Chapter 4

Intervention

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Introduction

4.1 Chapter 1 noted that it is one thing to identify ethical issues or problems with developments such as medical profiling and online medicine, and another to recommend remedial interventions by the state or other third parties. Only in a society where 'everything that isn't prohibited is compulsory' would every ethical issue be *ipso facto* translated into official rules or formal state intervention. The Working Party does not advocate such an approach, but in the previous chapter we set out a way of thinking about the sort of values that should underlie any such intervention and how we should deal with the conflicts or trade-offs that arise among those different values. Generally, law follows the kind of approach we outlined in the previous chapter, in that there is rarely any overarching legal value or principle that takes precedence over all others, and thus a balance needs to be struck.

4.2 In this chapter we turn to forms of intervention by the state or other parties that could be used to shape the developments in medical profiling and online medicine discussed in this report. As explained in Chapter 1, for formal intervention of any kind to be justified, we think the issue in question needs to cross a threshold of significance in terms of its likely harms (a 'proportionality' test); intervention has to be feasible; and there must be a broad enough basis of consensus about the evidence of the harms involved and the actions to be taken (see Paragraph 1.10). Moreover, it is necessary in every case to consider alternative possible forms of intervention in the light both of the considerations just mentioned and the values set out in Chapter 3; and we do that in each of the chapters that follow.

4.3 The idea of proportionality in policy intervention is a familiar one and it has appeared in previous Nuffield Council reports as well as many 'good governance' documents.[69] The idea of proportionality involves the presumption that, since individual liberty has a high value in liberal states, the coerciveness of intervention should be appropriate to the risks or harms involved and that costs should be proportioned to likely benefits. For instance, the 2007 Nuffield Council report *Public health: Ethical issues* used the term 'intervention ladder' to denote a range of possible interventions from monitoring the current situation to compulsory elimination of choice, which were likened to the rungs of a ladder.[70] That report argued that policy makers should select the rung appropriate for any given intervention by weighing up the benefits to individuals and society against the erosion of individual freedom, so as to ensure that no more coercive intervention is employed than is necessitated in each case. Broadly we follow the same approach here, though we consider two dimensions of intervention rather than one and the nature of our subject matter is different (the developments we are considering offer the prospect of benefits as well as harms, as explained in the previous chapter, and the possible harms we are considering are less well-understood and harder to quantify than those considered in the earlier report).[71]

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[69] For instance, proportionality is one of five principles of good regulation identified by the UK's (then) Better Regulation Task Force in 1998 (along with accountability, consistency, transparency and targeting). See: Better Regulation Task Force (2006) *Principles of good regulation*, available at: http://archive.cabinetoffice.gov.uk/brc/upload/assets/www.brc.gov.uk/principlesleaflet.pdf. It is also a guiding principle for the EU when defining how it should exercise its competences – EU action should not go beyond what is necessary to achieve the objectives of the European Treaties. See: European Commission *Better regulation glossary,* http://ec.europa.eu/governance/better_regulation/glossary_en.htm#_P. See also: European Commission (2006) *Better regulation – simply explained*, available at: *http://ec.europa.eu/governance/better_regulation/documents/brochure/br_brochure_en.pdf*.

[70] Nuffield Council on Bioethics (2007) *Public health: Ethical issues*.

[71] The case studies in this report were infectious disease, obesity, alcohol and tobacco and fluoridation of water.

Four types of intervention

4.4 Intervention can take several forms. We consider two basic dimensions of intervention here. One refers to whether an intervention is general in nature or applied to a specific product or service. Specific measures focus on particular products or services and are concerned with precisely what can be sold, done or provided under what conditions, following what standards. In contrast, other forms of intervention take the form of measures affecting the conduct of affairs in general that then have implications for specific products or services – for example, professional codes of conduct based on broad principles such as putting the patient's interest first, general rules of competition law and policy, the general law of tort and contract,[72] rules about transparency and data protection laws. General rules of conduct are often held to be preferable to product- or service-specific interventions for several reasons. One is that the latter are vulnerable to obsolescence (especially in fields such as those we are considering here, where technology is changing rapidly). Another is that service-specific interventions may be more prone to 'gaming' (where providers play the system to meet the rules and no more). A third is that service-specific interventions can lead to either over- or under-inclusive specification of the harms being addressed and inevitably lead to categorisation problems as to which specific products or services fall within the rules and which outside them.

