

Expert Report to the Infected Blood Inquiry: Medical Ethics

April 2020





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Preamble

This report has been written by a medical ethics expert group appointed by Sir Brian Langstaff in 2019 on behalf of the Infected Blood Inquiry ('the Inquiry'). In the Letter of Instruction from the Inquiry, we were asked to respond to a series of specific questions grouped into six sections, together with supplemental questions added at a later date. This report is organised into those six sections and we respond to each of the questions, numbered as per the letters of instruction.

Our report discusses the ethical principles that should govern and inform clinical decision-making. We are instructed to express our opinion on the matters set out from today's perspective and, where we identify changes or developments, to make reference to them. With regard to legal variations between the devolved administrations, we focus on English law simply because that corresponds to our expertise. With regard to terminology, we use 'child' as a shorthand for any person under the age of 18 and 'doctor'/'clinician' as a shorthand for healthcare professional.

Anyone reading the report from start to finish will notice a degree of repetition. Having tested for consistency, we felt it was important to answer each question as fully as necessary, even where similar points were being made. In some cases, we have cross referenced between questions to indicate the relevance of material covered in more detail elsewhere in the report.

Section 1: General

This section answers Questions 19–23.

Introduction

Question 19. What are the ethical principles and approaches that apply, broadly, to clinical decision-making and practice? Please include a consideration of the ethical principles and approaches that apply when patients are wronged or harmed.

Supplemental Q7. Please address what the ambit of medical ethics is and how medical ethics interact with the legal obligations of a clinician.

Fundamental ethical principles

In general terms questions regarding decision-making, treatment, testing, information disclosure and record-keeping rest on a series of fundamental ethical principles. These are that:

- (1) Medical and public health interventions should be offered where they promote the best interests (welfare and security) of patient and populations.
- (2) Consideration of best interests, and the design and delivery of healthcare more broadly, is justified by respect for persons, including respect for their autonomy. This, in turn, requires that due consideration be given to a person's values, needs, rights and preferences. In general terms, while respect for autonomy has always been an ethical cornerstone of medicine, the meaning of this has been strengthened and clarified – in ethics, law and clinical practice over the past decades. While medical decision-making was previously paternalistic, it is now recognised that decision-making should be shared and that informed patients should have the power to decide what happens to their lives, even if these actions may be judged by others to be imprudent.
- (3) The practice of medicine is concerned not simply with individuals but with populations, and so must inevitably be concerned also with equity, vulnerability and distributive, procedural and social justice. This requires the fair allocation of resources and explicit consideration of the limits of medical care, and the need to take account of efficacy, cost-effectiveness and opportunity cost.

Given the social nature of both illness and healthcare, healthcare professionals are obliged to consider what is ethically owed not only to individual patients, but also to their families and loved ones, and to the local and global communities in which they live. While the ethical obligations owed to individuals and society generally cohere, there are times, including where populations are threatened by pandemics or public health emergencies, where these may 'come apart'. Global pandemics, including HIV, provide clear examples of how a threat to public health challenged the ethical standards of medical care that existed at the time of its emergence, transformed medical practice, infection control policies and social institutions (including blood services), and shaped the development of new standards of ethics and law. Progress in the diagnosis and management of HIV also illustrates how public health threats can become normalised over time, and how interventions and policies applied at the emergence of particular threats may become abandoned when no longer justifiable.

Sources of moral guidance

Guidance on clinical decision-making comes in many forms, including legislation, legal judgments, moral theories, academic journals, handbooks, guidelines and codes. Relevant international and domestic professional guidelines are now abundant, but they are not always synchronous, or contemporaneous with legal, social and scientific developments. Historically, they were fewer, more generalised and less comprehensive.

In 1993 the GMC stated that medical law and ethics should be part of the medical curriculum,¹ and the importance of medical ethics training was recognised long before this.² Medical professionals have had greater exposure to ethical approaches as professional guidance has become more explicitly ethical in its approach. This can be challenging for individuals if different guidelines are written from different (and not necessarily compatible) ethical standpoints. One could argue that guidance relating to the doctor patient relationship has traditionally been crafted in deontological terms (where morality of an action is based on whether that action is right or wrong on the basis of whether it conforms to duties or obligations on the doctors' side, and whether it adequately respects rights and moral claims on the patients'). However, important medical issues, such as resource allocation and the introduction and use of new technologies, are now assessed from an explicitly consequentialist perspective (where morality of an action is based on its consequences) through bodies such as the National Institute for Health and Care Excellence (NICE).

Sources of moral guidance include the following:

(i) *Law and medical ethics*

In the 1970s, interest in medical law and ethics was renewed.³ In the USA, bioethics was taking hold. Beauchamp and Childress's 1979 *Principles of Biomedical Ethics*⁴ included sections on respect for autonomy, its nature, human capacity for autonomy, and the meaning and justification of informed consent. In England, Ian Kennedy's highly influential Reith Lectures, published in 1981,⁵ called for more external involvement in the development of professional standards and a greater role for bioethics. Professional guidance, and gradually also the law,⁶ put greater focus on values as well as facts, on patient-centred decision-making and the patient's participatory rights and interests.

The proliferation of ethical guidance provided by professional bodies in the 1980s coincided with the growth of bioethics/medical ethics and medical/health law as academic disciplines, and an increasing acknowledgment of their relevance to practice and policy.

¹ GMC. *Tomorrow's doctors*. 1993. And see Consensus Statement by Teachers of Medical Ethics and Law in UK Medical Schools. Teaching medical ethics and law within medical education: a model for the UK core curriculum. *J Med Ethics* 1998; 24: 118-192.

² See, for example, BMA. *Professional Standards*. 1972, para 5 on teaching of ethics.

³ Brazier M, Devaney S, Mullock A. Reflections on bioethics and law: Yesterday, today and tomorrow. *Med L Rev* 2019; 26(2): 179-182: 'While there was undoubtedly a dearth of medical law scholarship and practice in the late 19th century and the first 80 or so years of the 20th century, a look further back in history allows us to discover a rich array of legal cases, legislation, and scholarship. 'Yesterday' (if defined as the mid-19th to mid-20th century), medical law seemed to disappear from view. The day before yesterday it flourished.'

⁴ Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*. New York: OUP, 1979.

⁵ Published in Kennedy I. *The Unmasking of Medicine*. London: Allen and Unwin, 1981.

⁶ McLean, SAM. *Autonomy, Consent and the Law*. Abingdon: Routledge Cavendish, 2010, 216. See also response to Q20 which describes the developing law on informed consent.

While law rests on ethical foundations and is, itself, deeply normative, law and ethics are not always in harmony.⁷ The ethicist is concerned principally with what should or should not be done, and establishing whether there are ethical standards below which practice should not fall irrespective of time or place, as well as establishing standards to which we should aspire when defining best practice. The medical lawyer, in contrast, is most interested in whether the law is breached and whether it is just, consistent and in accordance with modern principles.

Societal shifts in morality are sometimes led by law, but because legal change can be cautious and slow, in other instances, the law does not keep up with social or scientific developments. Ideally, we would like to think that the law reflects high ethical standards, which are in turn reflected in the specific guidance professional bodies provide for those operating in a particular field, but on occasion they are, and were, out of step. An example of this, explored further in response to Q20, relates to the degree of professional autonomy given to doctors. During the 1970s, 1980s and 1990s, transformative social movements (such as the civil rights movement and feminism, greater recognition of human rights domestically and internationally, burgeoning litigation and scandals that dented the trust in doctors) reduced deference and led to patients demanding more involvement in decisions about themselves. In this instance, social change, moral scholarship and professional guidance evolved ahead of legal change. In situations like this, it is beholden upon practitioners to work to these higher standards, despite there being reduced threat of sanction or opprobrium.

(ii) *Principles*

Throughout the report we adopt the language of moral principles, but we do so mindful of the philosophical debates regarding their meaning and usefulness. In ordinary language a principle is defined as:

A fundamental truth or proposition on which others depend; a general statement or tenet forming the (or a) basis of a system of belief, etc.; a primary assumption forming the basis of a chain of reasoning.⁸

In 1979, the aforementioned Beauchamp and Childress set out four principles of biomedical ethics.⁹ The aim was to provide a framework for moral reasoning that derived from ‘common morality’ rather than high-level moral theory. The four principles are: autonomy (protecting the right of individuals to make their own choice), justice (fairness, equity and equality¹⁰), beneficence (doing good), and non-maleficence (expected benefits should outweigh expected harms). There has been criticism of the ‘four principles approach’, both by those who question the value and appropriateness of a principles-based approach to moral reasoning, and by those who question the broad-based appeal of what look to be very culturally-specific principles. Nonetheless, they have been highly influential, particularly among clinicians, and Beauchamp and Childress’s updated and revised treatise is now in its 8th edition (2019).

Our use of the word ‘principle’ is not tied explicitly to this work, rather it is an umbrella term for the guiding considerations, values and the shared moral goals that provide a basis for ethical decision-making in a medical setting.

⁷ Miola J. *Medical Ethics and Medical Law: A Symbiotic Relationship*. London: Hart, 2007.

⁸ Oxford English Dictionary: <https://www.oed.com/view/Entry/151459?rskey=3feAto&result=1#eid>.

⁹ Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*. Oxford: OUP, 1979.

¹⁰ Commitment to equality requires that healthcare should not vary in quality because of factors such as personal characteristics and socioeconomic status. Fairness also requires commitment to equity, which recognises that not all will start from the same position. For example, some patients will require more information, reassurance and time than others; some will require expensive treatment that will affect what is available to others.

(iii) *Professional guidance*

From the late-twentieth century, international and national guidance for healthcare professionals burgeoned. National advice was supplemented with government health circulars, memorandums and letters. We do not attempt to catalogue or cite them all – a task better suited to medical historians – but draw upon relevant and prominent guidance for comment in our report.¹¹

Guidance from the British Medical Association (BMA) and the General Medical Council (GMC) has been particularly influential. The BMA is a professional association for UK doctors, founded in 1832 and recognised as a trade union in 1974. The BMA produced a *Handbook of Medical Ethics* in 1974 which it updated in 1980, 1981 and 1988. Its handbook *Medical Ethics Today* was produced in 1993. The second edition in 2003 was twice the length. It is now published online.¹²

The GMC is one of 10 regulators overseen by the Professional Standards Agency. Standards of professional conduct promulgated by the GMC protect the public by requiring high levels of professionalism and generating trust. Failure to follow GMC guidance can lead to investigation of a doctor's fitness to practise. Historically, the Medical Act 1858 made provision regarding 'infamous conduct in a professional respect' (later changed to 'serious professional misconduct') where a doctor, in pursuit of his profession, brings disgrace or dishonour on the profession. The GMC publishes guidance, previously known as the 'blue book', on the essentials of good practice. Today, that guidance is very detailed and specific, but the 1963 and 1970 editions of the GMC's *Function, Procedure, and Disciplinary Jurisdiction* were incorporated into single 16-page documents. These documents gave *examples* of misconduct rather than a closed list. The Council equated infamous conduct to a 'serious breach of medical ethics'.¹³ In 1980 the guidance grew to 22 pages and the examples were expanded upon.

