Chapter 4 - Ethical Framework

Introduction

4.1 The brain has a special status in human life which implies that interventions upon this organ provoke concerns not raised to the same extent by other novel biomedical technologies or interventions. Our development of an ethical framework for these interventions starts from a consideration of the reasons we have for valuing our brains and the related imperatives for intervening when the brain ceases to function as it should due to injury or illness. We observe that the combination of the imperative to alleviate the harms resulting from brain damage and the limits to our understanding of how this may be effectively achieved gives rise to a particular tension between need and uncertainty.

4.2 Need and uncertainty find their natural ethical counterparts in the principles of beneficence and caution. The requirement to strike a balance between these is at the heart of the ethical framework set out here. However, we recognise that beneficence and caution are only general signposts; therefore we develop our ethical framework through a set of interests that mediate between these principles. The interests that capture the chief considerations relevant to the novel neurotechnologies discussed here are safety, autonomy, privacy, equity, and trust. Each of these interests is of fundamental value and importance to each of us, and requires special attention in the context of novel neurotechnologies.

4.3 We recognise that a list of principles and interests does not suffice for an ethical framework that seeks to provide guidance in balancing the demands of need and uncertainty. In this shifting dynamic, conflicting interests will often require recourse to practical judgement. Therefore we
also establish the virtues that actors in this field – those who research, develop, administer, use, fund, market, govern, and communicate the capacities of novel neurotechnologies – should exemplify in their professional conduct. In some cases, these also apply to patients and research participants with whom the technologies are used. As a third step in our ethical framework, we suggest that the virtues of inventiveness, humility and responsibility are those most pertinent to guiding ethical practice in the development and therapeutic uses of novel neurotechnologies.

4.4 We have constructed this framework on the premise that the most pressing ethical challenges are raised by therapeutic applications of novel neurotechnologies. This does not mean that non-therapeutic applications (in this report we consider those for enhancement, recreational, and military purposes) fail to raise relevant ethical considerations. We discuss these applications separately in Chapter 8 for two reasons: either because, where neurotechnologies are used for military purposes, the ethical issues raised are markedly distinct; or because, even where the ethical framework described in this chapter may be applied in contexts of non-therapeutic uses for enhancement or recreational purposes, the circumstances of use and the actors involved are sufficiently distinct to merit a separate analysis.

4.5 Before introducing the principles and interests, and the virtues associated with supporting their promotion and protection in the field of novel neurotechnologies, we will first address what we mean by the ‘special status of the brain’ in order to elucidate the fundamental personal interest that drives ethical concerns in this area.

The special status of the brain

4.6 The human brain is the organ of the human species that most profoundly distinguishes us from all other species, including other primates. It is an extraordinary network of neuronal structures, containing nearly 100 billion neurons, whose connections somehow underpin the capacities that are central to our lives. As we outline in the following paragraphs, it is the foundation of human existence – personal, sub-personal and interpersonal. This gives us reason enough to attach particular value to the brain, and to appreciate the profound concerns that surround interventions that act directly upon it.

Brain, mind and body

4.7 The processes by which mental functions are enabled by the brain remain largely unknown. Brain research has made enormous progress over the past five decades, but at present we have no comprehensive models of this structurally complex and functionally-dynamic system. The precise relations between mind and brain, between mental states and brain-states, are notoriously disputed but, for the purposes of this report, it is not necessary to take sides in this ancient debate. The broad dependence of human mental capacities, such as perception, thought, memory, feeling, and agency upon our brains, is now taken for granted.

4.8 A central aspect of the brain’s special status comes from its role as the organ through which the body as a whole is controlled. Our embodiment is an essential dimension of our existence, of our capacities for perception and action, for language and emotion. Since the brain is central to the management of this somatic existence, it provides the basis for the sense we have of ourselves as a material and historical presence in the world. We learn from neuroscience, particularly from the study of brain injuries, that this sense of ourselves is founded upon non-conscious processes in the brain that both prepare materials for conscious experience and manage the body’s routine autonomic systems – for example, breathing, digestion or sexual arousal – which are the basis of our embodied existence. Hence these non-conscious processes, as much as our conscious processes, make a significant contribution to the ways in which we see ourselves and are seen by others, to the maintenance of our independence and our relationships.
Identity and autonomy

4.9 The brain receives special attention because, for each of us, it is uniquely associated with ‘me’; with our subjective self-conception and capacity to develop and exercise this conception through our actions, pursuits and relationships with others. In many cultures (though not all), a high value is placed on the development of this individualised sense of oneself. This is associated with the belief that developing and realising this identity through the course of one’s life and relationships with others is a central aspect of living a fulfilling human life. Brain damage can, however, threaten this ideal of self-realisation, since injury or disease has the potential to disrupt this possibility at the most fundamental level by interfering with the capacity to form and maintain a connected sense of oneself over time. For example, where people with dementia experience serious memory loss this may, to varying degrees, impact on their own sense of their identity.426

4.10 Personal identity is closely bound up with our sense of autonomy. As autonomous agents, we are able to act for reasons that we ourselves identify with and endorse rather than, for example, following habits or instructions from others without reflection. We value our capacity to exercise this kind of rational control over our actions and to exhibit a degree of consistency of character, in part because this is the central means through which we develop our own sense of ‘who we are’ and the personalities by which others recognise us. This is particularly true where we act from desires and beliefs that we think of as ‘authentic’ or ‘true to ourselves’ - yet some serious neurodegenerative illnesses and mental health disorders have the potential to create a separation between precisely these kinds of motivations and an individual’s behaviour.427 Even where cognitive or affective functions are not damaged, serious movement disorders and conditions such as locked-in syndrome undermine autonomy in the most basic way, by preventing individuals from communicating or putting their desires into action.

4.11 Our intention is not to talk as if personal identity and autonomy are capacities of an individual existing in isolation. This is, of course, not the case. Our abilities to frame lives of our own are not merely dependent on the functions of our individual embodied brains, but are sustained by relationships with others. We develop a sense of our own identity through our dealings with others and we exercise our autonomy in the context of lives which we share with them. These relationships run very deep and should be seen as an essential dimension of the individual self.428 An adequate ethical framework must be sensitive to this interdependence of persons.

426 This is not to suggest that memory loss and its effect on self-perception make those with dementia any less deserving of respect as persons and in the context of others’ ethical and legal obligations to them. The Nuffield Council on Bioethics’ previous report on dementia explores these questions in depth, emphasising the importance of not stigmatising those living with this condition and that it is possible to live a fulfilling life with dementia. See: Nuffield Council on Bioethics (2009) Dementia: ethical issues, available at: http://www.nuffieldbioethics.org/sites/default/files/Nuffield%20Dementia%20report%20Oct%2009.pdf, at page 30.