4.5 But more general modes of intervention are not problem-free either, and that is why in some cases more product- or service-specific measures can be preferable. For example, the general value of transparency – measures that allow the public to gain more information about the operations and structures of firms, governments and other bodies – has been much stressed in recent years in ideas about good governance (and can be traced back at least to the ideas of Rousseau and Bentham in the eighteenth century),[73] and some have even argued that it can act as a substitute for more specific forms of intervention and regulation.[74] Empirical studies of the effects of transparency measures on the behaviour of consumers and citizens are few and far between; but it is often argued that transparency measures reach their limits where the information provided is not readily intelligible by the public at large or where such measures encourage one-way, defensive forms of communication by the organisations concerned.[75] At that point, more specific forms of intervention may be both necessary and desirable.

4.6 The second dimension on which intervention can vary that we are concerned with is broadly the same as that considered in the 'ladder of intervention' analysis mentioned in the previous section. This dimension relates to the formal powers being used for intervention and in particular whether or not an intervention involves formal coercive power. Many types of intervention, both by the state in all its various organisational forms and by other actors, involve no special legal powers, as in the case of prizes, grants, advice, information, advertising, non-binding agreements or voluntary codes. But some types of intervention involve powers of compulsion or coercion – powers to compel, prohibit, punish or permit what is otherwise prohibited – that are normally considered to be powers specific to the state (that is, the legislative, judicial and executive branches of government).[76] The term 'regulation' as ordinarily understood implies the use of such powers.[77] For example, voluntary standards or codes of conduct belong to the first

[72] Or delict in Scotland and other countries that draw on Roman law.
[73] See, for example: Hood C and Heald DA (Editors) (2006) *Transparency: The key to better governance?* (Oxford: Oxford University Press and Proceedings of the British Academy).
[74] See, for example: Thaler RH and Sunstein CR (2008) Disclosure is the best kind of credit regulation *Wall Street Journal* 13 August.
[75] See, for example: Roberts A (2006) *Blacked out: Government secrecy in the information age* (Cambridge: Cambridge University Press); O'Neill O (2006) Transparency and the ethics of communication, in Hood C and Heald DA (Editors) *Transparency: The key to better governance* (Oxford: Oxford University Press and Proceedings of the British Academy), pp75–90.
[76] In the Roman law, such power is denoted as the public power.
[77] There is no single agreed use of the term 'regulation'. It is often used by academics to refer to any form of state or other third-party intervention, whether involving the coercive powers of the state or other types of measures such as prizes or economic incentives (see, for example: Breyer S (1982) *Regulation and its reform* (Cambridge, MA: Harvard University

type of intervention; whereas standards or codes of conduct that can lead to formal punishment or prohibition if they are breached (for example if medical professionals are struck off the register that allows them to practice) belong to the second type.

4.7 It should be emphasised that this second distinction refers to the types of powers used in intervention, not to the particular types of organisations wielding those powers. Many kinds of organisations, running across different levels of jurisdiction from supranational to local levels, can be used for public policy, such as government departments, statutory authorities, state-owned corporations and notionally private or independent organisations. But organisations that are normally considered to be private or independent can be given powers of legal compulsion or coercion in some circumstances, as with those nineteenth-century railroad corporations that had powers of compulsory land purchase. On the other hand, organisations that are normally considered to be at the heart of the state, such as government departments, local authorities, military or police forces, often seek to use forms of intervention such as exhortation, education, monitoring (such as traffic surveys) or other activities designed to promote compliance, that require the coercive power of the state only in the indirect form of taxation to produce the necessary resources. In some cases, interventions by judges in law courts (for example in establishing or changing rules about medical negligence) can be just as important, or more important, than what legislatures or bureaucracies do. But we are more concerned with the types of powers used in intervention than the types of organisations wielding those powers, because the principle of proportionality that has already been referred to holds that powers of the second, coercive, type should be only used when the powers of the first type are insufficient for tackling any given problem, whatever type of organisation is doing the intervening.

