 2003. 'The State and Telecom Surveillance Policy: The Clipper Chip Initiative.' *Communication Law and Policy* 8 (4): 429–64. As of 16 December 2018: https://doi.org/10.1207/S15326926CLP0804_03

Pelkmans, Jacques. 2001. 'The GSM Standard: Explaining a Success Story.' *Journal of European Public Policy* 8 (3): 432–53.

Pingali, Prabhu L. 2012. 'Green Revolution: Impacts, Limits, and the Path Ahead.' *Proceedings of the National Academy of Sciences of the United States of America* 109 (31): 12302–8. As of 16 December 2018: https://doi.org/10.1073/pnas.0912953109

Priisalu, Jaan, and Rain Ottis. 2017. 'Personal Control of Privacy and Data: Estonian Experience.' *Health and Technology* 7 (4): 441–51. As of 16 December 2018: https://doi.org/10.1007/s12553-017-0195-1

Prince, Michael. n.d. 'The Second Crypto War and the Future of the Internet | HuffPost.' As of 16 December 2018: https://www.huffingtonpost.com/matthew-prince/the-second-crypto-war-and_b_6517528.html

Ricci, Ezra. 2004. 'Biosafety Regulation: The Cartagena Protocol.' As of 16 December 2018: http://www.ruig-gian.org/ressources/Brochure3Cartagenaprotoc.pdf

Riigi Teataja. n.d. 'Electronic Identification and Trust Services for Electronic Transactions Act – Riigi Teataja.' As of 16 December 2018: https://www.riigiteataja.ee/en/eli/527102016001/consolide

Riigikantselei. n.d. 'Osalusveeb.' Accessed October 19, 2018. As of 16 December 2018: https://www.osale.ee/

Riigikogu. 2000a. 'Digital Signatures Act.' As of 16 December 2018: https://www.riigiteataja.ee/en/eli/ee/508072014007/consolide

———. 2000b. 'Public Information Act.' As of 16 December 2018: https://www.riigiteataja.ee/en/eli/516012014003/consolide#

———. 2014. 'Knowledge Based Estonia 2014-2020.'

Ronald, Pamela. 2011. 'Plant Genetics, Sustainable Agriculture and Global Food Security.' *Genetics* 188 (1): 11–20. As of 16 December 2018: https://doi.org/10.1534/genetics.111.128553

Rosenfeld, David L., and Eileen Mitchell. 1979. 'Treating the Emotional Aspects of Infertility: Counseling Services in an Infertility Clinic.' *American Journal of Obstetrics and Gynecology* 135 (2): 177–80. As of 16 December 2018: https://doi.org/10.1016/0002-9378(79)90338-7

Runnel, Pille, Pille Pruulmann, and Kristina Reinsalu. 2009. 'The Estonian Tiger Leap from Post-Communism to the Information Society: From Policy to Practice.' *Journal of Baltic Studies* 40 (1): 29–51.

Sanger, David E., and Nicole Perlroth. 2015. 'Encrypted Messaging Apps Face New Scrutiny Over Possible Role in Paris Attacks - The New York Times.' *New York Times*, 2015. As of 16 December 2018: https://www.nytimes.com/2015/11/17/world/europe/encrypted-messaging-apps-face-new-scrutiny-over-possible-role-in-paris-attacks.html

Seibel, Machelle M., and Melvin L. Taymor. 1982. 'Emotional Aspects of Infertility.' *Fertility and Sterility* 37 (2): 137–45. As of 16 December 2018: https://doi.org/10.1016/S0015-0282(16)46029-2

Seifert, Jeffrey W. 2000. 'Unlocking the Key to Authority: The Contest Over Encryption Regulation.' *Journal of Conflict Studies* 20 (1). As of 16 December 2018: https://journals.lib.unb.ca/index.php/JCS/article/view/4338

Seshia, Shaila, and Ian Scoones. 2003. 'Tracing Policy Connections: The Politics of Knowledge in the Green Revolution and Biotechnology Eras in India.' As of 16 December 2018: https://opendocs.ids.ac.uk/opendocs/handle/123456789/3984

Sheldon, Sally. 2005. 'Fragmenting Fatherhood: The Regulation of Reproductive Technologies.' *The Modern Law Review* 68 (4): 523–53. As of 16 December 2018: https://doi.org/10.1111/j.1468-2230.2005.00550.x

Signatories. 1987. 'Memorandum of Understanding on the Implementation of a Pan European 900 MHz Digital Cellular Mobile Telecommunications Service by 1991.'