Box 4.1: Neuroscience and free will

The idea that human beings – of a certain age and not affected by illness or disorder – are agents capable of autonomy is central to prevailing western ideas of the person. However, we should note that some contemporary neuroscientists have questioned these beliefs. They argue that laboratory experiments on volition have shown that the brain prepares for an action – and in a sense has ‘decided’ on that action – before an individual is conscious of that intention. Many go on to argue that these results have implications beyond the laboratory, to decisions in everyday life, that much decision making takes place below the level of conscious awareness, and that our sense of conscious deliberation and choice is illusory. If this is the case, they suggest, agency and thus autonomy are illusory. This conclusion can, however, be disputed, as it depends on the extrapolation of results from highly simplified laboratory situations. While there is no reason to doubt that the brain does take the lead in preparing us for action, it does not follow that we do not also have a capacity for conscious deliberation and action which builds upon our sub-intentional acts. For the purposes of our argument here, therefore, we shall assume that our current conceptions of agency and autonomy are not radically undermined by neuroscience and that, fictional or not, beliefs in agency and autonomy are crucial to our sense of self, and real in their effects in social relationships.

Grounding our ethical framework: need and uncertainty

Why intervene in the brain?

4.12 The crucial role of the brain in the functioning of the mind, the body, and the development of self conceptions and autonomous agency makes it clear why neurological disorders and other conditions with a neurobiological basis threaten such profound and distressing personal consequences. Damage to the brain can rob individuals of their ability to participate fully in life by affecting the individual’s mood, capacity for organised action, their awareness of themselves and others, and their memory. Chronic pain and movement disorders such as dystonia are enervating and interfere with everyday activities. Equally, where brain disease or injury affects the body’s autonomic systems, even when higher functions are largely unaffected, life can become very difficult. People who have lived active lives find themselves dependent on others in ways that are difficult to manage. Neurological and mental health conditions can also be a source of social stigma, embarrassment, and social isolation.

4.13 Damage to the brain has the potential to disrupt the life history of a self that has emerged, grown and changed over time, as well as the imagined futures of this self. An evolving and dynamic identity is a normal and appropriate response to new experiences, but where changes in identity result instead from illness or injury they may be the cause of confusion and alienation. Sometime the condition itself may mean these changes are not appreciable by the individual herself or himself, but the effect on those with whom they share their lives may be no less distressing. Neurological and mental health disorders can profoundly affect relationships with family members and others close to them. Where relationships become ones of dependence, this can transform the lives of those who accept the responsibility for care, bringing domestic upheaval, social isolation and economic burdens. These personal impacts collectively provide powerful motives for seeking to alleviate these effects where possible.

4.14 Neurological and mental health conditions are also liable to present significant challenges for wider society. As we outline in Chapter 3, the global incidence and costs of disorders affecting the brain are considerable. The development and application of novel neurotechnologies plays a vital role in a society that values equal participation and equal access to life’s goods for all its citizens. Therapeutic applications also have the potential to contribute to the public good by

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minimising those individual and social harms arising from disorders or diseases of the brain, and by so doing, contributing to both individual and collective well-being and prosperity.432

4.15 As described in Chapter 2, it is a distinctive feature of the brain that it has only a limited capacity to heal itself. This is not to say that some recovery from stroke or brain injury is impossible. Our growing understanding of brain plasticity suggests that both the physical architecture and the internal organisation of the brain is modulated throughout our lives (see paragraphs 2.10 to 2.12). In some circumstances, rehabilitation can assist the brain in ‘rewiring’ itself, thereby recovering some or most lost function. Nevertheless, in many cases, where there is severe damage to the brain or progressive degeneration, it may only be possible to repair or alleviate this to a limited extent through medical interventions. While some existing surgical procedures or pharmacological therapies are available, there are few effective interventions at present. The increasingly pessimistic outlook for pharmacological options to address many mental health disorders is just one example of this gap.433

Therapeutic need and the principle of beneficence

4.16 There is therefore a need for effective treatments in this area that gives sufficient grounds for asserting that the familiar bioethical principle of beneficence – that is, the principle underpinning the responsibility to do good where possible – applies here. In the present context this principle attaches to the good achievable through promoting biomedical research, providing treatments, and seeking to improve upon neurotechnologies which could help to alleviate serious neurological and mental health disorders for which alternative effective interventions are not available. The kinds of novel neurotechnologies discussed in this report offer promising therapeutic avenues. At present they do not represent cures, but the possible impacts of these interventions on the health and quality of life for individuals (and their families), for whom there are few or no other therapeutic options, should not be underestimated. For example, assistive BCIs offer ‘locked-in’ users perhaps their only opportunities to interact with the world. DBS and non-invasive neurostimulation, meanwhile, can be targeted to mitigate the debilitating symptoms of chronic pain, depression or movement disorders that remain resistant to other forms of therapy.

4.17 As we have seen in Chapter 3, a significant obstacle to meeting need is securing funding to bring these technologies to market and to attempt to achieve, as far as possible, equitable access to the products of research and innovation. While beneficence is most obviously a principle that gives responsibilities to those with authority to direct public resources in this area (for example, in the UK, this will mean national governments, research funding councils, and the NHS), it is by no means limited to these authorities. For example, this duty will also extend to researchers, clinicians, and regulators. It extends also to other parties who are in a position to support innovation, for example through private funding. Each of these parties may be seen as a bearer of a duty to meet the needs of those who lack access to effective interventions. However, the obligation to ‘do good’ through the development and administration of therapeutic interventions in the context of neurotechnologies is importantly constrained, not only by economic obstacles to making these products widely available and the opportunity costs of doing so, but also by a responsibility to exercise caution in light of the persistent uncertainty about the possible consequences of intervening in the brain.