4.8 Table 4.1 puts together the two distinctions about types of intervention made earlier (between general and specific measures, and between coercive and non-coercive measures) into a table, and gives selective examples of each of the four types of intervention involved. It is meant to be indicative and illustrative, not comprehensive, and as with any scheme of categorisation, there are no doubt types of intervention that fall on the borderline between these four types. But as we shall see in later chapters, the overall 'regime' that shapes the provision of all the types of services discussed in this report tends to be a mixture of all of those four types of intervention, and this schema helped us to identify the existing pattern of interventions and consider possible alternatives or additions. For reasons already stated, our general presumption is that measures of type (1) in Table 4.1 are preferable to measures of type (2), that measures of type (3) are preferable to type (4), and that measures of types (1) and (2) are preferable to types (3) and (4), unless justified by the harm avoided or risk reduced by the measures concerned.

Press). Lawyers in the UK tend to use the term more narrowly to mean either a particular type of law passed by the European Parliament and Council, or secondary legislation in the form of statutory instruments that ministers or other delegated authorities are permitted to make.

Table 4.1: Selected examples of four types of intervention

Type of intervention	General	Product or service-specific
Do not involve formal coercive power	**(1)** Measures aimed at encouraging general forms of behaviour (e.g. self-reliance, health awareness)	**(2)** Voluntary product- or service-specific codes of conduct or accreditation schemes
Do involve formal coercive power	**(3)** General law of tort or delict governing principles of negligence General codes of professional conduct involving formal penalties for breaches Intellectual property rights (concerning trade marks, patents, copyright, database rights) and fair trading and competition law	**(4)** Product or service-specific permits or licensing schemes Product or service-specific prohibitions on supply, possession or research Mandatory conditions applying to sale of specific products or services (such as compulsory insurance, product or service standards)

Four goals of intervention

4.9 All of the four types of intervention discussed above and illustrated in Table 4.1 can be used to secure the following four (overlapping) purposes, which seem to us to be most relevant to the medical profiling and online medicine developments considered in this report:

- reducing errors and improving the quality of products and services;
- shaping or determining who has access to what products and services and on what terms;
- shaping or determining who has access to what kind of information and on what terms; and
- shaping or determining relationships between providers and users of various types (for example those aimed at providing a level playing field for competition between different types of providers, such as 'physical' and 'virtual', public and private, national and international).

4.10 Table 4.2 gives selected examples of types of intervention aimed at each of these goals, again distinguishing between those that involve the use of coercive power and those that do not (the aim is to indicate the range of interventions possible rather than provide a comprehensive list). We also note that there are external factors, such as the power of the market and competition from other providers, that have an impact on safety and quality but which do not come under the heading of 'intervention'.

Table 4.2: Selected examples of interventions aimed at four types of goals or purposes

	Non-coercive interventions	Coercive interventions
Reducing error and improving the quality of goods and services	Provision of authoritative information Voluntary or independent quality evaluation systems such as accreditation Voluntary compensation schemes for patients or consumers who suffer harm or loss	Compulsory error or adverse event recording Conditions imposed by compulsory insurance requirements Legal obligations on intermediaries such as internet service providers Legal liability for defective products
Shaping or determining who has access to what products and services and on what terms	Pricing practices (e.g. through tax or subsidy) designed to shape patterns of consumption	Prohibitions on sales e.g. to minors Prescription-only drug supply
Shaping or determining who has access to what kind of information and on what terms	Encouragement of information pooling initiatives (e.g. patient social networking sites, evaluation websites, biobanking schemes)	Data protection laws Transparency obligations (e.g. compulsory disclosure of records or mortality rates) Libel laws Restrictions and prohibitions on advertising
Shaping or determining relationships between providers and users of various types	Public education and advertising Corporate social responsibility initiatives Voluntary codes of practice	Contract law and tort of negligence Compulsory cooling-off periods Compulsory accreditation systems Compulsory codes of practice (as in statutory regulation of professional conduct)

