

## Executive summary

1. In this report we consider the ethical, legal and social issues that arise from the use of novel neurotechnologies. We address these issues primarily in the context of the therapeutic applications of these technologies, because it is here that there is the greatest potential for social benefit and where research and practical uses are most advanced.
2. Illness or injury that results in damage to the brain and its functions can lead to serious disorders that affect memory, cognition, movement, or consciousness or cause conditions such as chronic pain. The brain has a limited capacity to repair damaged tissue, although new functional connections may be formed. The novel neurotechnologies discussed in this report all have the potential – which is in some cases yet to be fully demonstrated – to address some of the distressing and disabling effects of brain damage by intervening in the functions of the brain itself.
3. The ethical dimensions of the development and uses of these technologies, however, extend beyond the contexts of clinical research and patient care. We also consider the economic pressures and regulatory controls that shape and challenge the development pathways and commercial availability of novel neurotechnologies, and the social impacts of their representation by researchers and the non-specialist media. We also give consideration to the potential non-therapeutic applications of these technologies.

### Chapter 1: Introduction

4. The neurotechnologies addressed in this report are those used in transcranial brain stimulation (TBS), deep brain stimulation (DBS), brain-computer interfaces (BCIs) and neural stem cell therapies. These are not exhaustive of every neurotechnology in use or under investigation today. We limit our discussion to those that intervene in the brain itself and that, because of their relative novelty, have not yet been subject to extensive bioethical commentary.
5. Our discussion begins by setting these ‘novel neurotechnologies’ in their historical context. Although those we discuss in this report are new, attempts to repair or alter brain function through surgery or electrical stimulation have a long, and sometimes troubled, history. During the twentieth century these methods were largely supplanted by use of pharmacological interventions. However, as these interventions have not always been as successful as had been hoped, attention is increasingly turning to new developments in neurostimulation techniques, and now also to stem cell therapies, for those conditions that remain intractable to other methods of treatment.

### Chapter 2: Intervening in the brain: current understanding and practice

6. Our report focuses upon the following four categories of novel neurotechnologies. None of these technologies provides a cure for neurological or mental health disorders, but they could ameliorate symptoms, or fulfil assistive roles in ways that help improve patients’ quality of life.
  - **Transcranial brain stimulation** refers to a group of non-invasive neurotechnologies, which stimulate the brain either by inducing an electrical field using a magnetic coil placed against the head (transcranial magnetic stimulation (TMS)), or by applying weak electrical currents via electrodes on the scalp (transcranial direct current stimulation (TDCS) and transcranial alternating current stimulation (TACS)). These technologies have been used as research tools, but their therapeutic applications are increasingly being explored, the most established application is in treating drug-resistant depression. The exact mechanisms by which TBS achieves its therapeutic effects are still being researched.

- **Deep brain stimulation** also alters the functioning of brain cells and neural networks by using electrical currents, but in this case the stimulation is delivered by electrodes implanted deep in the brain. Therapeutic uses of DBS include the treatment of movement disorders, such as those associated with Parkinson's disease, and of neuropathic pain. There is also considerable research activity exploring its use to treat a wide range of psychiatric disorders. The exact mechanisms by which DBS achieves its therapeutic effects are unknown.
  - **Brain-computer interfaces (BCIs)** use electrodes (either implanted in the brain, or resting on the scalp) to record users' brain signals which are then translated into commands to operate computer-controlled devices. By actively producing brain signals, users can control these devices. BCIs could in principle assist users to communicate, control prostheses or wheelchairs, support rehabilitation, or facilitate detection of consciousness – making these technologies potentially useful to those with paralysis. Therapeutic uses of BCIs are still confined to research contexts, in which non-invasive techniques are most prevalent.
  - **Neural stem cell therapy** involves the injection of stem cells into the brain in order to repair damage caused by acute events such as stroke or neurodegenerative conditions such as Alzheimer's disease. Although this technique could have substantial therapeutic potential, neural stem cell therapies are still at an early phase of development; the first clinical trials in humans in the UK are now being undertaken. The precise ways in which stem cell grafts may assist in repairing lost brain tissue are not known, but these could include direct replacement of lost cells or stimulating repair by the brain itself.
7. In discussing the ethical and social implications of these technologies, their potential therapeutic benefits must be considered alongside any unintended harms associated with their use. Non-invasive neurotechnologies pose the fewest risks to patients. Invasive neurotechnologies requiring neurosurgery (such as DBS or neural stem cell therapies), pose greater risks, including infection and bleeding associated with surgery itself, and potential unintended physiological and functional changes in the brain resulting from the implanted electrodes or stem cells. DBS can also be associated with complex unintended effects on mood, cognition and behaviour.