Why we face uncertainty

4.18 For many of the technologies discussed in this report, the balance between the therapeutic benefits of intervening in the brain and the risks of doing so remains unclear. This is, therefore, a chief concern for this report. The ‘novel’ nature of these technologies means that evidence

which addresses this lack of clarity is often unavailable, in particular in relation to longer-term unintended effects. Novelty is not the only reason for uncertainty, however; our knowledge about how the brain works is still strikingly limited. While neuroscience has made immense strides forward in recent decades, and we have gained much knowledge – for example, in respect of particular neural processes – the complexity of the brain as a whole and the dynamics of its relations with its bodily and external environment, is still largely beyond scientific understanding. As we observed in the Chapter 2, the precise mechanism by which some interventions (even those, such as DBS, that have been in use for several decades) achieve their therapeutic effects remains unknown. It is also the case that some of the unintended effects associated with novel neurotechnologies include psychosocial impacts – for example, to a user’s personality or sense of self – that are still poorly understood. There is little systematic research into or documentation of such effects, not least because their inherently subjective nature makes them harder to quantify than physiological risks.

4.19 While uncertainty, *prima facie*, requires that more research is conducted to fill evidence gaps, the ethical conduct of research itself relies on an understanding that participants will not be exposed to unnecessary risk, but this assurance is precisely what remains uncertain. There are also practical obstacles to gathering a robust body of evidence needed to address uncertainty. Conventional routes to evidence gathering, such as large scale randomised controlled trials (RCTs), may be unavailable or unsuitable in this content. The kinds of serious neurological and mental health disorders for which novel neurotechnologies are indicated mean that limited numbers of individuals are eligible to participate in these kinds of studies. This may require evidence to be generated through experimental treatment, which itself raises significant ethical issues and the conduct of which needs to be guided by the appropriate consideration of patients’ interests, as described further below and in Chapter 5.

4.20 The ethical challenges presented by uncertainty do not pertain to knowledge of risks alone; it is equally important that the *benefits* of intervening are well understood. Understanding of such benefits, however, is incomplete for some of the neurotechnologies with which we are concerned. For example, as medical devices are not required to prove efficacy to receive marketing approval in Europe, pursuing evidence of efficacy will not always be a high priority for those with a commercial interest. Even if, as in the case of non-invasive neurostimulation, risks are considered low, given the special status of the brain even less serious risks must be counterbalanced by clear indications of effectiveness in comparison with other therapeutic options if their use is to be supportable.

4.21 A distinct, but no less important, factor contributing to uncertainty about the long-term ratio of benefits-to-risks of any particular novel neurotechnology is the prospect of ‘dual use’ and spin-off developments. In this report, we seek to avoid speculation about the ethical implications of future applications of neurotechnologies that are unsubstantiated by current evidence. Nevertheless, it is important to reflect upon plausible future applications to understand the ethical implications of a technology’s development trajectory. While the ethical issues raised by future uses of technologies inevitably remain obscure, there is current evidence that the non-invasive neurodevices are particularly amenable to non-therapeutic applications - we consider these in detail in Chapter 8.

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436 ‘Dual use’ is the phrase used to describe the possibility of a technology being applied to hostile ends (in this case, as well as therapeutic) ends.
Uncertainty and the principle of caution

4.22 In bioethics, the principle of beneficence is often accompanied by a corresponding principle of non-maleficence, closely connected to the Hippocratic duty to ‘do no harm’. This duty applies to all areas of medical practice and research, but carries a particular imperative where interventions in the brain are concerned because of the brain’s special status in our lives. The history of such interventions, as described at the start of this report, shows clearly how terrible damage can be inflicted upon patients by clinicians, albeit by those who operate with the best of intentions. The possibility that new and current treatments may harm patients cannot be excluded. The obligation to avoid harm requires an ongoing commitment to develop a robust body of evidence, attention to the needs and vulnerabilities of particular individuals, and a willingness to reflect upon and review clinical practices and the development trajectories of these technologies. We may think of this as the ‘principle of caution’.

4.23 The principle of caution might be taken to require evidence of the absence of risk before research involving humans or treatment is employed, along the lines of ‘strong’ versions of the precautionary principle often invoked in public health and environmental policy contexts (see paragraph 6.25). But here we take the precautionary principle to be too restrictive where there is also a duty to promote research and find effective treatments. To argue for inaction or to set disproportionately high regulatory hurdles for innovation is itself ethically problematic: in the face of clear suffering and unmet need, the precautionary principle runs the risk of stifling the development of new neurotechnologies. The ‘principle of caution’ we adopt here recommends a less restrictive standard of behaviour, one which is tempered by the recognition that some risks, and some uncertainty about risks, may be tolerated where technologies could make a significant contribution both to individual patients and to the public good.

Developing the framework through interests

4.24 Beneficence and caution constitute the fundamental signposts of an ethical framework that is sensitive to the needs and uncertainties that are characteristic of therapeutic applications of neurological interventions. In navigating between these two (sometimes conflicting) ethical dimensions, a set of interests emerge as requiring particular attention, given what we have noted about the special status of the brain, the state of development of the neurotechnologies under consideration, and the conditions for which these technologies are used. We outline these interests – safety, autonomy, privacy, equity, and trust – in the paragraphs that follow.

Safety

4.25 The unintended effects of therapeutic uses of novel neurotechnologies include their potentially harmful impacts on patients’ health and brain functions. As observed in Chapter 2, these kinds of impacts vary between the different technologies. We do not repeat them in full here, but note that they are pertinent to any ethical consideration of neurotechnologies because of the importance of the healthy functioning of the brain to so many aspects of human life.

4.26 The concerns here relate chiefly to implanted neurotechnologies where the potential for harm is greatest. The risks associated directly with surgery to implant electrodes or stem cells (such as tissue damage, bleeding or infection) are considered relatively low compared with other more invasive forms of neurosurgery. However, the enduring implantation of foreign objects in the brain itself carries risks. Inadequately integrated cell grafts could give rise to pain. Where neurotechnologies work by stimulating the brain, it can be difficult to predict precisely what is

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437 In Chapter 2 we outline some of the chief technology-related risks and unintended consequences associated with these technologies and we discuss a wider range of psychological and social impacts in this chapter.
438 For example, the surgical removal of brain tumours may be considered more physically invasive and risky.
being stimulated.\textsuperscript{440} Possible consequences of neural stimulation can include seizures (though these are rare),\textsuperscript{441} weight gain,\textsuperscript{442} and disruption to cognitive functions (we consider these unintended cognitive and behavioural effects in the next section).\textsuperscript{443} In contrast to pharmaceutical therapies where treatment can usually be stopped if a patient suffers adverse effects, surgical interventions may not be reversible to the same degree. Electrical stimulation can be varied or switched off, but transplanted stem cells may not be easily removed.