Singer, M. F. 1977. 'A Summary of the National Institutes of Health (USA) Guidelines for Recombinant DNA Research.' *Gene* 1 (2): 123–39.

Singh, R B. 2000. 'Environmental Consequences of Agricultural Development: A Case Study from the Green Revolution State of Haryana, India,' 7.

Singhal, Anjali. 1995. 'The Piracy of Privacy - A Fourth Amendment Analysis of Key Escrow Cryptography Feature.' *Stanford Law & Policy Review* 7: 189–210.

Skopec, Marlene. 1998. 'Hearing Aid Electromagnetic Interference from Digital Wireless Telephones.' *IEEE Transactions on Rehabilitation Engineering* 6 (2): 235–39.

Smith, Yolanda. 2018. 'What Is Recombinant DNA?' News Medical. 2018. As of 16 December 2018: https://www.news-medical.net/life-sciences/What-is-Recombinant-DNA.aspx

Statens Serum Institut. 2014. 'Sammenfattende Om: Udredning Vedr. Ansøgninger Om Godkendelse Af DAMD Som Klinisk Kvalitetsdatabase, Fra 2007 Og Frem.'

Sundheds- og Ældreministeriet. 2017. 'Bedre Sundhed Gennem Moderne Og Sikker Brug Af Data.' As of 16 December 2018: https://www.denoffentlige.dk/sites/default/files/suppliers/news/files/bedre_sundhed_gennem_moderne_og_sikker_brug_af_data.pdf

Suri, Tavneet, and William Jack. 2016. 'The Long-Run Poverty and Gender Impacts of Mobile Money.' *Science* 354 (6317): 1288–93. As of 16 December 2018: https://doi.org/10.1126/science.aah5309

Sutherland, Ewan. 2001. 'International Roaming Charges: Over-Charging and Competition Law.' *Telecommunications Policy* 25: 5–20.

Swazey, Judith P., James R. Sorenson, and Cynthia B. Wong. 1977. 'Risks and Benefits, Rights and Responsibilities: A History of the Recombinant DNA Research Controversy Symposium: Biotechnology and the Law: Recombinant DNA and the Control of Scientific Research: II. History of the Recombinant DNA Research Debate.' *Southern California Law Review* 51: 1019–80.

Tarazi, Michael, and Paul Breloff. 2010. 'Nonbank E-Money Issuers: Regulatory Approaches to Protecting Customer Funds.' CGAP Focus Note 63. Washington, D.C.: The World Bank. As of 16 December 2018: http://mobile.gsma.com/mobilefordevelopment/wp-content/uploads/2012/06/fn63_rev_d_33.pdf

TechRadar. n.d. 'What Is Cryptography?' TechRadar. As of 16 December 2018: https://www.techradar.com/news/what-is-cryptography

Temple, Stephen. 2010. 'Inside the Mobile Revolution: A Political History of GSM.'