The GMC now has 32 guidelines. The core guide is called *Good Medical Practice* 2013 (first issued in 1995, then in 1998, 2001, 2006) and branching from this are more specific guidelines on issues such as confidentiality, consent, candour, and research. *Good Medical Practice* 2013 requires doctors to:

- make the care of your patient your first concern
- be competent and keep your professional knowledge and skills up to date
- take prompt action if you think patient safety is being compromised
- establish and maintain good partnerships with your patients and colleagues
- maintain trust in you and the profession by being open, honest and acting with integrity.¹⁴

¹¹ A list of documents provided to the group is set out in the Appendix to the Letter of Instruction, <https://www.infectedbloodinquiry.org.uk/sites/default/files/2020-02/2019-02-17.%20Supplementary%20letter%20of%20instruction%20to%20Ethics%20Expert%20Group.pdf>.

¹² BMA. *Medical Ethics Today*. <https://www.bma.org.uk/advice/employment/ethics/medical-ethics-today>.

¹³ GMC. *Function, Procedure and Disciplinary Jurisdiction*. 1963, p 7: 'In other words, [infamous conduct] means a serious breach of medical ethics.' And 1970, p 6.

¹⁴ GMC. *Good Medical Practice*. 2013. <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice>.

The Council acknowledges the need for professional discretion and judgement. It uses the terms ‘you must’ and ‘you should’. ‘You must’ refers to overriding duties and ‘you should’ to the ways in which a doctor can meet the overriding duties as well as to duties or principles that do not apply in all situations.

The NHS was formed on the basis that treatment is free at the point of delivery and provided on the basis of need. Behind this foundational claim lie other moral imperatives which have shaped the way in which care is delivered. Government guidance on clinical decision-making encourages compliance with the human rights of patients and the duties of healthcare professionals. This flows from international and domestic statements of human rights, such as the European Convention on Human Rights and the Human Rights Act 1998. Commitment to patient interests is now set out in NHS Constitutions and Charters¹⁵ which put the patient at the heart of everything the NHS does, and promotes accountability to the public, communities and patients. Commitment is made to values such as respect and dignity, commitment to quality of care, compassion and improving lives. Commitment to patient rights includes access to healthcare services, quality of care, nationally approved treatments, respect for consent and confidentiality, informed choice of provider, involvement in one’s healthcare, and the right to complain and to redress.

Moral judgements of past issues

Changes in law, professional guidance and practice, according to sociopolitical and cultural conditions, raise a difficult question about how to judge historical acts in the face of progress. Moral relativism is the idea that moral judgements are valid or invalid only relative to a particular culture or time and that no single position is privileged over all others. It can be contrasted with moral objectivism or realism, which is the idea that, notwithstanding cultural differences, some moral principles are universalisable (remain important in different contexts and at different times). Accepting that what may have been regarded as appropriate (by groups or individuals) has changed over time does not imply an acceptance of moral relativism. Rather, the fact that fundamental moral principles may be relatively stable and consistent and that individuals retain moral agency suggests that past behaviours and practices, that may have been unchallenged or standard practice at the time, may still be considered morally questionable.

There are numerous historical examples of once-accepted practice that horrify us today. Pelvic examination of women under anaesthetic at training hospitals without their consent was once common practice.¹⁶ It served educational goals and was considered preferable to doctors learning how to perform intimate examinations on conscious patients with their consent. Today, the practice is condemned as a violation of the woman’s bodily integrity and a gross breach of trust. Likewise, at Alder Hey Hospital between 1988 and 1995, organs from children who had died were retained for education and research purposes.¹⁷ Parental consent was not obtained, and this was justified by the medical profession on the basis that to do so would cause them distress. When the truth was revealed, parents were distraught that they had not been consulted and that their children’s organs had been kept in hospital

¹⁵ Patient Rights (Scotland) Act 2011 which made provision for a Charter of Patient Rights and Responsibilities; NHS Wales. *The Core Principles of NHS Wales*. www.wales.nhs.uk/nhswalesaboutus/thecoreprinciplesofnhs-wales; DHSC. *The NHS Constitution for England 2012* (updated 2015). <https://www.gov.uk/government/publications/the-nhs-constitution-for-england>.

¹⁶ Coldicott Y, Nesheim B-I, MacDougall J, Pope C, Roberts C. The ethics of intimate examinations—teaching tomorrow’s doctors. *BMJ* 2003; 326: 97.

¹⁷ House of Commons. *The Royal Liverpool Children’s Inquiry Report*. London: 2001. HC12-II. (The Redfern Report).

storage. In the course of the investigation it was revealed that the practice was widespread and the Retained Organs Commission was established. New guidelines, consent forms and legislation followed.¹⁸

Finally, it is clear that at various times individual rights of patients have, by today's standards, been inappropriately sacrificed for the common good. The possibility of achieving a substantial benefit for society as a whole has sometimes trumped our concern for those who might have to experience harms in its pursuit. This has been particularly true in the context of medical research, where we judge the actions of the past harshly irrespective of any scientific or medical advance that followed.

This Inquiry is asked to consider actions from the past which may or may not have been subject to the same ethical standards imposed today. It is therefore important to recognise that although people may have been operating in line with contemporary moral norms, their actions can be challenged where we can identify relevant fundamental moral values which should have been respected, irrespective of time or place.

Shifts in emphasis

While the ethical principles on which medicine is based have remained largely constant (although their scope and application may have changed), a series of sociocultural and philosophical shifts have occurred over the last 40 years that are relevant to the issues under review in this Inquiry. These changes relate to the evidentiary basis of medicine, the development of policy, the relationship between 'facts' and values, and the role of research and innovation in healthcare.

(i) *Facts vs Values*

Whereas previously, medicine was seen to be a purely scientific, fact-based practice, it is now generally recognised that medicine involves both facts and values (and value beyond the significance of disease). Even questions that were previously thought to be a matter 'purely' of science or data, such as whether a treatment 'works', what quality of life is and whether a treatment is 'futile' or not, are now recognised as value-laden.

Looking back to the late 19th and early 20th century, the profession was seen as having an expertise, status and power which made medical advice difficult to challenge or ignore once sought. Change came about incrementally.

(ii) *Evidence*

Medicine has always been based on evidence and (to a lesser extent) theory and understandings of the mechanism of disease. Over the last 30 years, medicine, and more recently public health, has changed to explicitly incorporate epidemiological and clinical evidence into practice and policy. While 'evidence-based medicine' and personalised medicine have each emphasised the importance of bioscientific knowledge and scientific methods in medicine, there has also been a gradual recognition that evidence has many forms and is not independent of the society in which it is generated, the healthcare professionals who interpret it or the individuals to whom it is applied. In this regard, randomised-controlled trials do not represent the totality of evidence; other forms of evidence, including philosophical insights, qualitative data and ethnographic understandings are all relevant to medicine.

¹⁸ Notably The Human Tissue Act 2004.

(iii) Policy making

Whereas policy was previously developed by ‘experts’ working in isolation of affected communities and using only ‘scientific’ or epidemiological data, this is no longer thought sufficient to enable the development of policy, particularly in health. Instead, it is now generally accepted that for policy to be regarded as robust and ethically defensible it must be defensible; be based on all relevant information; involve all relevant stakeholders; be open and transparent; be capable of revision; and be fairly enforced.¹⁹

(iv) Innovation and experimentation

It is now widely accepted that experimentation and innovation are necessary for the progress of medicine and for improving patient outcomes. These domains of practice are, however, not value-neutral and must always be ethically defensible. In this regard, clinical medicine and health policy are connected to the ethical issues that underpin research, including consideration of scientific merit, harms/risks and benefits, respect and consent and decision-making, social welfare, vulnerability and equity.

Harms and wrongs

It is self-evident that an act or omission in medicine can lead to multiple harms to many people. Patients can be harmed by the interventions they receive or fail to receive; the advice they are given or not given; and by the timing and manner of its delivery. In law, harm refers to loss, injury or damage. Bodily harm is physical, but harm can also be psychological, reputational, financial or social, and involve interference with a person’s social, economic or cultural rights.

While the Inquiry has directed our focus in Question 19 to the harms and wrongs to patients, it is important to note that harm can extend to the patient’s family, dependants and friends. Also, medical errors and incidents can harm the healthcare professionals responsible for the patient’s care, particularly if they lack control or culpability due to institutional problems or lack of guidance, regulation, funding or support. Harm to patients can also result in reputational harm to the profession and those responsible for its regulation.

Where a legal wrong is established, justice takes various forms. Procedural justice focuses on fairness; retributive justice on punishment. Distributive justice seeks to divide burdens and benefits fairly and equitably among members of society, whereas corrective justice aims to restore parties (as far as possible) to the pre-transactional state.

Not all harms are legal wrongs. In ethical terms we can accept that someone may claim to have been harmed even where society has refrained from establishing a legal prohibition or sanction. A particularly interesting form of harm in this context is that of denying a person an open future. This is a term first coined by Joel Feinberg in 1980 with respect to children.²⁰ The idea is that children hold rights in trust. These rights might be breached where the parent or others make important life decisions that limit the child’s right to make autonomous decisions in the future, in circumstances where they cannot exercise rights themselves, but will gain such rights on maturity. Clearly, children are an important focus of concern in this Inquiry.

¹⁹ Daniels N, Sabin J. Limits to health care: fair procedures, democratic deliberation, and the legitimacy problem for insurers. *Philosophy and Public Affairs*. 1997; 26: 303-350.

²⁰ Feinberg J. *The Child’s Right to an Open Future*. In Aiken W, LaFollette H (eds). *Whose Child?* New Jersey: Rowman & Littlefield, 1980, 124-53. For recent acknowledgement of its relevance to biomedicine see: Council of Europe, *Strategic Action Plan on Human Rights and Technologies in Biomedicine 2020-2025*, para 24. <https://rm.coe.int/strategic-action-plan-final-e/16809c3af1>.

However, one might wish to claim that it is important to address the extent to which adult patients were also denied an open future, if it can be shown that they were treated as if they could not make decisions they were capable of making in the present, or indeed prevented from doing so because they were not made aware of the need to address the matter.

Wrongs denote unjust treatment and can be moral as well as legal. It is possible (both logically and empirically) to harm someone and for them either not to feel harmed, or for them to be unaware of the harm. In this case they would be wronged further if the harm remained concealed or misunderstood. It is possible to argue that a healthcare system has wronged its patients if it does not ensure that they understand the ethical standards governing practice sufficiently to recognise when they are being harmed. It is also incumbent upon a healthcare system to ensure that a duty of candour operates where harm has occurred (see Q32 below).