4.27 It is not possible to assess the degree to which caution requires a patient to be protected from unintended health risks in isolation from an appreciation of the expected therapeutic benefits (and how these compare with the risk/benefit ratio of other treatment options). It is the responsibility of those developing and using these technologies, as well as those regulating their activities, to ensure there is adequate evidence that any risks are not disproportionate to benefits. However, as we have observed, for many of the technologies with which we are here concerned, this evidence is still being accrued.

Autonomy

4.28 We have already discussed the value we place on personal autonomy (understood as the capacity to act for reasons that we ourselves identify with and endorse), and have indicated the ways in which this capacity can be threatened by damage to the brain. There are two different (though not unconnected) ways in which ethical concerns arise in respect of autonomy in the context of the development and use of novel neurotechnologies. The first of these relates to the discussion at the start of this chapter regarding the value many of us place on being able to behave in ways that reflect our understandings of who we are, and the negative impacts of brain disease or injury upon this. The relevant ethical concerns here relate to the role of therapeutic neurotechnologies in restoring – or possibly disrupting – an individual’s capacity to exercise their autonomy and identity as \textit{a result of intervening in the brain}. The second context in which neurotechnologies raise autonomy concerns relates to the importance of respecting patients’ and research participants’ opportunities for self-determination through informed consent in the conduct of research, experimental treatment or treatment. We will discuss these two issues in turn.

The impact of neurotechnologies on autonomy and identity

4.29 As we have observed at the start of this chapter, the effects of disease or injury affecting the brain often go beyond poor physical health to impact upon individuals’ capacities to formulate motives or to act in ways that reflect who they are. Novel neurotechnologies that repair or counteract the effects of damage to the brain therefore potentially offer not only health benefits, but also significant improvements in quality of life by improving cognitive capacities and mood, or by substituting lost motor control in ways that increase individuals’ autonomy and restore their capacities to develop, and to express, their sense of their own identity. We do not accept here the suggestion that reliance on, for example, assistive BCI technology or neurostimulation in itself diminishes autonomy. Autonomy is not a capacity exercised in isolation, but is rather dependent on our social and physical environments and tools. As tools, therapeutic applications of novel neurotechnologies may rather be seen as potentially autonomy-enhancing. However, responsible research and clinical practice cannot proceed on the simple assumption that the relationship between these technologies and capacities for autonomy and self-realisation is straightforwardly positive; the reality is more complex.

\textsuperscript{440} See paragraph 2.18.


4.30 The first reason for this complexity is that the potential therapeutic benefits exist in tension with, and must be weighed against, the possibility that neurotechnologies may also have unintended negative impacts upon autonomy and identity. As we observe in Chapter 2, there is evidence – particularly in relation to treatment of with Parkinson’s disease – that the use of DBS can have effects on a patient’s mood, behaviour and cognition. In some cases, aggression, depression or mania can be amongst these effects and result in measurable alterations in personality. However, it may be difficult to distinguish changes due to neurostimulation alone from the effects of the progress of the illness itself and any associated changes to drug regimes. These kinds of unintended psychological and social effects are well documented for DBS used in Parkinson’s disease, but similar concerns also arise in relation the use of DBS to treat mental health disorders such as depression or OCD. Though there is no evidence of similar behavioural effects from neural stem cell therapies, commentators have suggested this possibility cannot be wholly dismissed.

4.31 A second layer of complexity is introduced because the evidence of these kinds of unintended risks of therapeutic interventions is no more amenable to a straightforward practical and ethical response than the evidence of potential benefits. Notwithstanding what has been said earlier in this chapter about the value of authentic, autonomous action as an important aspect of human well-being, personality and behavioural changes cannot be construed as unequivocal harms that clinicians should seek to avoid at any cost. As is perhaps most obvious in the case of serious mental health disorders, changing a patient’s sense of herself or himself and behaviour might be precisely the desired therapeutic outcome. Furthermore, when faced by the seemingly impossible choice between leaving debilitating physical or psychiatric symptoms untreated, or a degree of lost cognitive capacity and behavioural control (as unintended consequences of treatment), the latter option might be preferable for some patients (see Box 4.2).

Box 4.2: Choosing motor control over capacity

One case, much discussed in the bioethics literature, demonstrates several aspects of the complex ethical challenges presented by treatment using DBS. In this instance, a 62-year-old man had been treated for Parkinson’s disease using DBS. This had been effective in alleviating some of the illness’s serious motor symptoms that would otherwise have been so severe as to confine him to bed. It also led, however, to his being admitted to hospital three years into his treatment in a manic state, the consequences of which were "chaotic behaviour, megalomania, serious financial debts and mental incompetence". Changing the parameters of his stimulation restored his capacities for insight and reflection, but his physical incapacity returned. There was no middle ground between these symptomatic extremes. Whilst in a competent non-manic state, this individual voluntarily chose to proceed with a level of neurostimulation that controlled his severe movement disorder and thus allowed him to undertake for himself the routine activities of daily life, even though this meant committal to a psychiatric hospital due to his mania.

This case illustrates some of the serious possible unintended effects of DBS that are closely linked to self-conception and autonomy, and the potential challenges to obtaining informed consent to treatment when the intervention itself can interfere with relevant decision-making capacities. It also highlights the importance, in delivering care, of attending to patients’ own perceptions of what constitutes the best (or least-bad) treatment outcome and, from a public health perspective, of recording patient-reported outcomes as an essential part of building a better understanding of the risks and benefits of DBS. Similar issues are brought to life by the sociologist Helmut Dubiel’s memoir of receiving DBS.

445 Ibid, at page 5. The observation of these effects is highly variable between patients and between studies.
treatment for Parkinson’s disease, where he notes the difference between his surgeons’ criteria for determining that his neurosurgery had been a “complete success” and his own experience of distressing unintended effects, including those upon his mood and voice.451

4.32 A responsible approach to supporting prospective users of novel neurotechnologies, which could have both positive and detrimental impacts on autonomy and identity, must seek to accommodate the complexity outlined here. This must be managed as part of a commitment to sensitive, ongoing communication with patients, and those close to them, which takes account of both the needs of the particular patient and the general duty of informed consent. We turn now to consider the ethical challenges posed by novel neurotechnologies for informed consent itself.

**Autonomy and decision-making**

4.33 The requirement for informed consent is widely considered as the ‘gold standard’ for the protection of patients’ and research participants’ autonomy. Nevertheless, the limitations of informed consent as the principal means of protecting autonomy are widely recognised and are not unique to use of neurotechnologies.452 This notwithstanding, the nature of these technologies and the conditions they address mean that particular challenges come into sharp focus. These relate to: the experimental status and uncertainty about the longer term and unintended effects of some therapeutic interventions; the vulnerability and potential incapacity of patients with serious neurological or mental health disorders; and the possibility, that we noted in Chapter 3, that some clinicians may have vested economic interests in pursuing certain kinds of intervention (see paragraph 3.66 to 3.70).