## Chapter 3: Economic drivers of innovation

8. There are few effective treatments for many serious neurological and mental health disorders and therefore a significant degree of unmet need. Moreover, the high global incidence of these disorders generates considerable costs to national economies, not only through direct health care costs but also in lost productivity. The novel neurotechnologies we consider in this report offer potential routes to meeting these needs, but pathways to innovative and effective treatments must negotiate ethical and economic challenges.
9. Economic factors present both opportunities and constraints that shape the innovation pathways of novel neurotechnologies. This is especially so because even where initial research is publically funded, development of research into clinical products will often depend on commercial organisations with obligations to generate profits and shareholder value. For a number of reasons, therefore, it cannot be assumed that this putative area of economic opportunity will translate directly into the provision of therapeutic products where need is most pressing.
10. Private companies and investors are likely to focus on technologies that offer the greatest potential for financial return on investment, thus favouring those that target large or valuable markets. This threatens to divert investment away from potentially less profitable 'low tech' approaches to care, or treatments to address rarer neurological conditions. It may also leave the needs of those in less affluent parts of the world ill-served. Further challenges to equitable access arise from the fact that, even if the early production costs of the neurotechnologies fall, the wider costs of specialist care associated with their use will remain high in many cases. This raises the further risk that patients might travel to access more affordable treatment in countries with potentially less well-regulated systems of protection.

11. Large pharmaceutical companies might seem to be potential sources of investment in the field of novel neurotechnologies, when the limits of public funding are reached. However, their recent withdrawal from psychopharmaceutical research suggests that they have been discouraged by the complexity and costs of developing effective neurological interventions. The long, complex and costly development and regulatory pathways (associated with innovation in stem cell based technologies in particular) can be seen as economically too risky by private investors, such as venture capitalists, who look for swift returns on their investment. The development pathways of many novel neurotechnologies are, therefore, vulnerable to the ‘valley of death’ – where (often small) businesses fail due to a lack of funding to support them through the lengthy process of translating research into commercially viable products.
12. These kinds of challenges in obtaining funding can impose particular pressures on developers to pursue practices that secure greater market share and swifter returns on investment, but (in the field of medical devices in particular) they might also shape innovation pathways and practices in ways that do not best meet patients’ needs for access to safe and effective therapies. These practices might include: exploiting regulatory routes that do not require manufacturers to conduct clinical investigations prior to placing their device on the market; developing therapeutically superfluous consumable elements of otherwise reusable devices; engaging in patent disputes to impede competitors; or offering incentives to clinicians to trial particular products, thus introducing potential conflicts of interest.
13. The economic drivers and constraints on the development of novel neurotechnologies highlight the ethical importance of proportionate regulatory oversight that encourages innovation, but which helps direct responsible research, development and investment towards the production of safe and effective products that meet genuine patient needs. However, effective regulation alone is unlikely to be sufficient to secure equitable access to affordable therapies; incentives for innovative and responsible research, and funding mechanisms to support lengthy development trajectories, will also be needed.

## Chapter 4: Ethical Framework

14. The brain has a special status in human life that distinguishes it from other organs. Its healthy functioning plays a central role in the operation of our bodies, our capacities for autonomous agency, our conceptions of ourselves and our relationships with others – and thus in our abilities to lead fulfilling lives. This means that the novel neurotechnologies we consider in this report, each of which intervenes in the brain, raise ethical and social concerns that are not raised to the same extent by other novel biomedical technologies.
15. The ethical framework we construct to navigate these concerns is built up in three stages:
  - **Foundational principles:** A tension between need and uncertainty lies at the foundation of our framework. On one hand given the suffering caused by brain disorders and an absence of other effective interventions, there is a need for therapeutic applications of neurotechnologies. On the other hand there is uncertainty about benefits and risks of these technologies, due not only to their novelty but also to the lack of comprehensive understanding of how the brain works. The special status of the brain therefore provides both a reason to exercise **beneficence** by intervening when injury or illness causes brain disorders, and a reason for **caution** when we are uncertain what the effects of doing so will be.
  - **Interests:** In articulating the implications of the principles of beneficence and caution in the context of developing and using novel neurotechnologies, we identify a cluster of five interests that warrant particular attention. These encompass not only protection against the potential **safety** risks of interventions, but also those interests associated with unintended impacts on **privacy** and the promotion of **autonomy** both in treatment-specific decisions and in the wider context of patients’ lives. There are also important public interests in **equity** of

access to the products of innovation, the preventing of stigma and protecting and promoting public understanding and **trust** in novel neurotechnologies.