The White House Press Secretary. 1993. 'White House Clipper Statement (4/16/93).' As of 16 December 2018: https://www.epic.org/crypto/clipper/white_house_statement_4_93.html

Thompson, L. 1993. 'Should Dying Patients Receive Untested Genetic Methods?' *Science* 259 (5094): 452–452. As of 16 December 2018: https://doi.org/10.1126/science.8424165

Tiedje, James M., Robert K. Colwell, Yaffa L. Grossman, Robert E. Hodson, Richard E. Lenski, Richard N. Mack, and Philip J. Regal. 1989. 'The Planned Introduction of Genetically Engineered Organisms: Ecological Considerations and Recommendations.' *Ecology* 70 (2): 298–315. As of 16 December 2018: https://doi.org/10.2307/1937535

Timberg, Craig, and Greg Miller. 2014. 'FBI Blasts Apple, Google for Locking Police out of Phones.' *The Washington Post*, September 25, 2014. As of 16 December 2018: https://www.washingtonpost.com/business/technology/2014/09/25/68c4e08e-4344-11e4-9a15-137aa0153527_story.html?utm_term=.61bf9374255b

Tung, OJ Lim. 2014. 'Transboundary Movements of Genetically Modified Organisms and the Cartagena Protocol: Key Issues and Concerns.' *Potchefstroom Electronic Law Journal/Potchefstroomse Elektroniese Regsblad* 17 (5): 1739-1787–1787. As of 16 December 2018: https://doi.org/10.4314/pelj.v17i5.01

UK Department of Health. 2000. 'Stem Cell Research: Medical Progress with Responsibility: Executive Summary.' *Cloning* 2 (2): 91–96. As of 16 December 2018: https://doi.org/10.1089/152045500436113

BEIS. 2018. 'Industrial Strategy: Building a Britain Fit for the Future.' As of 16 December 2018: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/664563/industrial-strategy-white-paper-web-ready-version.pdf

UK Parliament. n.d. 'Glossary.' UK Parliament. As of 16 December 2018: https://www.parliament.uk/site-information/glossary/

U.S. Department of Commerce. n.d. 'Encryption and Export Administration Regulations (EAR).' As of 16 December 2018: https://www.bis.doc.gov/index.php/policy-guidance/encryption

U.S. Food and Drug Administration. 2018. *Code of Federal Regulations Title 21, Part 56 Institutional Review Boards*. As of 16 December 2018: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.107

U.S. National Library of Medicine. n.d. 'The Arthur Kornberg Papers: The Synthesis of DNA, 1953-1959.' As of 16 December 2018: https://profiles.nlm.nih.gov/ps/retrieve/Narrative/WH/p-nid/208

USAID. 2010. 'Mobile Financial Services Risk Matrix.' As of 16 December 2018: https://www.gsma.com/mobilefordevelopment/wp-content/uploads/2012/06/mobilefinancialservicesriskmatrix100723.pdf

Varshney, Ashutosh. 1989. 'Ideas, Interest and Institutions in Policy Change: Transformation of India's Agricultural Strategy in the Mid-1960s.' *Policy Sciences* 22 (3/4): 289–323.

Vaughan, Pauline, Wolfgang Fengler, and Michael Joseph. 2012. 'Scaling Up through Disruptive Business Models: The Inside Story of Mobile Money in Kenya.' In *Getting to Scale: How to Bring Development Solutions to Millions of Poor People*, edited by Laurence Chandy, Akio Hosono, Homi J. Kharas, and Johannes F. Linn, 189–219. Washington, D.C.: Brookings Institution Press.

Vodafone. 2017. 'M-Pesa.' 2017. As of 16 December 2018: https://www.vodafone.com/content/index/what/m-pesa.html

Wadmann, Sarah, and Klaus Hoeyer. 2018. 'Dangers of the Digital Fit: Rethinking Seamlessness and Social Sustainability in Data-Intensive Healthcare.' *Big Data & Society* 5 (1): 2053951717752964. As of 16 December 2018: https://doi.org/10.1177/2053951717752964

Walton, Lord. 1990. 'Embryo Research: Why the Cardinal Is Wrong.' *Journal of Medical Ethics* 16 (4): 185–86.