4.34 Where definitive information about the risks and benefits of intervening in the brain using a particular neurotechnology is not available, this presents a *prima facie* hurdle to securing informed consent. However, clinicians and researchers may nevertheless take responsible steps to assist individuals to make meaningful, autonomous choices to undergo such interventions where there is clear therapeutic need. These include being open about uncertainties, about current understandings of what constitutes a good outcome, and about how neurotechnological interventions compare with other more established therapeutic options. This is a particular imperative where an individual’s desperation for any chance to relieve their suffering might dispose them to overlook the possibility of poor outcomes. It is also important that investigators are vigilant to the risk of consent being given under a ‘therapeutic misconception’ – that is, the not uncommon belief of participants that, whatever they have been told as part of consent procedures, treatment of their individual health needs will be part of the aims and outcomes of the study.453 The possibility of this misconception raises particular concerns about managing the expectations and supporting the needs of participants in experimental studies to whom beneficial interventions may not be available beyond the end of the investigation.454

4.35 The final point to note here engages ethical concerns relating to both decision-specific autonomy and a more far-reaching capacity for autonomy and self-realisation in all aspects of life. Assistive BCIs and neural stem cell therapies that are intended for use by individuals with impaired cognitive capacities, or those who retain cognitive functions but cannot communicate

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454 As might be the case if, for example, the technology is not licensed for use outside investigational settings, or requires unaffordable ongoing clinical support for its continued use.
their wishes (for example as a result of locked-in syndrome), raise particular challenges. For each of these groups, novel neurotechnologies could offer, respectively, the potential to partially restore cognitive functions; or, using assistive technologies, the ability to interact with the world and communicate their wishes. These outcomes could restore a degree of autonomy. However, neither group is able to give valid consent ‘upfront’ in relation to the undertaking of a potentially risky intervention that would permit this to happen.

4.36 Legal provisions in the UK permit decisions to be made on behalf of those who lack capacity, provided certain conditions are met (these are discussed in more detail in Chapter 5). Where decision-making is delegated to another person(s), or ‘proxy’, the legal threshold for the lawfulness of any intervention is that the chosen path is judged to be in the ‘best interests’ of the patient or participant. However, some applications of novel neurotechnologies, where it is not yet possible to be sure of any benefit to patients (for example, the use of BCIs with locked-in patients) present a particular challenge to demonstrating whether they are in the patients’ best interests. This can leave proxy decision-makers in a quandary about whether and how to proceed from a legal standpoint. From an ethical point of view the alternative (of never pursuing research or experimental treatments with patients who cannot themselves give consent) is disproportionately cautious. It serves neither the needs of these individuals nor the wider public good, as it risks excluding serious neurological and mental health conditions from the scope of the quest for effective interventions. The best interests test must be recognised for the nuanced judgement-call that it is, despite any paucity of evidence.

Privacy

4.37 BCI devices function by obtaining and transmitting digital data about the brain activity of their users. It is conceivable that, in the future, implanted neurodevices, such as those used in DBS, might also record patients’ brain activity to enhance their therapeutic functions by, for example, predicting tremors. Our current understanding of the brain means that data about brain activity does not permit the content of someone’s thoughts to be ‘read’. Nevertheless, while popular conceptions persist that the brain’s activities are especially associated with ‘who we are’, the direct and automated collection of data on brain activity by neurodevices, or external interference with the functioning of these devices, may be seen as intrusions into an individual’s private domain.

4.38 Sensitivities may also arise insofar as information collected from neurodevices can be obtained and used to identify someone as undergoing treatment, or reveal their abnormal brain activity, particularly where this indicates a stigmatising neurological or mental health condition, or could otherwise be used for discriminatory purposes. Responsible clinical and research practices should protect patients’ and research participants’ informational privacy by ensuring they understand and agree to the collection of sensitive personal data by neurodevices and by providing adequate safeguards to protect confidential information derived from these. We return to discuss the legal restrictions in the processing of personal data in Chapter 5.

4.39 Neurodevices are also potentially vulnerable to malfunctioning, or to illegitimate information interception, due either to accidental signal interference or malware infections via devices’

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456 Ibid.
458 Limited exceptions might be BCIs that record brain signals associated with the user’s registering an external stimulus or with a change in affective state, which could potentially reveal what it was that piqued the user’s attention or crudely be seen as betraying a user’s mood. See, for example, Martinovic I, Davies D, Frank M et al. (2012) On the feasibility of side-channel attacks with brain-computer interfaces. In Usenix Security Symposium 2012. (Bellevue, WA).
wireless connections.\textsuperscript{459} At present, there is no evidence of malware affecting neurodevices specifically, but it has been suggested the increasing complexity of all medical devices makes illegitimate interception of information more likely.\textsuperscript{460} The adoption of measures to protect devices against external interference is an ethical matter not simply for reasons of safety; there may also be wider impacts on users’ private lives. Where those who depend on devices for managing serious symptoms, mobility or communication are unable to control (or lack confidence in) how their device functions, this may undermine their self-reliance and jeopardise the satisfactory integration of the device into their self-conceptions. Such concerns may render these technologies burdensome or alien rather than enabling.\textsuperscript{461}

Equity

4.40 The principle of beneficence requires the provision of treatments that alleviate suffering caused by brain-related disorders and, as such, may be seen to extend to a requirement to provide wide access to those treatments. However, this will not always be possible. Instead, the aim must be to offer the best treatment that is reasonably available and affordable in the circumstances that prevail, which raises issues of distributive justice.

4.41 In Chapter 3, we outlined the high national and global incidence of the kinds of neurological and mental health disorders that these neurotechnologies seek to treat (see paragraphs 3.11 to 3.15). Some disproportionately affect persons who are vulnerable, due to age, socio-economic status, and exposure to dangerous or toxic environments. Indeed, the problems posed by brain disorders might be seen to present more significant challenges in less developed regions, where they may carry significant stigma and where public health infrastructure and access to treatments for such disorders are very limited.