- **Virtues:** Finally we suggest that, in seeking to protect and promote these interests, there are three virtues which are especially relevant to guiding the practices of actors across a wide range of settings and applications of novel neurotechnologies. These virtues are: **inventiveness**, which may be exercised through, amongst other means, technological innovation and by identifying ways to provide wider access to therapies; **humility**, which entails acknowledging the limits of current knowledge and of our capacities to use technologies to alleviate the harms of brain disorders; and **responsibility**, which is exemplified by pursuit of robust research practices and refraining from exaggerated or premature claims for these technologies.

16. These virtues are helpful because they characterise the kinds of attitudes and practices that should be exemplified by those engaged in the development, funding, use, regulation and promotion of novel neurotechnologies, and fostered and supported by the institutions within which they work. All three steps of this framework provide the tools we use to assess the practices and oversight mechanisms examined in subsequent chapters.

## Chapter 5: Patients and participants: governing the relationships

17. The care of patients and research participants who undergo interventions using novel neurotechnologies presents the most immediate context in which to apply our ethical framework. Care does not only amount to administering safe interventions; it also entails promoting patients' and participants' autonomy and protecting them from psychological and social harms, minimising unrealistic expectations and guarding against privacy infringements.
18. Uncertainty about the long-term and unintended effects of intervening in the brain using novel neurotechnologies, a lack of alternative treatments for some neurological disorders, and the fact that many neurotechnologies address conditions that impair patients' decision-making capacities, all present challenges to responsible endeavours to support decision-making and informed consent by patients and participants and those close to them. Professional humility is particularly relevant here. Experimental therapies should not be characterised as offering a patient's 'last best hope' unless this is justified. We recommend that independent counselling, which acknowledges uncertainty, should be an essential part of treatment referral pathways (paragraph 5.9).
19. The lack of clear evidence of risks and benefits of some interventional techniques also presents challenges to responsible clinical decision-making. The National Institute for Health and Care Excellence's (NICE) Interventional Procedures Guidance (IPG) provides valuable advice to healthcare providers on clinical decision-making and oversight by drawing together the best available evidence. We recommend that compliance with NICE IPG should be mandatory (paragraph 5.24).
20. The NICE guidance and the other oversight mechanisms operating in the NHS will not, however, extend to protecting the interests of patients who use private treatment services. There is a need for professional guidelines that require patients to undergo medical evaluation by a doctor before accessing neurostimulation treatment (paragraph 5.31).
21. Data concerning brain function and neurological health collected by devices such as those delivering DBS or BCIs may be sensitive and stigmatising. We suggest that this, combined with the health risks posed by malfunctions in neurodevices, provides grounds for the Medicines and Healthcare products Regulatory Agency (MHRA) to monitor the vulnerability of neurodevices to interference or data interception (paragraph 5.54).
22. Two important issues arise when considering the responsible protection of research participants' interests. The first is the prospect of sham neurosurgery being used as a placebo control in clinical

trials of neural stem cell therapies. We recommend that research ethics guidance should be provided on this (paragraph 5.41). The second relates to the potentially serious impacts on participants from whom beneficial therapeutic or assistive neurodevices may be withdrawn at the end of a study. Where this is likely to be the case we recommend that submissions to research ethics committees must detail the information and support that will be provided to participants as part of consent procedures and at the conclusion of the study (paragraph 5.45).

23. It is not always possible to draw a neat line distinguishing therapy from research in a field where many novel applications of new technologies take place in the context of experimental treatments. Experimentation may be a necessary and valuable means of exercising inventiveness in this field, but it raises two concerns. First, there is a lack of clarity about whether interventions falling into this grey area should be governed as treatment or research. We recommend that this should be addressed by the provision of professional guidance on responsible conduct in experimental treatment (paragraph 5.60). Second, clinical experience gathered outside formal research studies may not be widely disseminated, thus perpetuating uncertainty. We suggest that publically accessible registers would provide a responsible approach to countering this risk (paragraph 5.63).