Welch, Eric W., Federica Fusi, Selim Louafi, and Michael Siciliano. 2017. 'Genetic Resource Policies in International Collaborative Research for Food and Agriculture: A Study of USAID-Funded Innovation Labs.' *Global Food Security* 15 (December): 33–42. As of 16 December 2018: https://doi.org/10.1016/j.gfs.2017.04.004

Wilson, James M. 2009. 'Lessons Learned from the Gene Therapy Trial for Ornithine Transcarbamylase Deficiency.' *Molecular Genetics and Metabolism* 96 (4): 151–57. As of 16 December 2018: https://doi.org/10.1016/j.ymgme.2008.12.016

Winston, Robert M. L. 2018. 'The 40th Anniversary of Human IVF: Time to Celebrate and Time to Reflect.' *Reproduction* 156 (1): E1–3.

Wivel, Nelson. 2014. 'Historical Perspectives Pertaining to the NIH Recombinant DNA Advisory Committee.' *Human Gene Therapy* 25 (January): 19–24.

Wolf, Susan M., Rishi Gupta, and Peter Kohlhepp. 2009. 'Gene Therapy Oversight: Lessons for Nanobiotechnology.' *Journal of Law, Medicine, and Ethics* 37 (4): 659–84.

World Bank. n.d. 'Overview.' Text/HTML. World Bank. As of 16 December 2018: http://www.worldbank.org/en/topic/financialinclusion/overview.

Young, Tom, and Amélie Labbé. 2017. 'The Shock of the New.' *International Financial Law Review*, 23.

Zetzsche, Dirk A., Ross P. Buckley, Douglas W. Arner, and Janos Nathan Barberis. 2017. 'Regulating a Revolution: From Regulatory Sandboxes to Smart Regulation.' *Fordham Journal of Corporate & Financial Law*.

Annex A. Methodological approach

In this annex, we provide a detailed description of the methodological approach adopted in this study, highlighting the key steps involved in the analysis along with the associated caveats.

A.1. Description of methods

The evidence was gathered using a mixed-methods approach that was specifically designed to meet the primary objectives of this study, which were to analyse existing knowledge and understanding on the current and historical landscape of emerging science and technology oversight, and to try and understand what can be learnt from different examples of oversight. In summary, our approach involved the development of a series of ten concrete examples of emerging science and technology oversight ('case vignettes') by bringing together desk research and, where possible, insights from key stakeholders in the field. Specifically, after an expert-driven shortlisting of a selected number of case vignettes, evidence obtained via a tailored rapid evidence assessment of existing literature and insights from a series of key informant interviews were assimilated in a workshop to cross-analyse the evidence.

The methodology we adopted enabled us to: (a) efficiently and effectively identify relevant past and present examples of the oversight of emerging science and technology; (b) ensure that these examples cut across different contexts and science/technology areas, sectors, countries, and characteristics of oversight; and (c) carry out an effective comparative analysis of the different examples so as to articulate common themes including drawing out 'lessons learnt'. The study was executed using seven primary tasks distributed across three phases, as illustrated in Figure 3 below. In the following sections, we provide details on the methods and approaches for each research phase and corresponding tasks.