4.11 The provision of healthcare within any country takes place within a legal and policy context that shapes the distribution of rights, responsibilities and liabilities among healthcare professionals, patients and other parties. Consequently, since we are much concerned in this report with applications of medical profiling and online medicine that relate to 'responsibilisation' and 'consumerisation', we set out in Box 4.1 the broad legal and policy context applying to the UK and its component countries. We refer back to this legal and policy framework in our later case study chapters to see how it impacts upon the new developments we consider, and the final chapter considers how this framework might appropriately respond to those developments.

Box 4.1: General duties, responsibilities and liabilities within healthcare in the UK

The responsibility for providing healthcare falls on the different governments of the UK. They are obliged by statute to, for example, "continue the promotion in England of a comprehensive health service" (under the National Health Service Act 2006, though the meaning of 'comprehensive' is not defined; and similar statues apply elsewhere in the UK). The Secretary of State can devolve these duties to various health service bodies. NHS healthcare is broadly provided free of charge, at the point of delivery, to all who are entitled to it based on clinical need,[78] though care can be restricted in the light of scarcity of resources (e.g. for medicines, treatments, organs for transplant) and patients are not ordinarily denied NHS treatment because they might have made 'irresponsible' choices. Adults are broadly free to seek private providers or alternative medical therapies and may, in some circumstances, also do so on behalf of their children.[79]

Patients are not legally obliged to undergo medical examinations, tests or treatment. Adults, and in most circumstances children, must ordinarily give valid consent before being treated, otherwise the touching of their body constitutes a battery and a negligent standard of care. Patients can, therefore, legally refuse treatment. Special rules concerning consent apply for those judged not to have sufficient mental capacity to make a decision about treatment at a particular time.[80]

Statements of policy (notably the NHS Constitution 2009 for England) have set out what the Government considers to be responsibilities of patients, including a general obligation to take "some personal responsibility [for one's health]", to register with a general practitioner, to provide accurate information about their health, condition and status, to follow agreed courses of treatment (or to talk to the clinician if it is difficult to do so) and to participate in public health programmes such as vaccination. None of those 'responsibilities' is legally binding.

Healthcare professionals and patients, as with everyone else, are bound by general laws such as criminal law, contract law, torts of negligence, battery and assault, laws of confidentiality and data protection. To avoid a finding of negligence, doctors and other service providers must show that their professional practice has met a standard accepted as proper by a responsible body of people in the same profession.[81] It may also be necessary to show that such professional opinion is logical and reasonable. Hospitals and other bodies are often vicariously liable for the negligence of their employees. They may also be directly liable if they have not met the standards of care expected of them. Tort also has implications for the responsibilities of patients, since if (for instance) patients can be shown to have lied about their medical history, failed to follow medical advice or prescriptions, or declined treatment, the courts could take such behaviour into consideration in deciding questions of negligence by healthcare professionals.

There are a number of other safeguards for patients and consumers. One is the requirement of healthcare professionals to be registered with the relevant regulatory body, and the power of those bodies to remove a person from their register if they pose a risk to patients.[82] Another is the various regimes of quality and safety inspection that apply to healthcare services provided by the NHS, local authorities and private companies or voluntary organisations.[83] A third is the safety regimes applying to medicines and medical devices.[84]

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[78] Except in limited circumstances.

[79] In 2008, it was announced in England that patients would be allowed to pay for additional drugs without losing their NHS treatment. Previously, patients had not been permitted to 'top up' their NHS care with drugs they had paid for privately. See: NHS Choices (2008) 'Top-up fees' Q&A, available at: http://www.nhs.uk/news/2008/11November/Pages/TopupfeesQA.aspx.

[80] If gaining such consent is not feasible, consent must either be obtained from a person legally able to act on the patient's behalf, or the treatment must be considered to be in the patient's best interests.

[81] See *Bolam v Friern Hospital Management Committee* [1957] 2 All ER 118.