## Chapter 6: Responsible research and innovation

24. The concept of ‘responsible research and innovation’ (RRI) has been adopted by policy-makers as a way of thinking more systematically about the public benefits of science and technology-based research. The precise definitions and constituent elements of RRI remain matters of debate and can appear abstract, so here we suggest six priorities that apply specifically to RRI in the context of novel neurotechnologies.

- **Clearly identified need:** It is important to justify innovation in terms of its public benefits. In the case of neurotechnologies this means meeting therapeutic need. This highlights the need to resist the technological imperative and the pursuit of novelty for its own sake. It also challenges the value of proliferating products that are indistinguishable in terms of the benefits they bring to patients.
- **Securing safety and efficacy:** Protecting safety is central the pursuit of RRI and to regulatory regimes governing medical technologies. Where the clinical uses of novel neurotechnologies are concerned, their risks can only adequately be assessed relative to their efficacy in delivering therapeutic benefits and the (possibly limited) availability of alternative treatments. This highlights the importance of assessing efficacy as part of the innovation pathway of a product – yet this is not a regulatory requirement for medical devices (such as those used in TBS and DBS) marketed in Europe.
- **Generating robust evidence:** There are both regulatory and methodological reasons why the development of medical devices in particular might not produce the most transparent, robust or balanced body of evidence. These include un-generalisable and dispersed data from small-scale studies, the influence of commercial interests, and methods that encourage the publication of positive, but not disappointing, findings. Alternative methods of linking and disseminating evidence are likely to be needed to address this.
- **Continuous reflexive evaluation:** The development of novel neurotechnologies is unlikely to follow simple linear innovation trajectories. Reflecting upon the directions in which research is (potentially) travelling, and responding to this, can help to guard innovation against lock-in to pathways that do not serve public benefit. It is also an important part of maintaining vigilance for implications of possible unintended dual-use or ‘off-label’ applications of neurotechnologies.
- **Coordinated interdisciplinary action:** Innovation in novel neurodevices, perhaps most markedly BCIs, is often multidisciplinary. Coordination between different disciplines is needed

to protect against potential risks posed by gaps in the collective understanding and oversight of a technology's risks and capabilities. Interdisciplinary collaboration also offers opportunities by introducing diverse visions of potentially fruitful development trajectories.

- **Effective and proportionate oversight:** The tension between need and uncertainty that lies at the foundation of our ethical framework presents a particular challenge to effective regulation and governance of novel neurotechnologies. Responsibility and humility require caution whilst also recognising that failing to pursue interventions also carries risks of extending suffering in the absence of effective treatment. This demands a proportionate approach to supporting innovation while protecting safety; hard-law regulation will not always be the most suitable means of achieving this.

25. This articulation of RRI provides a tool, complementing our ethical framework, which we go on to use to assess the strengths and weaknesses of the regulatory frameworks that govern the commercial availability of novel neurotechnologies. The concept of RRI also acts as an extension of our virtue-guided approach by highlighting the ways in which inventiveness, humility and responsibility should inform the practices and values of those engaged in supporting and pursuing innovation.