(i) *Consent to the risk of harm*

As outlined above, there is an ethical duty incumbent on doctors not to undertake actions expected to do more harm than benefit (non-maleficence). Most medical interventions have side-effects or carry risks. Where patients undergoing treatment or clinical research have given valid and informed consent (see Q20 below) most treatments can proceed on the basis that the patient understood the nature and likelihood of harm occurring.

However, not all harms can be consented to. It has been held that consent is not a justification for acts that are contrary to the public interest.²¹ It would not, for example, be ethical to enrol a person in clinical research where risks have not been minimised as far as possible, notwithstanding the individual's consent. Researchers and ethics committees seek to minimise harm and it is the responsibility of the researcher to ensure that the patient is made a 'fair offer'.

Likewise, in the context of clinical care, doctors should seek to balance harms and benefits when selecting the range of treatment options open to the patient. Patient choice is relevant, but a patient is not entitled to any treatment they desire. A clinician must ensure that alongside ensuring the patient's informed consent, they make an assessment of clinical benefit and abide by relevant guidance relating to resource allocation.²²

(ii) *When harm befalls the patient*

From an ethical perspective, when harm befalls a patient, three factors in particular are important:

- Responsibility must be attributed in order to ensure appropriate action is taken to prevent further harm and to understand who (be that individual or institution) should offer an explanation, apology and relevant redress.
- Openness and transparency are needed to ensure that lessons can be learned and so that the person harmed can assess the actions taken, understand their experience fully, and pursue further action if necessary.
- Recognition is required so that those responsible for the harm can understand its nature and the impact it will have had on the person(s) harmed.

²¹ *R v Brown* [1994] 1 AC 212 (HL).

²² Brazier M. Do no harm – do patients have responsibilities too? *Cambridge Law Journal* 2006; 65(2): 397-422; Cave E. Selecting treatment options and choosing between them: Delineating patient and professional autonomy in shared decision-making. *Health Care Analysis* 2020; 28: 4-24.

When harm befalls the patient as a result of a medical professional or institutional act or omission, there may be recourse to legal action by the patient or, if the patient has died, by close family. For example, a crime might be committed if there is a lack of valid consent (see Q20 below), or where unlawful treatment inflicts grievous bodily harm according to section 20 of the Offences Against the Person Act 1861 or causes death.²³

Where treatment is negligently performed, or material risks and reasonable alternatives are not disclosed and harm results, the patient or family may be able to sue in negligence. An aim of tort law is to award compensation for the actions that are proven and the harm that is affirmed. Compensation can include damages for the injury itself and for future financial loss, including treatment costs on a private basis. In negligence, the burden of proof is on the claimant. If harm has resulted, but the claimant cannot prove that it is due to negligence, there will be no claim.²⁴

Where a product is defective and it causes injury, producers may be strictly liable under the Consumer Protection Act 1987 (which implements the Product Liability Directive 85/374/EEC). What constitutes a product, when it is defective and what comprises injury is not straightforward. In *A v National Blood Authority*²⁵ ('*A v NBA*') it was not contested that blood products are products for the purposes of the Consumer Protection Act. A defence applies if the defect was not discoverable in the light of scientific and technical knowledge when the product was supplied. In *A v NBA*, it was held that the defence is not relevant if the defect was or should have been known, even if measures to rectify the defect did not exist.

Clearly, not all harms will result in a valid or successful legal claim. A problem with medical claims is that harms are often attributable to multiple factors such as individual errors, unsafe systems, and sometimes also to the acts or omissions of the patient or to the natural course of a medical condition. It can be difficult in practice to prove who or what caused the harm. This is exacerbated if there is a lack of openness and transparency when things go wrong.

Extralegally, bodies such as NHS Improvement aim to enhance safety, and to investigate and learn from errors. The NHS Constitution for England 2015 sets out a patient right to complain and to redress, and pledges to ensure that organisations learn from complaints and claims. Likewise, the Scottish Charter of Patient Rights and Responsibilities sets out a right to feedback about treatment and to have concerns and complaints heard.

The government has sometimes offered alternative payments for medical harm on a no-fault basis. We give two examples. In each, the difference between the support awarded and the monetary value of a successful claim in negligence is substantial.

Under the Vaccine Damage Payments Act 1979,²⁶ payments are awarded to claimants who can prove on the balance of probabilities that injury was caused by vaccination. They receive a one-off payment of £120,000. For these individuals, claims under the Consumer Protection Act or in negligence are less likely to succeed because the public health benefits of vaccination might justify risk to a small number of patients.

²³ A charge of gross negligence manslaughter might be brought against individual doctors or a charge of corporate manslaughter against a Trust or the DHSC under the Corporate Manslaughter and Corporate Homicide Act 2007. Claims predating the Act are reliant on the common law offence of corporate manslaughter and are less likely to succeed. See analysis in Kazarian M. Who should we blame for healthcare failings? Lessons from the French tainted blood scandal. *Med L Rev* 2019; 27(3): 390-405.

²⁴ See, for example, *Collyer v Mid Essex Hospital Services NHS Trust* [2019] EHC 3577 (QB). Note that there may be other exceptions to availability of a remedy in negligence. For example, the Coronavirus Act 2020, ss 11-13 will provide additional indemnity for clinical negligence liabilities arising from the COVID-19 response.

²⁵ *A v National Blood Authority* [2001] 3 All ER 289. See further discussion of this case below.

²⁶ UK Government, *Vaccine Damage Payment*: <https://www.gov.uk/vaccine-damage-payment>.

Since 1988, successive governments have provided support for people infected with HCV and HIV through NHS treatment. Reformed Infected Blood Schemes were introduced in Scotland, Wales, Northern Ireland and England in 2017,²⁷ though there have been significant disparities between them.²⁸ The provision of payment does not amount to an admission of fault and the aim is to support rather than compensate. In March 2019 there were 2,993 people registered for support under the English scheme which made annual payments ranging from £4,519 (for HCV stage 1) to £36,519 (for those co-infected with HIV and HCV stage 2), as well as certain one-off payments.²⁹ Additional funding was announced in April 2019.³⁰

²⁷ Scotland: <https://nhsnss.org/services/practitioner/medical/scottish-infected-blood-support-scheme/>; Infected Blood Payment Scheme for NI: <http://www.hscbusiness.hscni.net/services/2876.htm>; Wales: <https://wibss.wales.nhs.uk/>; England: <https://www.nhsbsa.nhs.uk/england-infected-blood-support-scheme>.

²⁸ See, for example, BBC News. Contaminated blood scandal: Welsh payouts 'not fair'. <https://www.bbc.co.uk/news/uk-wales-48337719>.

²⁹ NHS Business Services Authority. *England Infected Blood Support Scheme Annual Report 2018/2019*. <https://www.nhsbsa.nhs.uk/sites/default/files/2019-10/EIBSS%20Annual%20Report%202018%2019%20FinalV2.pdf>.

³⁰ DHSC. *Infected Blood Scandal: Increased Financial Support for Victims Confirmed*. 20 April 2019: <https://www.gov.uk/government/news/infected-blood-scandal-increased-financial-support-for-victims-confirmed>.

Consent

This section answers Questions 20–23.

Question 20. What are the principles of informed consent?

Basic principles

Adult patients with requisite mental capacity should not be subjected to medical intervention unless they have given a valid and informed consent. If clinicians proceed without it, they are liable in law. They are also accountable to regulatory bodies and should take into account ethical guidance on consent.

The philosophical basis for informed consent is the principle of patient autonomy – by knowingly considering, and then accepting rather than rejecting a proposed course of action based on adequate information, a patient expresses their autonomy and their responsibility for the decision, while also accepting the expertise of the clinician.

It is important to note that the concept of autonomy is contested and has multiple definitions. The ascendancy of individual autonomy in medical ethics, driven by liberal and rights-based Western philosophies, has not been without its critics. An ethic-of-care approach³¹ argues that relational autonomy³² is more in tune with patient needs and desires, and globally many commentators have argued that autonomy is only of value or valued within very specific cultural groups and/or settings. Onora O’Neill in her Gifford and Reith lectures³³ argued that the focus on individual autonomy has driven a breakdown of bilateral trust. For O’Neill, a principled, non-individualistic version of autonomy might help rebuild two-way trust between doctors and patients.³⁴

In addition to protecting autonomy, the doctrine of informed consent also promotes patient dignity, partnership and trust. It requires the clinician to treat each patient as an individual. This does not always occur. The 2020 independent inquiry reporting into issues raised by breast surgeon Ian Paterson found many failings with respect to consent. Operations were carried out needlessly and patient trust was breached.³⁵ Paterson was convicted of criminal offences and the report made recommendations for reform to which we will return (see response to Q24e).

Consent is more than the patient simply agreeing to or refusing what is proposed. Consent should be voluntary, denoting an absence of control by others, and informed, requiring sufficient information and understanding to allow autonomous choice. Three elements of consent therefore include agency (capacity), liberty (absence of coercion), and autonomy. In considering the issue of coercion it is important to remember that one can effectively coerce someone without intending to do so, particularly if one holds a position of power and operates within a context where the other person is disempowered by their circumstance or role. So, for example, a clinician has high status and a hospital is a challenging environment even for long term patients, therefore the ethical imperative to avoid coercion requires a more sophisticated approach than simply desisting from actual force.

³¹ An ethic-of-care approach is based on individuals maintaining just and caring relationships.

³² Relational autonomy respects the person’s control over their own life but within the social context in which that takes place. It recognises that other people (such as clinicians and family) often have a central role in decision-making.

³³ Gifford lectures Edinburgh 2001; BBC Reith Lectures 2002.

³⁴ O’Neill O. *Autonomy and Trust in Bioethics*. Cambridge: CUP, 2002.

³⁵ James G. Rev’d (Chair). *Report of the Independent Inquiry into the Issues raised by Paterson*. 2020 HC 31.

Consent should be dynamic and responsive to the patient's health, needs and views. Though the law considers informed consent in relation to separate interventions, such as a treatment or examination, this does not signal the beginning or end of the consent process. The law also focuses largely on the relationship between the patient and treating clinician, but in practice the patient's family (with the patient's agreement) and a team of healthcare professionals may be involved in decision-making.

Patients who cannot give consent

Some patients are not able to give a valid consent in law. In the 1970s, the Victorian attitude that gave fathers control of their children (including in matters relating to medical treatment) was challenged. In *Hewer v Bryant*³⁶ Lord Denning said:

The common law can, and should, keep pace with the times. It should declare ... that the legal right of a parent to the custody of a child ends at the 18th birthday: and even up till then, it is a dwindling right which the courts will hesitate to enforce against the wishes of the child, and the more so the older he is. It starts with a right of control and ends with little more than advice. (p 369)

However, it was not until 1985 that the *Gillick* case established that children under the age of 16 who are 'competent' (having the ability to fully understand relevant information and make a decision)³⁷ can give a valid consent without the need to involve their parents. Children over the age of 16, on the other hand, were treated as adults for the purpose of consent to treatment and diagnosis, in accordance with the Family Law Reform Act 1969, s 8. Child consent is considered in more detail in response to Questions 23, 24i, 26i, 30g.