4.42 Various structural factors create significant barriers to accessing treatments, especially in the developing world: we noted in Chapter 3 that the costs of delivering treatment using many of these technologies are and will remain high. Despite the great need for effective treatments for neurological and mental health disorders, without further resources and interventions it is likely that, in the short to medium term, these new treatments will be available only to the citizens of wealthy states, and then only to some of them. It is therefore desirable that research scientists, technologists, funders and industry partners should work together to develop ways of making access to novel neurotechnologies a more realistic possibility for those who need and desire them, by making them cheaper, easier to use, and more widely available. Given the difficulties discussed in Chapter 3 in relying on current market mechanisms to bring new products into use, this goal is likely to require the development of alternative funding models and closer relationships between science, industry and non-governmental organisations.

4.43 There are also other, more local, problems of justice associated with neurological and mental health disorders and their treatment which merit action of a different kind. Some individuals will have difficulty finding meaningful and valued social engagements, due, in part, to the nature of the disorders themselves, but also because of the stigma that accompanies these disorders, which generates fear, anxiety, and lack of understanding. The relationships between the use of novel neurotechnologies, social stigma and discrimination may well be complex. Treatment itself can be a cause of embarrassment or discrimination, particularly while these interventions remain novel. Paradoxically, however, neurotechnologies that support some individuals’ capacities to be ‘more normal’ might be seen as inherently discriminatory – and exacerbating


misunderstanding and discrimination – against those who continue to live with neurological and mental health disorders. All relevant stakeholders should work steadfastly to combat social stigma and discrimination against individuals with brain-related disorders and their families on a societal level, in the interest of equity and justice.

Trust

4.44 Brain disease and damage present frightening prospects because they threaten many capacities central to our leading fulfilling lives. As more of us live longer and experience age-related conditions such as stroke or dementia, more of us have a stake in technologies that offer treatments for such conditions. Accounts of the therapeutic promise of novel neurotechnologies in both academic publications and the mainstream media are compelling. It is, therefore, all the more important that trust is preserved through responsible and transparent practices in publication and reporting.

4.45 There are strong economic incentives for researchers and the neurotechnology industry to emphasise the translational value of their findings in order to secure public funding and private investment. Those seeking to market products to healthcare providers or directly to consumers have an incentive to expand the therapeutic applications of novel neurotechnologies. Indeed, novel neurotechnologies occupy a field characterised almost as much by what we do not know as that which we do. Hype is likely to result in a loss of trust and confidence if its promises are not sustained in practice.\(^\text{462}\) Despite the understandable motives for optimistic claims and projects, the pressure to secure scarce resources to fund costly development paths, there is a need to build and maintain trust if there are to be long-term scientific and economic gains. This is best achieved through development trajectories that are based on the most robust clinical evidence and transparent communication of this evidence by those involved in conducting, funding and regulating innovation in novel neurotechnologies.

4.46 Trust is not only an overarching economic and scientific interest; it is also an ethical demand grounded in relationships with patients. Representations of research findings in the mainstream media that underplay potential risks or extrapolate beyond that which is supported by available evidence are more than just regrettable exaggerations. Hype may also perpetuate popular reductive misconceptions of the brain and our abilities to understand and influence its functions.\(^\text{463}\) More acutely, however, it also carries the risk that the hopes of potential patients and their families will be raised without justification. As well as threatening disappointment and distress, this creates particular problems for informed consent. The challenges facing clinicians and researchers in conveying the limits of current knowledge to secure valid consent, outlined above, are compounded where their efforts to secure patients’ realistic understanding of the efficacy and risks of the neurotechnology in question must operate against a background of overheated expectations. We discuss these issues of responsible communication of research by the media in more detail in Chapter 9.

Putting principles and interests into practice: a virtue-guided approach

4.47 The ethical framework outlined so far is grounded in the principles of beneficence and caution as ethical foundations that correspond to the overarching tension between uncertainty and need in the context of novel neurotechnologies. These foundations give rise to a set of interests: safety, autonomy, privacy, equity and trust, which are elaborated above. However, it is clear that the complex network of technologies, therapeutic applications, risks and benefits in the field of novel neurotechnologies means that it is insufficient to lay out a set of principles and interests


and expect their practical application to be obvious. This is particularly so because the need for, and uncertainty about, the development and uses of these technologies exist in mutual tension. This is an area of competing priorities in which ‘doing what is right’ is not simply a matter of following rules, but frequently requires the exercise of informed practical judgement.

4.48 Moreover, this is not a unified or static ethical landscape. As the discussion in this chapter has emphasised, a potentially wide range of actors is involved in the development and use of novel neurotechnologies. An adequate ethical framework must, therefore, remain open to the diverse contexts faced by these actors in a variety of settings, and guide them through the fundamental tension between seeking to do good while navigating uncertainty. Furthermore, in an emerging area of biotechnology such a framework must also be able to respond to fresh evidence of the capabilities of these neurotechnologies and to changing social attitudes to what they offer.

4.49 In light of these considerations, our ethical framework is reinforced by the introduction of virtues as means of guiding the practical application of the principles and interests we have already identified. We suggest that a virtue-guided approach is appropriate in this context for several reasons. A virtue-guided approach is particularly (though perhaps not uniquely) well-suited to accommodating the kind of flexibility and balance between need and uncertainty that our framework requires. Intrinsic to virtue ethics is the idea that, in doing the right thing, we must apply practical judgement to identify a response that is appropriate and proportionate to the particular circumstances at hand. Virtue ethics is also associated with supporting the efforts of each of us to ‘flourish’; that is, to pursue the most fulfilling and rich lives we can. We are concerned here with interventions that impact on lives in deeply personal and pervasive ways. The imperative is to attend to potential recipients of neurotechnological interventions not merely as the owners of damaged brains, but as whole individuals with particular values, life plans, and relationships.

4.50 Each of these features highlights the value of a virtue-guided approach where sensitivity to particular circumstances is so important. An emphasis upon virtue does not overlook the importance of ‘doing the right thing’, but encourages us to look to the wider moral landscape of perceptions, priorities, and values in which actions are located. This inclusivity captures some important intuitions about what makes someone, for example, a good clinician or a good friend who is well-equipped to recognise and respond to the needs of individuals with serious brain illness or injury in a way that attending to duties or outcomes alone might not. We explore further the central tenets of virtue ethics and some challenges to these in Box 4.3 below.

4.51 The virtues we highlight here for particular attention are inventiveness, humility and responsibility. These are intended to complement, rather than replace, the all-purpose virtues that are characteristic of almost any decent human life and society (see Box 4.3). Instead, we seek to identify those whose practice is especially important in the development and use of novel neurotechnologies. These virtues are not exercised in the abstract, but conceived of as guiding reasoned and evidence-based judgement that attends to the principles and interests we have identified as part of this framework. These principles and interests help define the meaning of the virtues as applied in this field, and set limits to their scope.