## Chapter 7: Regulating the technologies

26. The regulatory frameworks that apply to medical devices and to advanced therapeutic medicinal products (ATMPs), such as neural stem cell therapies, govern the entry of the technologies onto the European market, including the clinical investigations preceding this.
27. Using our ethical framework and the elements of responsible research and innovation developed in the preceding chapters we assess whether current regulatory provisions are effective and proportionate given the requirement to protect patients' safety, while also enhancing access to safe and effective therapies. The regimes applying to medical devices and ATMPs share a historical objective of securing a harmonised European market and each is concerned both with supporting innovation while protecting patient safety. However, the regulatory obligations upon manufacturers differ significantly between these two sectors in a number of respects. Concerns regarding effective oversight of medical devices apply especially urgently to invasive neurodevices, as these pose greater risks to patients' safety.
28. Pre-market oversight of medical devices in Europe is decentralised and relatively light-touch (especially for non-invasive devices) in terms of the evidence manufacturers must supply to demonstrate that their products conform to statutory safety and performance requirements. While this may support innovation by limiting regulatory burden, we nevertheless welcome European proposals to narrow the circumstances in which manufacturers can rely on evidence concerning similar devices (rather than conducting new clinical investigations) to demonstrate conformity. We recommend that, since neurodevices intervene in the brain, the case for relying on pre-existing evidence must be particularly sound (paragraph 7.33 and 7.47). We also recommend greater transparency about the basis of all decisions about the conformity of devices with regulatory requirements (paragraph 7.27).
29. Since pre-market scrutiny of neurodevices is light-touch, it is all the more important that post-market surveillance mechanisms are robust. We recommend that these should be strengthened by making it mandatory for clinicians to report adverse events – supported by a scheme to alert them to newly approved devices – and by making all information on adverse incidents and incident trends publically accessible (paragraph 7.55).
30. Uncertainty about the benefits, risks and mechanisms by which some novel neurotechnologies achieve their effects presents one of the central ethical challenges in this field; yet the regulation of medical devices does not itself encourage collection of extensive clinical evidence. In addition to recommending enhanced transparency in the regulatory system (paragraph 7.28), we suggest that collaborative efforts to improve information governance and data linkage by manufacturers,

practitioners and others are needed. Improved evidence on the efficacy (or otherwise) of neurodevices is a particular priority as the regulatory system itself does not currently address this.

31. In contrast to medical devices, the steps required under the multiple regulatory frameworks applying to the licensing of ATMPs as commercial products are many, potentially lengthy and include centralised European authorisation. This complexity and the potentially overlapping roles of the various regulatory bodies involved is a source of concern, particularly given the economic risks that delays pose to companies developing products. Neural stem cell therapies, however, could present significant health risks if they do not perform as expected, so robust regulation is vital. We suggest that a responsible and proportionate approach to oversight should allow an evolution from a mode of protection to one of promotion as the science progresses (paragraph 7.72). We welcome recent developments in the governance of stem cell therapies that aim to streamline and speed up the regulatory and ethical oversight processes involved whilst maintaining rigorous standards for protecting patient safety.
32. There are various routes by which patients with particular needs can access medical devices and ATMPs that are not approved for wider market availability. These are welcome insofar as they may address otherwise unmet needs. However, given the intrinsic vulnerability of patients undergoing more experimental interventions, we raise concerns about the scope of regulatory and ethical oversight of therapies delivered via these routes. Some, such as ‘off-label’, ‘in-house’ and investigative uses of medical devices which are not aimed at commercial applications, may fall outside the regulator’s remit altogether. Even where the supply of some technologies for exceptional or non-routine use is regulated by the MHRA, we suggest that there need to be more thorough mechanisms for collecting and making publically accessible information on approval for these uses and their outcomes (paragraph 7.89).

## Chapter 8: Non-therapeutic applications

33. We discuss three areas in which novel neurotechnologies might be used for non-therapeutic purposes: neural enhancement, gaming and military uses.
  - **Enhancement:** A number of small studies using non-invasive neurostimulation report improvements in participants’ performance in laboratory tasks, for example involving memory or language skills, or in their mood that could be construed as ‘enhancements’. However, there is need for great care in extrapolating from small studies conducted under laboratory conditions to lasting real-world effects; the potential use of neurostimulation for neural enhancement is still far from proven.
  - **Gaming:** There are already games on the market claiming to use non-invasive electroencephalography (EEG) based BCI technology, although whether they all actually utilise brain signals is questionable. Nevertheless, there is considerable research activity to develop commercially viable games that are genuinely BCI-controlled. These recreational neurotechnologies overlap with EEG-based neurofeedback ‘games’ that are already being marketed for use as treatments for attention deficit / hyperactivity disorder or that purport to improve capacities such as concentration.
34. Uses of non-invasive neurostimulation or BCIs either for putative ‘enhancement’ purposes or gaming are unlikely to pose serious health risks. Nevertheless, the large number of people targeted by these applications and the lack of any clear associated health benefits mean that it is important to attend to several ethical concerns. In particular, to minimise the pursuit of unnecessary brain interventions, there is a need to ensure the originality and rigour of research investigating non-therapeutic uses in humans (paragraph 8.39) and also to disseminate existing evidence through publically accessible registers (paragraph 8.41).
35. Non-therapeutic applications of neurodevices (such as BCI games and those that purport to offer enhancements) are likely to be used privately and without medical supervision. This places

greater onus on the effective regulation of the devices themselves. We recommend that the European Commission considers designating neurostimulation devices as products that should be regulated under the medical devices regime irrespective of the purpose for which they are marketed (paragraph 8.52).