[82] To practise medicine in the UK all doctors (NHS or otherwise) must hold both registration and a licence to practise from the General Medical Council under the Medical Act 1983. Other health professional regulatory bodies register health professionals in the UK and (under various statutory instruments) have powers to remove professionals from their registers and prevent them from practising where they consider such action to be in the best interests of public safety. They are the General Chiropractic Council, General Dental Council, General Optical Council, General Osteopathic Council, Health Professions Council, Nursing and Midwifery Council, Pharmaceutical Society of Northern Ireland and Royal Pharmaceutical Society of Great Britain (whose regulatory function is being replaced by the General Pharmaceutical Council).

[83] Assessed and inspected by the Care Quality Commission in England, the Scottish Commission for the Regulation of Care, Healthcare Inspectorate Wales and the Northern Ireland Regulation and Quality Improvement Authority. Pharmacy premises

Our approach to selecting forms of intervention

4.12 As stated earlier, our presumption (consistent with our approach to softening or reducing dilemmas posed by conflicts of ethical values, as set out in the previous chapter) is to look first for interventions of the type that do not involve formal coercive power (i.e. contained in the upper rows of Table 4.1) rather than those that do (in the lower rows) unless we judge the degree of harm and consensus in a particular case merits the more stringent and intrusive type of intervention.

4.13 However, there are cases where even if the conditions for the more coercive types of intervention can be considered to be met, such measures could not be enforced, could be enforced only at prohibitive cost, or could be expected to have adverse side-effects. Such circumstances, as we will see, are not just a theoretical possibility, and that is why we need the criterion of feasibility as well as that of proportionality. Further, following conventional processes for assessing regulatory or other proposals, we think it is necessary to show that general interventions such as transparency rules (illustrated in the left-hand column in Table 4.1) are inadequate before recommending product- or service-specific measures.

4.14 As will become clear in the following chapters, most of our recommendations focus on interventions of the type not directly involving coercive legal power (upper rows of Table 4.1). In a few cases, though, we think the three tests noted in Paragraph 4.2 (sufficiently serious harms, consensus and feasibility) are met and thus more intrusive state-introduced regulation is warranted. However, it is often difficult to find a clear way of ascertaining 'acceptable risk', meaning that proportionality and risk is inherently indeterminate and often politicised. For example, it is rarely the case that a fundamental justification can be given for, say, setting the speed limit on motorways at 70 miles per hour rather than 75 or 65, although no doubt some arguments can be given. But it is often possible to find a form of regulation that is acceptable, if not ideal, from a variety of viewpoints, and to a wide group of stakeholders and citizens who are otherwise opposed. Moreover, tricky judgments have to be made in so-called risk-risk decisions, where reduction of one risk may increase another,[85] or in conditions where interventions designed to protect one group of people adversely affect others. That is why the 'softening dilemmas' approach described in the previous chapter seems particularly appropriate to the developments we are considering here.

4.15 In each of the case study chapters that follow, we trace out the existing landscape of interventions affecting the developments we are looking at as well as identifying conflicts between ethical values and, where possible, assessing the benefits and the seriousness of the harms involved in each case. None of the developments we are concerned with exists in a void, and in most cases there is already a set of interventions in existence that involve some or all of the four basic types of interventions illustrated in Table 4.1. Moreover, many of the developments we are considering involve services that are provided across borders, meaning that we need to assess intervention at an international rather than national level. Taking these existing interventions into consideration, we recommend further intervention where we think it meets the threshold conditions referred to earlier and where we think it would help to reduce or soften the value-dilemmas we find.

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in England, Scotland and Wales are regulated at present by the Royal Pharmaceutical Society of Great Britain (currently changing to the General Pharmaceutical Council). The Pharmaceutical Society of Northern Ireland fulfils an analogous role.

84 The Medicines Act 1968 and subsequent UK regulations implementing EU legislation provide the legal framework for the control of medicines and medical devices in the UK. The Medicines and Healthcare products Regulatory Agency is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe.

85 See, for example: Wiener JB (1998) Managing the iatrogenic risks of risk management *Risk: Health, safety and environment* **9(1)**: 39–82.