The test for adult incapacity was not set out in law until 1994. Even then, there were divergences between law and professional guidance.³⁸ Previously, the BMA and GMC provided ethical guidance on assessing capacity.³⁹ In *Re C*⁴⁰ Mr Justice Thorpe held that a patient has capacity to refuse to consent to medical treatment if he or she can understand and retain the information, believe the information, and weigh the information to arrive at a choice. This three-fold test was later the basis for the assumption of capacity and test for incapacity applicable to people aged 16 and over, set out in the Mental Capacity Act 2005 in England and Wales. Capacity is decision-specific and can sometimes fluctuate. Where an adult cannot consent due to lack of capacity, decisions must be made according to a best-interests test set out in section 4 of the Act.⁴¹ In Scotland, the Adults with Incapacity (Scotland) Act 2000 applies and in Northern Ireland the Mental Capacity Act (Northern Ireland) 2016. There are differences between the devolved approaches, but we do not consider them to be of sufficient relevance to merit a full explanation here.

³⁶ [1970] 1 QB 357.

³⁷ *Gillick v W Norfolk & Wisbech AHA* [1985] 3 All ER 402.

³⁸ Tan JOA, McMillan JR. The discrepancy between the legal definition of capacity and the British Medical Association's guidelines. *J Med Ethics* 2004; 30: 427-429.

³⁹ BMA. *The Handbook of Medical Ethics*. 1980, para 1.13; BMA/Law Society. *Assessment of Mental Capacity: Guidance for Doctors and Lawyers*. 1995; GMC. *Seeking Patients' Consent: The Ethical Considerations*. 1998, paras 19-21.

⁴⁰ *Re C (Adult: Refusal of Treatment)* [1994] 1 WLR 290.

⁴¹ The NHS Constitution for England 2015 encapsulates this in the following way:

'You have the right to accept or refuse treatment that is offered to you, and not to be given any physical examination or treatment unless you have given valid consent. If you do not have the capacity to do so, consent must be obtained from a person legally able to act on your behalf, or the treatment must be in your best interests. You have the right to be given information about the test and treatment options available to you, what they involve and their risks and benefits.'

The tests for capacity govern when a patient can give a valid consent or refusal to medical interventions. In the years before a legal test was set out, uncertainty as to the appropriate test had potential to result in invalid consent or refusal being relied upon and, conversely, assumptions that patients lacked capacity, notwithstanding their ability to understand the information and make a decision. The latter risk was higher in relation to people with a disability. The social model of disability was developed in the 1970s and 1980s to challenge the medical model which focused on the nature of the condition rather than what was required by society to ensure that individuals are not excluded or restricted. The UN Convention on the Rights of Persons with Disability 2006 reaffirms that all people with disabilities enjoy all human rights and fundamental freedoms and expects bodies to make ‘reasonable adjustments’ to allow this to happen.

Whether or not the individual can give a valid consent, it is important that they are given opportunities to participate in decisions about them, and that their views and values are given due consideration. In clinical research, the assent of participants should generally be sought where they are able to participate but not able to give the requisite legal permission. This is discussed further in response to Q30g.

We have moved away from category-based assumptions about who is and who is not competent, just as we have moved away from the idea that capacity is an all or nothing state. So once again, judgement is required to ensure that patients (even young children) are given the opportunity to consent when they can.

Valid consent

In law, a valid consent is required to protect the doctor from a claim in battery under the civil law or assault under the criminal law. An exception exists in cases of emergency (see Supplemental Q12 below). To be valid, consent must be given by someone who has legal capacity, be freely given, and the patient must be informed in broad terms of the nature of the procedure. Battery is a non-consensual touching and is not dependent on proof of bodily harm.⁴² Battery has a long legal history with recorded decisions going back to the 13th century.

The legal consequences that might flow from not obtaining consent depend on the circumstances. If a doctor performing a bladder operation on an anaesthetised patient finds an unrelated abnormality of the uterus, and undertakes a non-urgent hysterectomy, the doctor would commit a battery, even if the operation improves the patient’s health. Consent to a new procedure cannot be implied on the basis that it would be good for the patient. Going a step further, if the doctor has performed the bladder operation knowing it was unnecessary, then consent – however explicit – will be invalid and there may be a public interest in prosecution. Prosecutions are rare, in part because the burden of proof is proof beyond reasonable doubt. In 2017, Ian Paterson was found guilty of 17 counts of wounding with intent and three of unlawful wounding for performing unapproved procedures and unnecessary operations.⁴³ An independent inquiry (referred to above) found that: ‘Paterson was not alone in breaking the rules. Others – for example, the hospitals and the regulators – were aware of his malpractice and allowed it to continue, as well as breaking the rules themselves.’⁴⁴

⁴² *Chatterton v Gerson* [1981] 1 All ER 257.

⁴³ His sentence was considered unduly lenient in *R v Paterson* [2017] EWCA Crim 1625.

⁴⁴ James G. Rev’d (Chair). *Report of the Independent Inquiry into the Issues raised by Paterson*. 2020 HC 31.

Unfortunately, public understanding of consent sometimes overemphasises its role in protecting the doctor from prosecution, as opposed to that of protecting the patient from inappropriate or unwanted interventions. It is therefore important to link the legal requirement to obtain consent to the ethical requirement to respect bodily autonomy and integrity and emphasise the importance of avoiding the harms associated with overriding either.

Development of the doctrine of informed consent

The legal consequences of not giving sufficient information differ according to the cause of action. To avoid committing a battery, one aspect of a valid consent is that the doctor must give the patient *basic* information. Basic information means letting the patient know broadly what they are potentially agreeing to, such as an operation on the left leg to address a swollen knee. Basic information is insufficient to ensure that the patient participates in the decision in a manner that will protect their autonomy. For that, the patient would need to know more about the operation proposed, such as its likely risks and benefits.

Today, a patient can sue in negligence if reasonable care is not taken to ensure that they were given sufficient information about risks and benefits of treatment and reasonable alternatives so as to make a choice.⁴⁵ Technically, valid consent is not lacking in such a case, provided that the requirements of the law of battery are satisfied, but the patient can nonetheless sue in negligence, because the consent was not sufficiently informed. Not all patients *want* to receive information about risks and alternatives, and there is no obligation to disclose information to patients who have made it clear that they do not want it.⁴⁶

Though, like battery, the law of negligence has a long history, its development in relation to informed consent has been incremental. Historically, the civil common law doctrine of consent has waxed and waned in response to cultural and social developments in its protection of patient autonomy. Dalla-Vorgia et al., have found evidence of reliance on consent in medical practice in the works of Plato and Hippocrates. They argue that the moral foundation was respect for patient autonomy and fear as to the consequences of medical failure.⁴⁷ More recently, in 1767, the importance of informed consent was recognised by the courts. In *Slater v Baker & Stapleton*, a surgeon and apothecary were found negligent for having unskillfully and unreasonably failed to tell a patient that they intended to reset his badly healed broken leg so that the patient ‘may take courage and put himself in such a situation as to enable him to undergo the operation’.⁴⁸

In the late 19th century, medicine and professionalism advanced and safety and pain relief improved. By 1954, faith in these advances led doctors and the courts to reduce emphasis on managing patient expectations of the ordeal to come through information provision.⁴⁹ In *Bolam v Friern Hospital Management Committee* (1957) (*Bolam*) in England and Wales,⁵⁰ the court determined that the standard of care in negligence for skilled professionals in relation to both treatment/diagnosis and the giving of advice about treatment was that of the ‘reasonable doctor’. Where there were different or discordant expert medical opinions, the doctor had

⁴⁵ *Montgomery v Lanarkshire HB* [2015] UKSC 11.

⁴⁶ *Ibid*, [85].

⁴⁷ Dalla-Vorgia P, Lascaratos J, Skiadas P et al. Is consent in medicine a concept only of modern times? *J Med Ethics* 2001; 27: 59-61.

⁴⁸ *Slater v Baker & Stapleton* 95 ER 860, 2 Wils KB 359 (1767). And see *Gerber v Pines* [1934] 79 Sol Jo 13.

⁴⁹ McLennan EB. Legal decisions and legislation. *The Medical Annual* 1955; 212: 217-218, discussing *Daniels v Heskin* [1954] IR 73.

⁵⁰ *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582. See also *Hunter v Hanley* [1955] SLT 213 (Scotland); *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871.

only to comply with one of them in order to escape liability in negligence. *Bolam* marked the height of a period of judicial deference and medical paternalism. Beauchamp and Childress define paternalism as:

the intentional overriding of one person's preferences or actions by another person, where the person who overrides justifies this action by appeal to the goal of benefiting or of preventing or mitigating harm to the person whose preferences or actions are overridden.⁵¹

The courts feared defensive medicine practices⁵² and were slower to react to ethical developments in support of patient autonomy than international counterparts.⁵³ In 1985, Raanon Gillon argued that: 'Consent ... requires action by an autonomous agent based on adequate information and is by definition informed consent.'⁵⁴ He urged doctors to recognise the ethical relevance of informed consent, even if the law was slow to do so:

Accounts of what the law stipulates in any particular jurisdiction ... do not in themselves provide moral justification for a moral claim. At most they can be used as part of a moral claim that there is a general presumption that it is a good thing to obey the law.⁵⁵

Gillon argued that even if the law left it to doctors to decide what information to give to patients, doctors are still required to act morally: 'to be given the legal responsibility of making a moral decision is precisely not to be absolved from doing so.'⁵⁶

In 1997, a gloss was added to the *Bolam* test in *Bolitho*, requiring that the body of medical opinion is logical and defensible in the judge's opinion.⁵⁷ And in 2015, the UK Supreme Court in *Montgomery v Lanarkshire Health Board (Montgomery)* held that *Bolam* should no longer apply in the context of negligent non-disclosure of risk:

An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken.⁵⁸

Lords Kerr and Reed gave the leading judgment with which the other five Supreme Court Justices agreed. They made clear that doctors have a duty to take reasonable care to inform patients of material risks and reasonable alternatives of treatments:

The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it. [87]

⁵¹ Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*, 7th edn, OUP 2013: 215.

⁵² Lord Woolf, Are the courts excessively deferential to the medical profession? *Med L Rev* 2001; 9(1): 1-16.

⁵³ Other countries that had adopted the *Bolam* test with respect to medical treatment/diagnosis had ruled that the test should not apply to information disclosure. USA: *Canterbury v Spence* (464 F2d 772, 782 DC Cir 1972); Canada: *Reibl v Hughes* [1980] 2 SCR 880; Australia: *Rogers v Whitaker* (1992) 175 CLR 479; Malaysia: *Foo Fio Na v Dr Soo Fook Mun* (2007) 1 Malayan Law Journal 593.