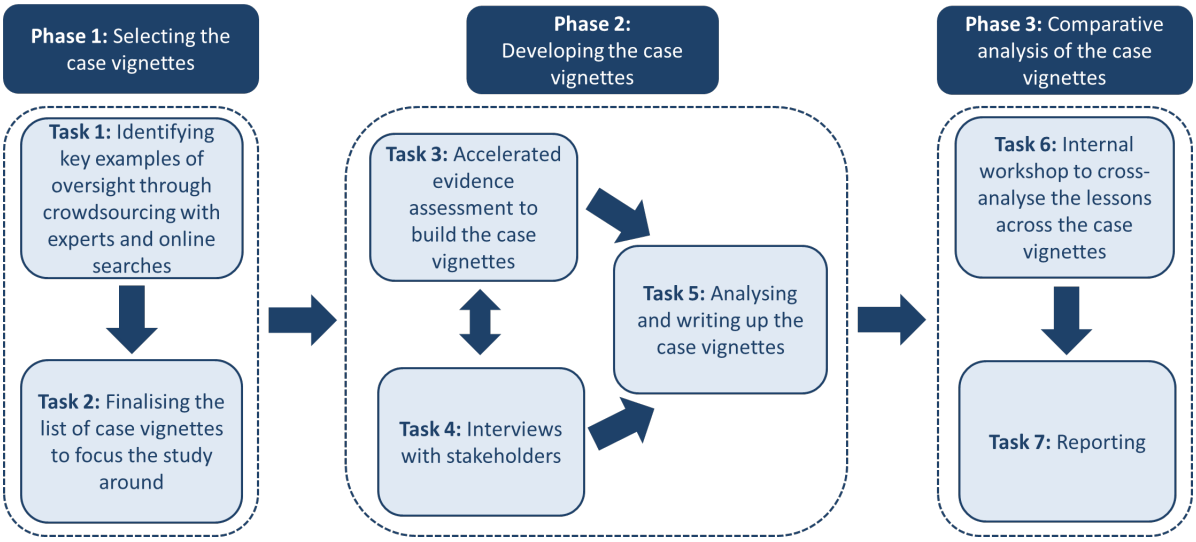
A.1.1. Phase 1: Selecting the case vignettes

In the first phase, we identified a collection of case vignettes of emerging science and technology oversight, around which the rest of the study was focused. The vignettes were selected through a process of crowdsourcing of examples from experts and online searches (Task 1), followed by shortlisting (Task 2). The aim was to arrive at a list of examples that spanned oversight types, science/technology areas, sectors, countries and time periods.

Task 1: Identifying key examples of oversight through crowdsourcing with experts and online searches

We used crowdsourcing with experts and online searches to develop a list of possible case vignettes. For the crowdsourcing exercise, we developed a data collection template

Figure 3: Study phases and associated methodologies used to carry out the research



covering the key elements we would want to use to select the case vignettes: country/ies of notable oversight; impacted sector(s); type of oversight; comments on why the example is interesting; literature/articles for further information; other sources of information and other comments (see Table 1). The template was developed on a Google Sheet that was openly available to anyone who had the weblink to it.

Table 1: Template for the crowdsourcing exercise

Name or short description of example	Country/ies of notable oversight	Impacted sector(s)	Time period (i.e. the time period the oversight was carried out when the science/technology was emerging)	Type of oversight (e.g. regulatory method, governance, standards, etc.)	Comments on why the example is interesting (e.g. brief details about the example, the level of success, etc.)	Literature/articles for further information	Other sources of information on this example (e.g. experts to contact, organisations of interest)	Other comments

We compiled a list of 80 individuals with a broad range of expertise and from a range of countries, and emailed them all an invitation to participate in the crowdsourcing. In the email we encouraged individuals to share the link with colleagues. We sent one reminder to all experts (unless they had already input into the spreadsheet and informed us that they had done this). The crowdsourcing exercise ran for two weeks.

In total we received 55 inputs to the crowdsourcing document.[87] Some experts also emailed us inputs that were added to the final overall list of examples.

Alongside the crowdsourcing exercise we ran a series of online searches to identify examples of interest (see Table 2 for a list of example search terms we used in the searches) alongside additional targeted searches covering topics such as history of science and technology, regulation, and governance. Searches were run in Google and Google Scholar.

Following both exercises we had a list of 81 different examples of oversight.[88]

Table 2: Example search strings used to identify examples of oversight

(*Governance* OR *regulat** OR *oversight*) AND (*science* OR *technolog**) AND (*emerging*)
(*Governance* OR *regulat** OR *oversight*) AND (*health* OR *financ** OR *telecom** OR *energy* OR *environment** OR *education** OR *transport* OR {*other sectors*}) AND (*emerging technolog**)

Task 2: Finalising the list of case vignettes to focus the study around

To select the examples to use as case vignettes, two of the study team worked though the list to establish a longlist of examples that covered the range of dimensions mentioned in Task 1: i.e. science/technology area, country, sector, timescale, method and characteristics of oversight, and level of success of oversight. For each example we also considered whether there appeared to be enough information to develop a case vignette. The final list of ten case vignettes to focus the study around was chosen from this list collaboratively by the RAND Europe team and Wellcome.[89]

A.1.2. Phase 2: Developing the case vignettes

For each selected example, we produced a case vignette. Information for the case vignettes was gathered through desk research (Task 3), and interviews with stakeholders connected to the vignettes (Task 4) and were then written up according to a set template (Task 5).