36. Those marketing neurodevices and services with unsubstantiated or misleading claims about their putative benefits may be exploiting consumers and undermining wider public trust in neurotechnologies. We recommend that there is a need for responsible self-governance by businesses operating in this sector, establishing best practice standards both for the provision of honest and accurate information and for delivering services using neurodevices within parameters of safe use (paragraph 8.59).
37. Given the lack of evidence of the efficacy of these neurotechnologies for enhancement, we do not examine in detail the ethics of human enhancement *per se*. However, two concerns familiar from wider bioethical debates about human enhancement may arise. The first is that pursuit of non-therapeutic innovation might represent an opportunity cost at the expense of investigating applications of greater social value. The second is that, provided some believe that enhancements using neurodevices are realisable, pressure might be exerted on individuals to use these. This latter is a particular concern in children, in whom the effects of neurostimulation or BCIs on the developing brain are not well understood. We recommend that observational research with children who are already using neurotechnologies is needed to address this (paragraph 8.40) and also that advice is issued to teachers and parents about the current evidence of the efficacy of neurofeedback as an educational enhancement tool (paragraph 8.62).
  - **Military:** Novel neurotechnologies have potentially valuable applications in treating physical and psychiatric injuries caused by combat. However, in this chapter our concern is with their non-therapeutic uses, and there are indications from the US that there is considerable investment in non-therapeutic military applications. These include the use of brain-computer interfaces (BCIs) in enhancing fighters' effectiveness by augmenting their perceptual or cognitive capacities, or by permitting neural control of remote weaponry. It is also plausible that BCIs or neurostimulation could be used for interrogation purposes. The existing international conventions outlawing the use of biological and chemical agents in war do not cover the use of neurodevices.
38. We recommend that advice is issued to armed forces highlighting that the use of neurodevices in interrogation would be coercive and illegal under the Geneva Conventions (paragraph 8.84). Military applications of novel neurotechnologies raise particular challenges for research ethics. We suggest that military clinicians can play an important role in protecting the wellbeing of personnel within their own forces who may be subject to professional coercion to participate in experimental uses of neurotechnologies (paragraph 8.87). We further recommend that the education of neuroscientists should include ethical training that draws attention to the dual-use applications of neurotechnologies for military as well as civilian ends (paragraph 8.89).

## Chapter 9: Communication of research and the media

39. The novel neurotechnologies discussed in this report attract considerable media attention. We consider issues raised by the reporting and representation of scientific research in the popular and non-specialist media. In particular we look at the representation of novel neurotechnologies and the possible impacts of these representations.
40. The ways in which science and technology are reported and framed in the media may help to shape public understanding and expectations and to influence social norms and the policy and investment landscapes. However, it should not be assumed that media representation determines public attitudes in straightforward or predictable ways.
41. Some of the ways in which science is reported in the media can be attributed to the pressures upon journalists in an increasingly competitive and accelerated media environment. The demands

of this environment can, for example, lead to uncritical reproduction of press releases. Scientists themselves are increasingly engaged in the public communication of science. However, the political and economic pressures on academic researchers to demonstrate the practical and economic impacts of their work can encourage practices that lead to misleading reporting of research evidence through premature emphasis upon commercial applications, or publication bias towards positive or newsworthy findings. These combined factors can contribute to a cumulative spiral of hype.