⁵⁴ Gillon R. Consent. *BMJ*. 1985; 291: 1700-1701.

⁵⁵ Gillon R. *ibid*.

⁵⁶ Gillon R. *ibid*.

⁵⁷ *Bolitho v City and Hackney Health Authority* [1998] AC 232.

⁵⁸ *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [87] (Lords Kerr and Reed).

The *Montgomery* decision is based on principles of self-determination [80], partnership [77]-[78], support [90] and choice [75] and of a move away from paternalism [81]. Devaney and Holm consider it to have brought about a *revised* deference: *Montgomery* does not deny the relevance of medical expertise, but it firmly recentres the focus on the interests of the patient.⁵⁹ It should be noted that *Montgomery* only goes so far. If a clinician breaches the duty of care, it remains for the claimant to establish that the breach caused them harm. Failure to warn of a material risk as defined in *Montgomery* is not sufficient to give rise to liability.⁶⁰

Though the case of *Montgomery* is rightly seen as ‘landmark’, the effect on clinical practice is limited by two factors. First, the case law was already shifting away from *Bolam* in order to enhance protection of patient autonomy.⁶¹ Second, professional guidance from the GMC already endorsed a patient-centred standard of disclosure, which was approved in *Montgomery*.⁶²

Situations governed by statute

It is notable that legal development of consent is not confined to the common law. Consent provisions are also included in certain statutes. This was not routine in the 1960s – for example the Abortion Act 1967 does not refer to consent. However, it is a presumed requirement in section 1 of the Human Tissue Act 1961, which set out requirements by which an individual could authorise the use of part of their body after death for therapeutic purposes.

Today, legislation sets out fundamental standards for NHS service providers in England, including the requirement of consent of persons aged 16 or over who have capacity:

11(1) Care and treatment of service users must only be provided with the consent of the relevant person.⁶³

Providers are required to register with the Care Quality Commission (CQC – the independent regulator of health and social care in England) which inspects them and holds them to standards. It can prosecute a provider for breach of the regulations or take other regulatory action. The CQC advises that:

Providers must make sure that they obtain the consent lawfully and that the person who obtains the consent has the necessary knowledge and understanding of the care and/or treatment that they are asking consent for.⁶⁴

Informed consent is also defined for certain purposes in statute, for example the new EU Clinical Trials Regulation (not yet applicable) defines it as follows, for the purposes of clinical trials:

⁵⁹ Devaney S, Holm S. The transmutation of deference in medicine: An ethico-legal perspective. *Med L Rev* 2018; 26(2): 202-224.

⁶⁰ *Shaw v Kovac* [2017] EWCA Civ 1028. Thus, if the patient is not sufficiently informed to make an autonomous decision, but the patient does not suffer resulting harm, there will be no claim flowing from the *Montgomery* decision.

⁶¹ See *Pearce v United Bristol Healthcare NHS Trust* [1999] PIQR 53; *Marriott v West Midlands HA* [1999] 1 Lloyd’s Rep Med 23; *Wyatt v Curtis* [2003] EWCA Civ 1779; *Birch v University College London Hospital NHS FT* [2008] EWHC 2237 (QB); *Chester v Afshar* [2004] UKHL 41.

⁶² GMC. *Consent: Patients and Doctors Making Decisions Together*. London, 2008. https://www.gmc-uk.org/static/documents/content/Consent_-_English_0617.pdf.

⁶³ Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 11.

⁶⁴ CQC Regulation 11: Need for Consent. <https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-11-need-consent#guidance>.

‘Informed consent’ means a subject’s free and voluntary expression of his or her willingness to participate in a particular trial, after having been informed of all aspects of the clinical trial that are relevant to the subject’s decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical trial.⁶⁵

Not all aspects of care involve physical contact and so the law of battery is not always relevant. Consent remains a relevant concept. Under the EU General Data Protection Regulation 2016/679, for example, processing personal data is generally prohibited. Freely given, specific, and informed consent is one of the legal bases for processing personal data, but there are five other bases including public interest, contract, legal obligations, vital interests of the data subject, and legitimate interest.

Statute can also modify the requirements of consent, to make them more stringent (for example, fertility treatment requires written consent) or less so (for example, compulsory treatment can be carried out in some circumstances without consent under the Mental Health Act 1983).

The Human Tissue Act 2004 (which does not apply in Scotland⁶⁶) governs the removal, retention and use of body parts from the dead and the retention and use of ‘relevant material’ from the living. It applies in relation to organs and tissue, including blood and plasma.⁶⁷ It creates an offence to remove, store or use human tissue for certain purposes without ‘appropriate consent’. The 2004 Act defines appropriate consent by reference to established common law.

In the case of deceased individuals, consent can come from the patient in advance of death, or from a nominated representative or a relative (or exceptionally, a friend).⁶⁸ In relation to the living, the Act does not regulate the initial removal of a body part, which is governed by common law principles of consent. Retention of tissue for medical purposes comes under the Act and the lawfulness of retaining tissue depends on the purpose. If the purpose is to obtain information relevant to others, explicit consent is usually required, subject to an exception if the donor cannot be traced. If it is to be used for research, consent is required, unless the source of the tissue has been anonymised and the research is approved by an accredited research ethics committee.⁶⁹ Where consent is required, generic consent can be sought for multiple research purposes (see Q21).

Prior to 2004, removal, storage and use of human tissue was governed by common law and statutes. The focus was on deceased patients. Family members could not and cannot assert a right of ownership over the corpse of a family member. But executors of an estate were entitled to possess the body in order to discharge their right to dispose of the body decently.⁷⁰ The Anatomy Act 1984 allowed people to donate their body and body parts for anatomical examination. The Human Tissue Act 1961 dealt with removal and retention of organs after hospital postmortem which was permitted where there was no reason to suspect that the deceased would object or his relatives object. Guidance from the BMA from 1970 required written consent from living donors ‘after a full explanation of the procedure, and the possible

⁶⁵ EU No 536/2014, Art 2(2)(21).

⁶⁶ The Human Tissue (Scotland) Act 2006 applies in Scotland.

⁶⁷ But excluding gametes, embryos and hair and nails from living subjects.

⁶⁸ From 20 May 2020 the law moves to an opt-out system following passage of the Organ Donation (Deemed Consent) Act 2019.

⁶⁹ Human Tissue Authority. *Code of Practice and Standards: Code E Research*. 2017, para 63.

⁷⁰ *Williams v Williams* (1882) 20 Ch D 659, discussed in Brazier M, Cave E. *Medicine, Patients and the Law*. Manchester, MUP, 2016, 549.

consequences to the donor'.⁷¹ And the Nuffield Council on Bioethics produced a report in 1995 emphasising the need for 'genuine consent'.⁷² Storage and use of residual blood or tissue, left over from clinical or diagnostic procedures, now requires consent unless it is anonymised and approval has been given by an ethics committee, but in the past it may have been deemed 'abandoned' and therefore utilised for research purposes without consent.⁷³

Clinical research

(See also responses to Q29 and Q30)

Because clinical research does not promise to benefit the participant, but rather to benefit others through the advancement of scientific knowledge, the requirements for valid and informed consent are especially important.

Some clinical research is non-intrusive, such as research on medical records. Where it is intrusive, it may be invasive or non-invasive (e.g. interviews involving no contact with the patient's body might still be highly personal and potentially invasive). Research that is not combined with medical care, such as 'first-in-man' studies on volunteers,⁷⁴ can be particularly contentious and may require extra precautions to ensure that consent is informed and voluntary.

It is important to appreciate that unethical practice in relation to the treatment of research participants has occurred in a wide variety of settings and over time. The drive to progress scientific understanding and to provide responses to major health problems has sometimes led to the interests of individuals recruited to medical research being overlooked or overridden.

There are a number of key documents which have set the ethical framework for medical research since the aftermath of World War Two. The atrocities committed in the preceding period were a main driver for international agreement, most famously the Nuremberg Code⁷⁵ and the Declaration of Helsinki.⁷⁶ Both were replicated in 1970 guidance on medical ethics from the BMA. The Declaration has been revised several times to keep abreast of modern developments. Its focus is on voluntary consent and the appropriate balance between the advance of medicine and the rights and interests of individual research participants.

More recently, the Council for International Organizations of Medical Science (CIOMS)⁷⁷ has published ethical guidelines concerning research involving human participants. The first version was published in 1982 with subsequent versions in 1993 and 2002. The most recent version is the *International Ethical Guidelines for Health-Related Research Involving Humans*, 2016 which states that:

⁷¹ BMA. *Medical Ethics*. London: 1970, p 5.

⁷² Nuffield Council on Bioethics. *Human Tissue: Ethical and Legal Issues*. 1995. <https://www.nuffieldbioethics.org/publications/human-tissue>.

⁷³ See NCOB *ibid*, 4.2–4.4 and Royal College of Physicians. *Guidelines on The Practice of Ethics Committees in Medical Research Involving Human Subjects*. 1990, Second edition, para 29.

⁷⁴ 'First-in-man' trials test the medicinal product on human participants for the first time (after laboratory and/or animal testing).

⁷⁵ Nuremberg Code. 'Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10', Vol. 2, pp 181-182. Washington, DC: U.S. Government Printing Office, 1949. Available at <https://history.nih.gov/research/downloads/nuremberg.pdf>.

⁷⁶ The Declaration of Helsinki was adopted in 1964 at the Eighteenth World Medical Association Assembly and has since been revised several times. The latest version is WMA. *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*. 2018, available at www.wma.net.

⁷⁷ CIOMS is an international non-governmental organisation established by the World Health Organisation and UNESCO in 1949.

The ethical justification for undertaking health-related research involving humans is its scientific and social value: the prospect of generating the knowledge and the means necessary to protect and promote people's health.⁷⁸

Views differ on the extent to which this or any other globally-focused guidance has gained traction in particular settings, but the basic principles are generally well known and will be referenced below.

While it is important to acknowledge the recommendations set out in these documents, it is also important to question the extent to which individual clinicians were aware of, or understood, the obligations they were under. It has been suggested the professions were slow to adhere to the principles set out in the Helsinki Declaration.⁷⁹ The Medical Research Council responded to these concerns in 1963 in a report setting out key ethical responsibilities for researchers,⁸⁰ but it was not until 1967 that the Royal College of Physicians called for the establishment of an ethical review process for research involving humans.⁸¹ It was recognised that due to the wide array of research types 'formal codes can provide only general advice, and their application to specific problems must often remain a matter of opinion'.⁸² The RCP's proposal was endorsed by the Ministry of Health in 1968.⁸³ Although research ethics committees (RECs) started to form thereafter, developments were inconsistent across the country and between institutions, and there was little formal guidance for RECs until 1991.⁸⁴

Research governance has become a very visible and relatively well supported activity within the NHS with the establishment of a National Research Ethics Service in 2007 and the creation of the Health Research Authority as a special Health Authority in December 2011. The Health Research Authority is responsible for coordinating and standardising the regulation of research. Its approvals process usually requires ethical review from a research ethics committee. Clinical trials in the EU are governed by Clinical Trials Directive 2001/20/EC. Introduced in 2001 to harmonise the provisions governing clinical trials in Europe, it will be repealed by the Clinical Trials Regulation in 2020.