Task 3: Accelerated evidence assessment to build the case vignettes

For each case vignette we conducted an accelerated evidence assessment of the academic and grey literature. Accelerated evidence assessments aim to be rigorous, transparent and explicit in method, but take into account the time available for the study. For each case vignette we carried out searches

87 The final data within the online sheet can be seen at the following link: https://docs.google.com/spreadsheets/d/1v99JW8Jn89idk_sA09MiCcrJduevN__nfaXXIi4-LFs/edit#gid=0 (as of 13 December 2018). The first three examples in the sheet were provided within the templates as illustrations of the type of information we were interested in.

88 While the examples were all different, some examples covered different aspects of similar topics (for example, a number of the examples related to different aspects of the oversight of genetically modified organisms),

89 The final selection of case vignettes was carried out subjectively to provide a set that covered, to the extent possible, a balanced representation across the dimensions of interest (i.e. science/technology area, country, sector, timescale, and type of oversight).

in Google Scholar, replacing the word [subject] with the topic of the case vignette (see Table 3 for example search terms). For example, for the case vignette on M-Pesa in Kenya, we used the term 'Kenya mobile finance', so '[subject] AND oversight' was searched as 'Kenya mobile finance AND oversight'.

Table 3: Example search terms for each case vignette

[subject] AND oversight
[subject] AND (oversight OR regulation)
[subject] AND regulat*
[subject] AND policy
[subject] AND public engagement
[subject] AND oversight AND lessons
[subject] AND oversight AND (issues OR problems)
[subject] AND exclusion
[subject] AND risks

We also enhanced our final database of articles to review, with examples of literature suggested by our interviewees (in Task 4), and through snowballing[90] and additional targeted searches on topics of particular interest where more information was needed.

Task 4: Interviews with stakeholders

We carried out a series of interviews with stakeholders (spanning academics, industry, government and policymakers) connected to the case vignettes to get deeper insights into the specific examples, focussing in particular on areas where less literature was available. The interviews were semi-structured, thereby ensuring a similar set of questions were asked of all interviewees but allowing for emergent issues to be explored, and aiding the comparative analysis across the vignettes undertaken in Phase 3. The template for the case vignettes (see Task 5 and Table 4) was used as the interview protocol. Interviews were conducted by telephone and lasted up to one hour. In total we carried out ten interviews across the case vignettes. Interviewees are cited throughout using the identifier 'INTXX' where XX is a number between 01 and 10. For confidentiality reasons we have not included a list of respondents.

Task 5: Analysing and writing up the case vignettes

The information collected in Tasks 3 and 4 was integrated to develop complete case vignettes for each example. Each vignette was written up in a set template, which was agreed with Wellcome in advance of starting Phase 2. The template was tweaked once the data was collected to ensure all case vignettes could be written up in a comparable way. The final template is shown in Table 4.

90 Snowballing refers to the process of identifying additional articles from the reference lists of the originally identified articles.