4.52 In this report, we are chiefly concerned with the attitudes and conduct of those acting in their professional capacities. Though virtue ethics is normally associated with the moral characters of individuals, our use of the virtues here is not intended to preclude or minimise the role of communities and institutions. Organisations ought, through their functions and norms, seek not only to support and facilitate virtuous behaviours, but also to foster amongst their members

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464 Indeed, on many views, all moral virtues are mutually supporting and it would not be possible to exercise responsibility, humility or inventiveness appropriately in the absence of, for example, kindness or prudence. The idea that the virtues are ‘unified’ in this sense may be found in Aristotelian ethics and some contemporary writers: see, for example, Wolf S (2007) Moral psychology and the unity of the virtues Ratio 20(2): 145-67.
virtuous ways of seeing and understanding situations. Virtues may also be thought of as the qualities that support practices aimed at achieving that which is valuable and worthwhile, in particular shared endeavours such as patient care, or innovation to meet therapeutic needs. Even where, for example, regulatory and governance regimes pre-empt the exercise of personal virtue, it would still be desirable for the intentions underlying these to motivate and instil the virtues in the professional practices of those they govern. The three virtues we highlight here do not, however, all apply equally to every actor or practice involved in the development and use of novel neurotechnologies. In the following paragraphs and subsequent chapters, we provide some illustrations of how we might see each applying chiefly to professional practices and, in some circumstances, to patients themselves.

Box 4.3: Virtue ethics

Virtue ethics is an approach to addressing questions about how we should live and conduct ourselves that places particular emphasis on moral character. It is most closely associated with the Aristotle’s ethics, but is also connected with elements of eastern philosophies and Christian ethics. For some time, virtue ethics was overshadowed in western ethical traditions – and in bioethics in particular – by two other approaches: deontology (according to which an action is right if it accords with a moral rule); and consequentialism (in which the right action is that with the best outcome). However, virtue-based approaches are now regaining greater prominence.

According to traditional virtue ethics, a person is good if they possess and exercise particular character traits (virtues), while lacking others (vices). ‘Virtue’, as used in this way, does not carry the term’s everyday connotations of piety or abstinence. Virtues are instead understood as those characteristics of people, and their actions and attitudes, which are a necessary part of ‘flourishing’ or living well. This is not simply a matter of leading an enjoyable life, but a worthwhile one. This worth is not determined on wholly subjective or superficial grounds, but by the kinds of things that are held to be important in the groups and traditions to which we belong.

Insofar as perspectives on what constitutes a good life can change, there is room for variation amongst the kinds of virtues that are seen as important. Nevertheless, there tends to be agreement about some key virtuous characteristics, for example: kindness, justice, courage, generosity and prudence. Each of these can be seen as contributing not only to an individual’s own life ‘going well’, but to the impact they have on others’ lives and thus as underpinning the shared endeavours and mutually supportive relationships that are central to a good life. Virtues can, therefore, be seen as the characteristics of collective undertakings and practices of communities and need not be construed individualistically.

One prominent criticism of virtue ethics is that it is (too) concerned with what sort of people we should be, rather than what we should do. Moreover, it is objected, virtue ethics provides neither guidance about how to go about doing the ‘right thing’, nor the means to resolve conflicts between competing demands. These criticisms may be seen as particularly problematic for the application of virtue theory to bioethics, where the challenge tends to be determining the right things to do, often in the face of hard choices.

The response from many virtue ethicists is that it is possible to give a virtue-based account of what makes an action right and thus provide guidance on how to behave. However, doing the right thing is often not straightforward or formulaic, but requires practical judgement. Such judgement cannot be codified in simple rules, but depends upon life experience and education through which appropriate ways of seeing and understanding are developed. Right actions are those that are done from the kinds of perceptions and motives that a good person would have in similar circumstances. This is not equivalent to acting out of duty. Instead, acting in a kind way, for example, entails doing so because a person values kindness, and recognises and is moved by distress in others, and because they understand how they could (or just as importantly, could not) usefully do something to alleviate this. Adopting a virtue-based approach, it is argued, equips us no less well to navigate difficult dilemmas than trying to accommodate conflicting moral duties or decide between which of two comparably terrible outcomes to avert.

The ethical framework we have developed in this chapter reflects an approach where the virtues are seen as vital to navigating the tension between the principles of beneficence and caution, and in seeking to promote and protect the key interests outlined in the previous sections.

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472 Ibid.
Inventiveness

4.53 Novel neurotechnologies are attempts to advance understanding and provide urgently-needed treatments for some of the most distressing disorders of contemporary life. What is required from research scientists and clinicians who are working towards new therapies in this area is a willingness to develop new products and techniques, or to explore new uses of existing technologies to find new ways of confronting sometimes familiar problems – in short, a creative inventiveness that moves forward the standard of treatment.

4.54 As we have observed in Chapter 3, the development trajectory of many potentially useful applications of these technologies and their successful translation from laboratory to market is vulnerable to structural funding gaps. Inventiveness might be exercised by researchers, funders and patient activist groups to explore novel funding models that permit new technologies to cross the ‘valley of death’. However, creativity directed chiefly at attracting investment rather than meeting the most pressing patient needs, or attending inadequately to accompanying interests, is not the virtue we intend here. Inventiveness is not just a matter of doing something new, which perhaps turns out to be beneficial but might also jeopardise patients’ safety, autonomy or sense of self, or exploit their trust. Rather, it concerns helping to develop genuinely beneficial therapies that can be applied in ways that promote equitable access.

4.55 Inventiveness amongst clinicians and service providers can help to extend the benefits of these technologies to those with profound therapeutic needs, but who lack the opportunity or resources to access licensed treatments. Sometimes clinicians will be in a position to offer more experiential treatments to patients in such circumstances. Indeed, patients and those close to them may themselves exhibit inventiveness (coupled with impressive courage and altruism) by volunteering to participate in investigations of this kind (or by finding new ways of living with serious disorders). Respect for patients’ autonomy in these circumstances demands absolute clarity about when the relationship involved is one of treatment (where patients’ therapeutic needs are primary), or one of research (directed chiefly at wider public benefits). Inventiveness does not justify unsystematic experimentation or offering interventions in the absence of robust evidence, however great a patient’s needs. The principle of caution constrains its exercise, as do the corollary virtues of responsibility and humility.