Not all research requires informed and explicit consent, as we saw in relation to the above section on human tissue and explored further in response to Q21 and Q23 below.

20a. What information about risks and benefits ought to be disclosed?

(See also response to Q24f)

Information about risks and benefits comes to light through a range of mechanisms and processes and gives rise to different duties to disclose information to particular groups.

⁷⁸ CIOMS, *International Ethical Guidelines for Health-Related Research Involving Humans*. 2016, p 1. <https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/>.

⁷⁹ Pappworth MH. *Human Guinea Pigs: Experimentation on Man*. London: Routledge and Kegan Paul, 1967.

⁸⁰ Medical Research Council. *Responsibility in Investigations on Human Subjects*. In *Report for the Year 1962-3*. London: HMSO 1964 (Cmnd 2382).

⁸¹ RCP. *Supervision of the Ethics of Clinical Research Investigations in Institutions*. London: HMSO, 1967.

⁸² Rosenheim ML. Medical Ethics: Supervision of the Ethics of Clinical Investigations in Institutions: Report of RCP Committee. *BMJ* 1967; 3(5562): 429-430.

⁸³ Ministry of Health. *Supervision of the Ethics of Clinical Trial Investigations* HM(68)33. London: HMSO, 1968.

⁸⁴ Department of Health. HSG(91)5 (known as 'The Red Book') replaced HSC(IS)153 1975 which had endorsed RCP proposals, and introduced local RECs in England. Scotland and Wales introduced LRECs shortly afterwards. Previously the BMA. *The Handbook of Medical Ethics*. 1981, 4.5 recommended that 'Because of the ethical problems which may arise, controlled clinical trials should always be approved and supervised by a properly constituted ethical committee.' RCP. *Guidelines on the Practice of Ethics Committees Involved in Medical Research Involving Human Subjects* 1984 provided guidance that was updated in 1990, 1996, 2007.

How do risks and benefits become known?

Prior to market authorisation, medicines and devices must undergo clinical trials during which adverse events are recorded, analysed for causality and reported to the competent authority. If clinical trials show the product to be sufficiently safe and effective, the product is brought for marketing authorisation. The UK regulator for medicines, medical devices and blood components for transfusion is the Medicines and Healthcare products Regulatory Agency (MHRA). Medicines can be licensed for EU and EEA use via the European Medicines Agency, which produces guidance on what information is needed to apply for marketing authorisation for particular drugs.⁸⁵

Post market authorisation, manufacturers must keep products under review, warn of any new risks that come to light, and modify or withdraw a product if risks are too great to be managed by means of warnings.⁸⁶ Clinical trials and other research projects are reported in medical journals which are in turn available to commissioners, public bodies and clinicians.⁸⁷ The MHRA is responsible for ensuring that medicines work and are acceptably safe.

The MHRA is also responsible for ensuring that the supply chain for blood components is safe and secure. SABRE – Serious Adverse Blood Reactions and Events – is the MHRA’s online system for reporting blood safety incidents.⁸⁸ European regulations and subsequent national legislation govern the importing and exporting, manufacturing, and quality and safety of blood and blood products. Historically, the Ministry of Health took over blood banks and set up a National Blood Transfusion Service in 1946. We do not have sufficient evidence of the safety policies in force in the 1970s to comment in detail, but it is clear that certain risks associated with reliance on non-voluntary donation were anticipated and reported in the medical literature.⁸⁹

The researcher’s duty to warn research participants

(See also response to Q30b)

Subject to certain exceptions explored in response to Q23, it has long been accepted that participants in research should be informed of known risks. The 1975 version of the Declaration of Helsinki⁹⁰ required an assessment of ‘predictable risks in comparison with foreseeable benefits to the subject or to others’ (para 5) and that the participant was informed of them (para 9). It stipulated that the research should not go ahead unless the hazards are considered predictable and should be halted if the newly discovered risks outweigh the benefits (para 7). It also required the safeguarding of the privacy and integrity of the research participant (para 6). Equivalent requirements are still in force today.

⁸⁵ See EMA. *Guideline on the clinical investigation of recombinant and human plasma-derived factor VIII products*. 2018: <https://www.ema.europa.eu/en/clinical-investigation-recombinant-human-plasma-derived-factor-viii-products>.

⁸⁶ General Product Safety Regulations 2005 SI 2005/1803, implementing directive 2001/95/EC.

⁸⁷ And also to the public, though they are often behind a pay wall.

⁸⁸ See MHRA. <https://aic.mhra.gov.uk/mda/sabresystem.nsf/Login?Open>. See also Serious Hazards of Transfusion www.shotuk.org; HSE incident reporting under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 SI 1995/3163. <https://www.hse.gov.uk/biosafety/blood-borne-viruses/incident-reporting.htm>.

⁸⁹ Titmuss R. *Choice and the Welfare State*. London: Fabian Society, 1967; Titmuss R. *The Gift Relationship*. London: George Allen and Unwin, 1970; Editorial. Blood donors and the transfusion service. *BMJ* 1974: 212-213; Editorial. The National Blood Transfusion Service today. *BMJ* 1980; 281: 405-406.

⁹⁰ WMA *Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects*. October 1975: <https://www.wma.net/wp-content/uploads/2018/07/DoH-Oct1975.pdf>.

The manufacturer's duties to warn consumers

Where a product is defective and causes injury, the Consumer Protection Act 1987 imposes strict liability on manufacturers (see further response to Q19). Blood products are considered 'products' under the Act.⁹¹ There is no need to prove that the manufacturer was at fault in causing the defect. The Act applies to products put into circulation after March 1988. Pre-1988 liability is governed by the laws of negligence and contract.

In determining whether a product is defective under the Act, account will be taken of all circumstances, including compliance with regulations and whether the risks could be avoided. Side-effects of drugs are often unavoidable so the court will balance potential benefit against the risk.⁹² Sufficiently serious anticipated risk must be warned against.⁹³ In a recent Australian case (where the Act does not apply), a court found that certain vaginal mesh devices were defective and that the instructions for use and marketing information was misleading or deceptive.⁹⁴

Product information should be supplied with the product. Depending on the product, this might or might not also be seen by the patient. In *Wilkes v DePuy*,⁹⁵ warnings to medical intermediaries (surgeons) were taken into account by the court as part of the broad circumstances considered in determining whether a replacement hip was defective. Where detailed information was provided to the surgeon, a failure to pass it on to the patient does not render the product defective, though it may lead the patient to claim against the intermediary in negligence for failure to warn of material risk (explored in the next subsection).

Outside the Act, manufacturers also owe a duty to take reasonable care to warn of risks associated with a product, breach of which may result in liability in negligence if it causes harm. Once again, warnings to intermediaries may discharge the duty.

With regard to medicines, patient information has been regulated since 1977, but few medicines were supplied with leaflets until the 1992 EEC Directive came into force.⁹⁶ Today, there are clearer rules and guidelines regarding scope and readability of information leaflets, and greater potential to claim against the manufacturer if there are insufficient warnings regarding risk.

The treating clinician's duty to warn patients

The Supreme Court in *Montgomery* recognised a duty of care on doctors:

to take reasonable care to ensure that the patient is aware of material risks involved in any recommended treatment and of any reasonable alternative or variant treatments.⁹⁷

⁹¹ *A v National Blood Authority* [2001] 3 All ER 289. See discussion above.

⁹² The approach taken in *A v National Blood Authority* [2001] 3 All ER 289 equating what the public was 'entitled to expect' to the 'legitimate expectation of persons generally' was criticised in *Wilkes v DePuy International Limited* [2016] EWHC 3096 (QB) and rejected in *Gee and others v DePuy International Limited* [2018] EWHC 1208 (QB). *Gee* does not overrule *A* (both are High Court cases), but it does signal a more holistic approach to defining defect. See also *Hastings v Finsbury Orthopaedics Ltd* [2019] CSOH 96 Court of Session (Outer House).

⁹³ *Palmer v Palmer* [2006] EWHC 1284 (QB): a seatbelt device was defective as the instructions and warnings were insufficient to allow safe use.

⁹⁴ *Gill v Ethicon Sàrl & Ors (no 5)* [2019] FCA 1095 (Au).

⁹⁵ *Wilkes v DePuy International Limited* [2016] EWHC 3096 (QB).

⁹⁶ Council Directive 92/27/EEC on the labelling of medicinal products for human use and on package leaflets.

⁹⁷ *Montgomery v Lanarkshire HB* [2015] UKSC 11, [87].

In their leading judgment, Lords Kerr and Reed were influenced by professional guidance on consent from the GMC in 2008, which asserted a very similar position to that endorsed by the court. Revised GMC guidance (replacing the 2008 guidance) will be issued in 2020 to give additional operational support regarding the implementation of the *Montgomery* judgment.

Today there is extensive guidance on informed consent from the GMC, BMA, Department of Health and from the Royal Colleges. However, for many years, patient participation and information disclosure were not focal in clinical guidance. There are several factors that contributed to this phenomenon. For example:

- The National Health Service Act 1946 in providing free healthcare at the point of delivery created a culture of trust, gratitude and deference. This led to a reluctance among patients to question medical advice and a paternalistic attitude among doctors. It also gave considerable decision-making power to doctors in determining what was good practice.⁹⁸ The cost of the NHS reforms might also have posed practical limitations on patient choice.⁹⁹
- As is set out above, it was historically more difficult to bring a claim in negligence for non-disclosure of information about risks inherent in treatment.
- In the early 20th century, codes and guidelines tended to focus on prescriptive ethics (setting out how things should be done with respect to certain issues). Professional guidance began to tackle ethical dilemmas in the late 1970s and 1980s.

Notwithstanding the limited remedy in negligence for non-disclosure in the mid-to-late 20th century, we consider there was nonetheless recognition of the need to inform patients about important risks associated with medical interventions.¹⁰⁰ The BMA's pamphlets, *Medical Ethics*, 1970 and 1974¹⁰¹ focused on etiquette designed to protect the reputation of the profession, and replicated the Declaration of Geneva and Declaration of Helsinki. The BMA guidance referred readers to Medical Defence Union (MDU) pamphlets on *Consent to Treatment*. The MDU's 1971 edition opened with a quote from an American case:

No amount of professional skill can justify the substitution of the will of the surgeon for that of his patient.¹⁰²

It made clear that treatment without authorisation would constitute a battery and that: 'The patient should ... be told, in non-technical language, of the nature and purpose of the operation' and 'If the operation contemplated carries special risks which are probably unknown to the patient he should, as a general rule, be informed of these risks.'¹⁰³

⁹⁸ Brazier M, Montgomery J. Whence and whither 'modern medical law'? *NILQ* 2019; 70(1): 5-30, 16.