Table 4: Reporting template for the case vignettes

Case vignette title
Background and context
• This section will include a brief description of the emerging science or technology area in the context of this vignette (i.e. in this country, sector and time period). • Where information is available, this section could also include reference to the stage of development the emerging science or technology area was at when oversight was introduced. • This section will also provide an indication of the time period during which the oversight was carried out when the science/technology was emerging.
Why was oversight required?
• What were the issues with the emerging science or technology area in the context of this vignette (i.e. insights into any country, cultural, sector and time period influences)? • This section could also capture the benefits and risks of the science or technology that meant oversight was required at the time in the given context.
How was oversight carried out?
• What 'method' or 'approach' of oversight was used (e.g. legislative act, treaty, regulation, governance, standards, agreement, guiding principles, co-operation, collaboration, public engagement, etc.)? • How specifically was the oversight implemented? • Which bodies and stakeholders were involved in the oversight? • This section could also include information about the timeline/process involved in its development.
How effective was the oversight?
• What effect did the oversight have on (for example): (a) businesses, industry and wider innovation; and (b) the public (e.g. in relation to health and safety)? • What effect did the oversight have on the country/countries?
What 'lessons' can be learnt from this example?
• Why was the oversight effective or not effective? • What worked and/or did not work, and what were the reasons for this (e.g. challenges in implementation; stakeholder buy-in)? • Which elements of the oversight are particularly contextual, and which can be compared?

A.1.3. Phase 3: Comparative analysis of the case vignettes

In the final phase of the project, we synthesised and analysed the information across all the case vignettes to extract common themes and lessons learnt in relation to the oversight of emerging science and technology.

Task 6: Workshop to cross-analyse the lessons across the case vignettes

To enable a rounded understanding and rigorous assessment of the evidence collected as part of Phase 1 and 2, we held a workshop that was attended by the study team and representatives from Wellcome. At the workshop, we focused on the lessons learnt

from each case vignette, triangulating these across the case vignettes comparing them for different methods and characteristics of oversight. This allowed us to draw out common themes from cases where oversight has and has not worked well. The workshop also helped to provide additional comments for consideration and validate the evidence for robustness. Specifically, at the workshop we discussed each case vignette in turn. The member of the study team that had taken the lead developing the case vignette gave a two-minute summary of the case vignette, covering the overall story and the key lessons that can be learnt from it. The group then had a discussion about the case vignette and captured the key lessons learnt on post-its. As we progressed through the vignettes, we started to group the post-its into similar themes. Finally we went through and characterised and labelled the different groups of post-its based on their contents. Following the workshop, we went back through the case vignettes to ensure we had captured the specific lessons and to refine the overall lessons.

Task 7: Reporting

The evidence from all the tasks was assimilated and written up as a final report including the ten case vignettes and the lessons learnt across the vignettes. For each of the lessons learnt we provide a description of the lesson and examples from the case vignettes that illustrate the lesson.

A.2. Limitations of the analysis

There are some caveats that should be taken into account when interpreting the analyses presented in this report. First, the analysis with regard to each case vignette is not a rigorous evaluation of the impact of the example. Instead, we present a snapshot view in which we have used the qualitative information gathered from an accelerated evidence assessment of ten diverse examples to extract broader themes associated with emerging science and technology oversight. Second, the case vignette descriptions are relatively short: they are not meant to be exhaustive, they do not cover all possible literature, and do not necessarily capture all details and nuances of the examples. On the basis of an accelerated evidence assessment, we have attempted to provide the essential background and context for each example and focus the analytical component of the research on examining the effectiveness of the examples, and then drawing out any lessons that can be learnt from the examples. Third, the common themes and lessons that we have outlined in Chapter 3 have been arrived at on the basis of the analysis across the ten case vignettes. The case vignettes were selected following a crowdsourcing exercise, as well as some online searches, and therefore the longlist of examples is, in part, shaped by the individuals who participated. As such, there may be more lessons that could be learnt from other examples of oversight of emerging science and technology in different contexts. And equally, there may be examples that run counter to our lessons if we were able to look more widely. Additionally, while we have considered the vignettes in their historical context, the lessons are drawn with the benefit of hindsight. Notwithstanding this, the ten vignettes that we have covered in our analysis provide a diverse illustration of the varied and innovative ways in which science and technology oversight has been carried out in different countries, sectors and time periods. Looking across the vignettes, we have examined both what has worked well and not so well with regards to oversight, and have articulated a set of common learning – or principles – for discussion and debate that are wide-ranging enough to be usefully considered in other contexts of science and technology oversight.