Humility

4.56 Humility in the context of novel neurotechnologies refers to the acknowledgment of the limitations of our understanding of the brain and our current capacities to cure or remove all suffering associated with brain disease or damage. The virtue of humility goes beyond merely enacting the duty of caution and suggests a need for conscientious deliberation (even within oneself) about the right action in a given situation with due attention to protection of the interests at stake. For example, it is premature to think we can intervene precisely to control a particular brain function or state without unknown or unpredictable short, medium or long term consequences for other brain functions. A profound appreciation of the unknown consequences of intervening on the brain, particularly using physically invasive technologies, means that clinical practices may need to proceed in incremental steps. This is especially true where risks include unintended effects on complex mental functions such as cognition, emotion and intention and thus impact upon patients’ autonomy or sense of self.

4.57 These risks also serve as a reminder that the ‘novelty’ of novel neurotechnologies should not lead to the neglect of the possibility of other, effective, cheaper and more transportable technologies and practices to support those with these disorders. Humility importantly tempers

[473] The concept of the ‘valley of death’ refers to the funding gap in product development where a company needs investment to develop a prototype, but has not yet reached the point at which it can secure funding on the basis of a commercially viable product. We discuss this problem in more detail in Chapter 3 at paragraph 3.41 to 3.47.
inventiveness by cautioning against the technological imperative – the drive to develop high-tech solutions to the problems of brain disorders in order to demonstrate technical prowess rather than better and more accessible treatments.

4.58 Humility also builds on the interests of trust and autonomy to instil a mutual appreciation that patients and medical professionals occupy different roles, with different levels of access to power and knowledge, recognising that it is difficult for each to know the needs, obligations and commitments of the other. Establishing and preserving trust requires that medical professionals endeavour to gain empathetic understanding of the experiences of patients who live with neurological and mental health disorders and of the situation of those on whom they depend. Professional humility will sometimes require respecting the choices of competent patients to expose themselves to the unavoidable risks of treatment. At the same time, patients and those close to them need to have an appreciation of a doctor’s difficult and uncertain position in a situation where a patient has a condition for which there might be no approved or safe treatment. Thus the virtue of humility suggests that patients’ entitlement to the best care be exercised with an awareness of constraints under which medical professionals and researchers necessarily operate.

Responsibility

4.59 A responsible approach to the development and use of novel neurotechnologies is one that strives to strike a proportionate balance between the competing demands of the principles at the heart of our framework: beneficence and caution. The virtue of responsibility requires that, even where much is unknown, those involved in the research and development of novel neurotechnologies need to be able to articulate the justifications for their endeavours. Responsibility and accountability, as applied to the protection and promotion of each of the interests we have identified in this framework, may be enforced through regulatory measures, but they are also fostered through a commitment to self-governance and ethical reflexivity and accountability among the researchers, and within the communities and organisations that contribute to the development and application of novel neurotechnologies. Responsibility thus requires attention to the ethical formation of researchers themselves, especially where this takes place in a climate where short term gains and economic benefits are often valued above longer term, public values.

4.60 The virtue of responsibility also connects with the social responsibilities of researchers, medical professionals and regulators as members of democratic communities in which the costs of brain-related diseases and the hope of new treatments are collective interests. Therefore, this virtue requires those developing and exploring the applications of these technologies to consider how to achieve the translation of their work into the public sphere in a way that meets pressing therapeutic needs and contributes to the interest of equity. This entails the close engagement of various communities – commercial interests, patients and families, policy-makers, other researchers and laypersons – in order to address two central obstacles in this field: the limited evidence of efficacy, and longer-term and unintended effects on one hand, and the challenges of securing sufficient investment to translate innovation into widely available therapeutic applications on the other.

4.61 Responsibility precludes those involved in developing novel neurotechnologies (and their application) from making exaggerated claims, but rather allowing this field room to develop appropriate paradigms and to ensure that technologies are as fully formed and well evaluated as possible before they are widely implemented. This virtue is particularly pertinent in countering the pressures on those developing new technologies to overstate the capacities, or underplay the risks and limitations, of novel neurotechnologies to attract funding or to enter the market as swiftly as possible. Failures to exercise this kind of responsibility – whether in academic publications, the popular media, or marketing activities – raise unsustainable expectations,
exploit the trust of patients and those close to them, threaten disappointment and undermine autonomy and informed consent. 474

4.62 Finally, patients and those close to them can also play a role in ensuring that high quality evidence and treatments are translated into the public domain. This role includes treatment compliance and regular communication and follow-up with doctors. This is not to suggest that the virtue of responsibility requires that patients should be unquestioning or compliant in their roles. Rather, it is to assert their interests in autonomy and their potential for agency. A paternalistic or overly protective view of patients can overlook the activities and responsibilities that these stakeholders willingly take on in research, when they are able and enabled to do so.

Concluding remarks

4.63 The ethical priorities outlined here provide a framework to guide the activities of all parties involved in the development and use of novel neurotechnologies in the context of both research and treatment. This framework is action-guiding in three complementary ways. First, it establishes the central ethical imperative for action: to provide reasonably safe and effective treatment or assistance for those living with the effects of brain disease and injury for which other effective interventions are not available. Secondly, recognising that this imperative exists alongside a responsibility to avoid harm from uncertain and unintended effects, we have suggested that ethical conduct must navigate a tension between need and uncertainty. We suggest that, in doing this, the interests that come into play include safety, autonomy, privacy, equity, and trust. Finally, we have proposed that three virtues – inventiveness, humility and responsibility – capture the values and perspectives that should be exemplified in activities that seek to protect and promote these interests, whilst permitting actors room to respond to particular circumstances and negotiate the tension between uncertainty and need.

4.64 Amongst other aims, regulation and governance mechanisms can help to guide and institutionalise ethical conduct. In the next three chapters, we turn to consider the regulatory and governance landscape in which the development and uses of novel neurotechnologies operate. The ethical framework set out here provides an important benchmark against which to assess current approaches to regulating the development, marketing and clinical uses of novel neurotechnologies to determine where there might be problems and deficiencies and to help us to construct normative recommendations about how these could be addressed. In Chapter 5, we look at the governance of relationships between professionals and those undergoing interventions in treatment and research contexts. In Chapters 6 and 7, we turn to consider the regulation of the technologies themselves, asking first what responsible research and innovation looks like with respect to these technologies and then interrogating the formal regulatory frameworks that operate in this field.