⁹⁹ Schwartz R, Grubb A. Why Britain can't afford informed consent. *The Hastings Center Report* 1985; 15(4): 19-25, 22.

¹⁰⁰ See, for example, Ormrod Sir R. Medical ethics. *BMJ* 1968; 19(2): 7-10. <https://www.bmj.com/content/bmj/2/5596/7.full.pdf>: '[The patient] will be entitled to demand a bona fide statement in broad terms of the risks to life or future health or of pain and discomfort involved in the contemplated procedure or to a frank admission that in the given circumstances these cannot be assessed with any accuracy. He must also be given a fair appreciation of the probable value of his sacrifice, to the recipient if he is to be a donor, and to medicine in general if he is to enter a clinical trial. ... The greater the risk the greater will be the obligation on the doctor to ensure that the patient understands. The lesser the risk the lesser will be the onus on the doctor. It is merely pedantic to insist that the patient be fully informed of a mass of facts which he cannot assimilate or assess.'

¹⁰¹ BMA. *Medical Ethics*, BMA 1970; 1974.

¹⁰² *Bennan v Parsonnet* 83 A 948 (1912).

¹⁰³ Medical Defence Union. *Consent to Treatment*. 1971, p 3.

The Medical Act 1978 gave the GMC additional powers to advise doctors on medical ethics,¹⁰⁴ and a brief 'medical ethics' section was duly added to GMC guidance in 1980, focusing on the importance of maintaining trust between doctors and patients.

In 1980, Professor (now Sir) Ian Kennedy's Reith Lectures¹⁰⁵ prompted critical reflection of the traditional role and power of doctors and hastened further development of a 'patient-centred' approach to health-related decision-making. The BMA's 1980 guidance included two paragraphs on adult 'consent',¹⁰⁶ which speaks to consent's growing importance and also recognition that it is potentially contentious. In this guideline, focus on patient understanding moved beyond the basic legal requirement of battery, and the doctor was required to adapt information to meet the needs of the patient and situation. The BMA 1980 guidance put the onus on the doctor to give an explanation adequate for the patient to understand 'the nature and consequences of what is proposed'. The doctor's duty, then, was to decide which option was preferable, and to furnish the patient with information sufficient that they could accept or refuse it. The degree of information required depended on the patient's education and intelligence and the seriousness of the condition. The BMA guidance was revised in 1981, adding that: 'Doctors offer advice but it is the patient who decides whether or not to accept the advice' (para 2.6).

In 1988, the GMC released specific guidance on *HIV Infection and AIDS: The Ethical Considerations* which incorporated two earlier statements and new guidance on issues of confidentiality and consent. Based on the broader 1980 GMC guidance, it (somewhat defensively) reminded doctors that guidance cannot be comprehensive and will often be responsive:

In all areas of medical practice doctors need to make judgements which they may later have to justify. This is true both of clinical matters and of the complex ethical problems which arise regularly in the course of providing patient care, because it is not possible to set out a code of practice which provides solutions to every such problem which may arise (para 4).

Consent is dealt with in paragraphs 12–14. Paragraph 12 begins:

It has long been accepted, and is well understood within the profession, that a doctor should treat a patient only on the basis of the patient's informed consent.

It is made clear that informed consent is required for investigative procedures, whether performed for the purposes of routine screening or for specific purposes of diagnosis. Paragraph 13 makes clear that the same principle applies in the case of testing for HIV infection which 'provide a strong argument for each patient to be given the opportunity, in advance, to consider the implications of submitting to such a test and deciding whether to accept or decline it.'

In 1998, the GMC produced a specific guideline on consent for the first time.¹⁰⁷ It set out a patient's right to information about their condition, prognosis and the treatment options and risks and made clear that information should be tailored to the patient's needs and priorities. It said that information required to make an informed decision should not be withheld unless it would cause 'serious harm'.¹⁰⁸

¹⁰⁴ GMC. *Professional Conduct and Discipline: Fitness to Practise*. 1980.

¹⁰⁵ Published in Kennedy I. *The Unmasking of Medicine*. London: Allen and Unwin, 1981.

¹⁰⁶ BMA. *Handbook of Medical Ethics*. London: 1980, para 1.8 and 1.9.

¹⁰⁷ GMC. *Seeking Patients' Consent: The ethical considerations*. 1998. Replaced 2008.

¹⁰⁸ *Ibid*, para 11.

Exceptions to the clinician's duty to warn

The duty to inform is not absolute. As we have seen, some patients may opt not to be informed of material risks and alternatives. In emergency cases too (on which, see response to Supplemental Q12 below), the duty may not apply. Furthermore, in *Montgomery* a 'therapeutic exception' was set out. This applies in exceptional circumstances where clinicians consider disclosure of material information to be detrimental to the health of the patient.¹⁰⁹ In *Montgomery* it was recognised that patient participation itself has therapeutic value:

The submissions on behalf of the GMC acknowledged ... that an approach based upon the informed involvement of patients in their treatment, rather than their being passive and potentially reluctant recipients, can have therapeutic benefits, and is regarded as an integral aspect of professionalism in treatment.¹¹⁰

The GMC is clear in its current guidance that the possibility of a patient becoming upset or even seriously distressed is not a good enough reason not to disclose material information. The therapeutic exception might, however, apply if the information would cause 'serious harm'. It seems unlikely that the therapeutic exception will be relied upon to any great extent today.¹¹¹

In the mid-20th Century, the therapeutic exception had wider relevance due to the paternalistic tendencies of the medical profession. However, in 1970s Britain, it is unlikely to have been viewed as an *exception* to the duty to inform patients as such, and would instead have been seen as a part of the wide discretion doctors had under the *Bolam* test to decide what information it was reasonable to give the patient.¹¹² This fits with its historical nomenclature: the 'therapeutic *privilege*'. Risks that would be 'material' (relevant to the decision) to the average or particular patient might nonetheless have been withheld if disclosing them would cause harm.

The MDU's 1971 guidance on consent advised that patients should be informed of risks 'as a general rule', but that the doctor might minimise or not disclose risks 'if he thinks it necessary to do so in the interests of the patient'.¹¹³ The guidance cites the 1954 case of *Hatcher v Black*.¹¹⁴ Here, a patient asked her doctor, Mr Tuckwell, if a thyroid operation would pose any risks to her voice and was told it would not. When the risk materialised, she sued Mr Tuckwell. Finding for the doctor, Lord Justice Denning stated:

What should the doctor tell his patient? Mr Tuckwell admitted that on the evening before the operation he told the plaintiff that there was no risk to her voice, when he knew that there was some slight risk, but that he did it for her own good because it was of vital importance that she should not worry. In short he told a lie, but he did it because he thought in the circumstances it was justifiable.

This attitude prevailed for some time. In a 1994 case, Rougier J. described the therapeutic privilege in the following terms:

¹⁰⁹ *Montgomery v Lanarkshire HB* [2015] UKSC 11, [85], [91].

¹¹⁰ *Ibid*, [78].

¹¹¹ Cave E. The ill-informed: consent to medical treatment and the therapeutic exception. *Common Law World Review* 2017; 46(2): 140-168.

¹¹² Jones M. Informed consent and other fairy stories. *Med Law Rev.* 1999; 7(2): 103-134, 113.

¹¹³ Medical Defence Union, *Consent to Treatment*. 1971, p 3.

¹¹⁴ *Hatcher v Black* (1954) Times, 2 July QBD.

a doctor may be genuinely and reasonably so convinced that a particular operation is in the patient's best interests that he is justified in being somewhat economical with the truth where recital of the dangers is concerned. Again that all comes within the umbrella of a question of clinical judgement.¹¹⁵

The dominance of the *Bolam* test in the 1970s, 1980s and early 1990s meant that doctors only had to tell patients what a responsible body of doctors would consider reasonable. In 1992, Brazier stated:

The law relating to consent to treatment pays little more than lip service to patient autonomy. The patient has the right to reject any treatment at all, and to demand that she be injected in the right, not the left arm. Gross interventions without any consent are penalized, as are gross errors ... Beyond this, the English courts seem to say that patients must accept and acquiesce in a degree of medical paternalism many enlightened doctors now reject. This is not good for patients, and it is not good for doctors.¹¹⁶

Consider the case of *Chatterton v Gerson*.¹¹⁷ Miss Chatterton had been informed of the nature of the treatment and so lost in battery. She also failed in negligence. While there was a duty incumbent on the doctor to tell her about the risks inherent in treatment, he could take into account '... the personality of the patient, the likelihood of misfortune and what in the way of warning is for the particular patient's welfare.' If information on the risks would be detrimental to the best interests of a patient, then it might be excluded without fear of action in negligence.

Commitment to patient autonomy would require that the therapeutic privilege is used only exceptionally, but to the best of our knowledge, this was not made clear in professional guidance until the late 1990s. The GMC's 1998 guidance advised that information is not withheld unless disclosure could cause 'serious harm' and that 'serious harm' 'does not mean the patient would become upset, or decide to refuse treatment'.

Supplemental Q8a. Consider in particular what information ought to be disclosed about the risks and benefits of existing, proposed and/or alternative treatments.

Today, *Montgomery* requires disclosure of information regarding material risks and benefits of the treatment proposed and of reasonable alternative and variant treatments. Similarly, the CQC requires healthcare providers to give information 'about the risks, complications and any alternatives.'¹¹⁸ In response to Q24d we consider how alternatives are selected. The *identification* of reasonable alternatives and variants is a matter that is likely to be governed by *Bolam*, but the decision to inform the patient is governed by *Montgomery*¹¹⁹: by what the reasonable or actual patient needs to know rather than what the reasonable clinician would disclose. In response to Q24e we look at the kinds of information clinicians should provide to patients about possible treatments, their risks and benefits. If material risks are not explained,

¹¹⁵ *McAllister v Lewisham & North Southwark Health Authority* [1994] 5 Med LR 343.

¹¹⁶ Brazier, M. *Medicine, Patients and the Law*. London: Penguin, 1992, 92.

¹¹⁷ *Chatterton v Gerson* [1981] 1 All ER 257.

¹¹⁸ CQC. *Regulation 11: Need for Consent*. <https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-11-need-consent#guidance><https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-11-need-consent#guidance>.

¹¹⁹ *Kennedy v Frankel* [2019] EWHC 106 (QB), [12] applying *Duce v Worcestershire Acute Hospitals NHS Trust* [2018] EWCA Civ 1307, [32]-[33].

the patient is denied an effective choice.¹²⁰ In response to Q24f we look at the responsibilities of clinicians to inform patients of the risks of treatment and the ways in which the legal obligation has developed over time.