42. Some of the hallmarks of poor science reporting practices in general are evident in communication about novel neurotechnologies. These include: headlines that misrepresent research, stories that emphasise the benefits of interventions without mentioning risks or longer-term uncertainties, speculation and extrapolation beyond the evidence and lack of contextual balance in the use of compelling images or personal stories.
43. Social media might be assumed to provide a more direct connection between scientific researchers and the public and an outlet for personal stories. Indications are, however, that content about novel neurotechnologies on social media platforms is significantly populated by commercial and academic organisations promoting therapeutic services and innovations.
44. Using the media to promote research into novel neurotechnologies may encourage investment and foster inventiveness, but hype can also be harmful. For example, it may offer false hope to patients and those close to them by failing to alert them to the limits or risks of current technological capabilities. This in turn may undermine their abilities to make informed, autonomous treatment choices. Wider risks include loss of public trust in these technologies and engendering misplaced conceptions that individuals are reducible to their brain functions. Communication practices, therefore, need to exhibit the virtues of humility and responsibility no less than clinical research and care practices do.
45. Responsible communication of the capabilities of novel neurotechnologies should not only include accurate, evidence-based reporting, but it should also take account of the possible personal and social impacts of the (mis)representations of the capabilities of these technologies. These impacts provide a particular ethical dimension of the ways in which novel neurotechnology research is framed by the media. We recommend that the behaviour of researchers, press officers and journalists involved in the communication of novel neurotechnologies should be informed by humility and responsibility, exercised through reflecting on how their representations of these technologies might contribute to cumulative hype. Points on which to reflect include: vigilance for institutional pressure to hype; the need to contextualise compelling, but potentially misleading, images; attention to use of language that might prematurely imply availability of effective treatments; and recognition that novel neurotechnologies may not be the preferred therapeutic route for every eligible patient (paragraph 9.72).
46. In addition to research institutions and journalists, we recommend that two further groups of actors should reflect on their role in practices that might drive hype: policy makers and higher education funding councils in framing the value of research in relation to the impact agenda (paragraph 9.73); and commercial enterprises in seeking to attract investment and promote their products (paragraph 9.74).

## Conclusions

47. This report draws together a number of diverse neurotechnologies that differ in several ethically relevant respects. They encompass both physically invasive and non-invasive technologies, devices and stem cell products; some alleviate symptoms or assist users, while others offer non-therapeutic applications; some are already in use, while others are still undergoing investigation. The development and uses of these neurotechnologies engages a wide variety of actors and oversight of their activities involves a complex and sometimes overlapping network of professional ethical norms, governance frameworks and statutory regulations.

48. Despite this diversity, one central feature remains: these technologies intervene in the human brain, the healthy functioning of which plays a central role in our capacities for leading fulfilling lives, for sustaining both our senses of ourselves and our personal relationships. We do not argue that the ethical issues raised by novel neurotechnologies that intervene in the brain are necessarily unique or exceptional. Nevertheless, the significance of the brain in human existence does give us both a powerful reason to intervene when illness or injury damages its functions, and a reason to pause before intervening without good evidence that it will be safe and beneficial to do so. This tension, and the consequent need to steer a proportionate path between providing access to treatments whilst exercising caution, provides the foundation for our ethical framework. It is a tension that is also echoed in the cross-cutting ethical themes that we identify in the concluding chapter of the report. In particular:

- We recognise that novel treatments will often have to be explored through experimental interventions. This creates particular obligations to safeguard those patients rendered vulnerable by incapacity or constrained choices, who are most likely to be candidates for more experimental therapies.
- This is a field marked by uncertainty and hype. Decisions taken by professionals and patients to use novel neurotechnologies must be based on the best available evidence of their benefits and risks. Achieving this demands responsible communication that is open about the limits of our current understanding of efficacy and risk, while maintaining trust in these technologies. It must also be underpinned by collaborative approaches to capitalise more effectively on existing evidence.
- In focusing upon therapies that intervene in the brain, we must not to lose sight of the fact that neurological disorders and methods of treating them affect the whole person and their personal relationships. In assessing the benefits and risks of these neurotechnologies we must therefore attend to the outcomes that patients themselves value and look also to the wider social and psychological impacts of their use.

49. Many of the neurotechnologies we have discussed are currently available only to those participating in research, or as expensive interventions offered when others have failed. Our hope is that, in time, safe and effective neurotechnologies will emerge, which will be cheaper, easier to use, and more widely available. The considerable unmet needs of patients with some of most serious and intractable neurological and mental health disorders, combined with the challenges of securing funding for the development of new therapies, provide ethical imperatives to support inventiveness in this field. However, uncertainties about the longer term and unintended impacts of intervening in the brain need to be acknowledged. The first priority for responsible oversight must be the protection of patients' safety and wellbeing. We believe that through proportionate regulation we can better promote innovation that delivers safe and effective technologies.