The legal duty is underpinned by ethical duties to respect autonomy and to foster trust. If information about risks of reasonable treatment alternatives is withheld, then the patient cannot make an informed selection and is more reliant on the paternalistic considerations of the clinician in choosing on their behalf. As we have seen, some patients might choose not to be so informed (which is itself an exercise of their autonomy), and in rare cases the therapeutic exception might apply if the information would cause the patient serious harm. We have also described a wider therapeutic *privilege* that historically gave clinicians greater scope to withhold information if they considered it to be harmful.

In order to inform patients of risks, clinicians need to be aware of them. As we discuss in response to Q24b, clinicians are expected to keep up to date, but not to know every research paper in their field.

Supplemental Q8b. Set out the categories of information that a person would need to know and understand in order to give consent to treatment.

What must be known by the patient to give consent to treatment?

We have made a distinction between the legal informational requirements relevant to battery and negligence. If the patient is not made aware of the broad nature of the treatment proposed, then a battery may be committed if the treatment involves physical touching. If they are not informed of the material risks, benefits and alternatives, they may be able to sue in negligence if they can prove that the lack of information caused them harm.

What duty is there on the clinician to ascertain patient knowledge and understanding?

The Mental Capacity Act 2005 requires doctors to work on the assumption that their patients have capacity until proven otherwise. While assessing capacity, all efforts must be made to communicate effectively and override any obstacles to understanding. Where reasonable adjustments would aid a patient in making a decision, these should be provided.

If it emerges that the patient cannot understand, retain and use relevant information due to an ‘impairment of the mind or brain’,¹²¹ notwithstanding efforts to facilitate that understanding,¹²² the patient may be found to lack capacity,¹²³ in which case section 4 of the Act guides others in making a decision for and (where possible) with the patient in the patient’s best interests.

Where the patient is judged to have the competence/capacity to make a decision regarding their healthcare, the clinician has a duty to provide information and to communicate it. The clinician should not, however, bombard the patient with technical information but should engage in dialogue so that it might be shaped to the patient’s needs. In *Montgomery* it was stated:

¹²⁰ See James G. Rev’d (Chair). *Report of the Independent Inquiry into the Issues raised by Paterson*. 2020 HC 31, p 113: ‘Paterson did not always explain to his patients that he would leave breast tissue behind during a mastectomy, or when he did so he failed to make the risks inherent in his practice clear. If he did discuss a CSM with them, he told patients any tissue left behind would be fatty tissue. Patients were unable to give true consent in these circumstances.’

¹²¹ This phrase (Mental Capacity Act 2005, s 2) refers to people with learning difficulties or disabilities or psychological, psychiatric or neurological disorders.

¹²² Mental Capacity Act 2005, s 1(3).

¹²³ Mental Capacity Act 2005, ss 2-3. See response to Q20 above.

The doctor's advisory role involves dialogue, the aim of which is to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision.¹²⁴

In *Thefaut v Johnson*, Green J. (as he then was) recognised that 'the issue is not so much the means of communication but its adequacy'. Sufficient time and space are required to allow dialogue between the clinician and patient.¹²⁵

Supplemental Q8c. Consider how a clinician should determine if a person has understood the information and is in a position to give informed consent.

While the focus in *Montgomery* is on disclosure of information, it is implicit in the judgment that the aim is to enhance and secure understanding by putting the information in a way the patient can understand. The CQC makes clear in their guidance that information must meet people's communication needs: 'This may include the use of different formats or languages and may involve others such as a speech language therapist or independent advocate.'¹²⁶

While the clinician's duty is to do what they can to enhance understanding, they are not necessarily accountable if the patient fails to grasp all aspects of what is explained. Recently, in the case of *Worrall*, the court held that a clinician was not to blame for the patient misunderstanding what was said, provided she was not responsible for the patient's wrong impression or did not fail to take steps to correct a misunderstanding that ought to be apparent.¹²⁷ Furthermore, there are some cases where specificity is impossible and understanding of the issue cannot be complete.

Having said this, in ethical terms the use of consent in a medical setting is suggestive of a quasi-contractual relationship between doctor and patient, and it is important to establish that a patient understands what they have agreed to. This is particularly true when they are agreeing to hand over control of their wellbeing to another person. There is a moral obligation upon doctors to be sure that they give their patient every opportunity and assistance to understand what they are consenting to. This in turn places the onus upon doctors to judge their own actions as well as to test (in a limited sense) their patient's understanding.

20b. What are the principles which ought to govern gathering more information prior to disclosure to the patient?

(See also responses to Q24c and Q24d where we consider the doctor's obligations to identify and offer the best treatment and alternatives for a patient)

It is clear that a patient will benefit from their clinician gathering and considering as much relevant information as possible before commencing clinical decision-making and/or communicating with their patient about what should/will happen next. Whether doctors will have the relevant information to hand will depend on multiple factors such as the doctor's specialism, their experience in dealing with that condition and the state of medical knowledge as to its possible treatment. A doctor who fails to give appropriate advice in a timely manner

¹²⁴ *Montgomery v Lanarkshire HB* [2015] UKSC 11, [90].

¹²⁵ *Thefaut v Johnson* [2017] EWHC 497 [58] and see [78].

¹²⁶ CQC Regulation 11: Need for Consent. <https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-11-need-consent#guidance>.

¹²⁷ *Worrall v Antoniadou* [2016] EWCA Civ 1219.

may be breaching their duty of care to their patients, in which case a claim may lie in negligence. The legal test of whether a doctor ought to have known particular relevant expert information, is whether the doctor's conduct fell below the standard expected of a competent medical professional (the *Bolam* test). Healthcare professionals are judged by the standard of skill and care appropriate to the post they fill.¹²⁸

In all cases, a guiding principle of medical ethics is that a doctors' first duty is to their patient: patient needs should dictate the level and detail of information. In 1998, GMC guidance on consent (applicable until 2008) stated:

When providing information you must do your best to find out about patients' individual needs and priorities. For example, patients' beliefs, culture, occupation or other factors may have a bearing on the information they need in order to reach a decision. You should not make assumptions about patients' views, but discuss these matters with them, and ask them whether they have any concerns about the treatment or the risks it may involve. You should provide patients with appropriate information, which should include an explanation of any risks to which they may attach particular significance. Ask patients whether they have understood the information and whether they would like more before making a decision.¹²⁹

The GMC's 2008 guidance on consent recognises that the information disclosed will depend on the individual patient and what they want or need to know.¹³⁰ Of course, these may not be one and the same thing given our earlier concerns (see Q19) around not knowing what one needs to know, or indeed being unaware of what one does not yet know. Information should include potential side-effects, complications, and the risks that it will not achieve the desired aim. The GMC recognises that there may be obstacles to information disclosure including time pressures and limited resources.¹³¹ It recommends using leaflets, support groups and advocacy services.

Question 21. Should consent always be expressly obtained (assuming that the patient has capacity)?

Supplemental Q9. Consider how the patient's consent should be obtained and recorded.

The Inquiry's Letter of Instruction distinguishes between the extent to which consent must be express in Q21 and the extent to which it must be express *and informed* in Q23. Given that we have established, in response to Q20, that consent should be both voluntary and informed, it is important to read the responses to Q21–23 in conjunction. We begin by focusing on the patient's expression of consent. We ask: To what extent must it be express (Q21) and when can it be implied (Q22)? We then consider what information must be made explicit by the healthcare professional in Q23.

¹²⁸ *Wilshire v Essex AHA* [1987] 1 QB 730; *FB v Princess Alexandra Hospital NHS Trust* [2017] EWCA Civ 334.

¹²⁹ GMC. *Seeking Patients' Consent: The Ethical Considerations*. 1998, para 6. <https://www.gmc-uk.org/-/media/documents/patient-consent-1998---2008-55678021.pdf?la=en>.

¹³⁰ GMC. *ibid*, para 28.

¹³¹ GMC. *ibid*, paras 23-25.

We take ‘express consent’ to mean explicit consent and ‘implied consent’ (Q22) to mean that consent is implicit. It is worth noting that the qualifying terms ‘express’ and ‘implied’ should only refer to the manner in which a person’s consent is established – that is through a clear and direct statement in the first case, or by a justified assumption that less direct action/omission is indicative in the latter.

Subject to exceptions,¹³² there is no *legal* requirement that consent is express or that it is evidenced in writing. It is, however, good practice to record discussion in notes and to obtain written consent to more risky interventions, such as surgery.¹³³ The GMC’s 2008 guidance on consent states:

49. You should also get written consent from a patient if:
 - a. the investigation or treatment is complex or involves significant risks
 - b. there may be significant consequences for the patient’s employment, or social or personal life
 - c. providing clinical care is not the primary purpose of the investigation or treatment
 - d. the treatment is part of a research programme or is an innovative treatment designed specifically for their benefit.

In line with post-*Montgomery* understandings of consent, an accurate record of the consent process and the discussions that have taken place will be of far greater value than a mere signature on a consent form when refuting a claim that a patient has not consented.

How far explicit consent is required or can be achieved depends on what is being consented to; be it treatment, diagnosis, examination, referral, research, tissue storage, or release of personal data. We do not attempt to cover them all but focus instead on the underlying principles.

Sometimes statute requires explicit and written consent for a procedure and sometimes it provides that an alternative to explicit consent is sufficient. In between these positions, legal and ethical principles support explicit and specific consent in relation to most research and many aspects of treatment, examination and diagnosis, but there are circumstances where this is not required:

- (i) *Where treatment is compulsory.* The exercise of choice by adults with capacity is a cornerstone of medical law and ethics, and explicit consent is the primary mechanism for honouring it. As discussed in response to Q20, a doctor who treats without consent may commit a battery. There are limited exceptions to this requirement that apply even in relation to patients with capacity. The Mental Health Act 1983, for example, permits compulsory treatment in some circumstances even if patients do not satisfy the Mental Capacity Act 2005 test for incapacity. The scope is limited to treatment of the mental health condition which has led to the patient being treated under the Act.

¹³² Such as fertility treatment or in some types of clinical trial.

¹³³ GMC. *Seeking Patients’ Consent: The Ethical Considerations*. 1998, para 28: <https://www.gmc-uk.org/-/media/documents/patient-consent-1998--2008-55678021.pdf?la=en> advised that written consent is obtained ‘where:

- the treatment or procedure is complex, or involves significant risks and/or side effects;
- providing clinical care is not the primary purpose of the investigation or examination;
- there may be significant consequences for the patient’s employment, social or personal life;
- the treatment is part of a research programme.’

- (ii) *Where consent is deemed or assumed.* Sometimes consent requirements are modified because other considerations trump patient autonomy. For example, individuals may be given the option to opt out of something, and, unless they do so it will be deemed that they have consented to take part. Recent legislation moving to an opt-out system for organ donation is a case in point¹³⁴ and biobanks (considered below) are considered of such benefit to the public that ‘generic’ consent is sometimes considered acceptable.
- (iii) *Where consent can be implied.* Consent is sometimes implied from the circumstances. Overt acts and outward manifestations of intent can indicate consent in light of the surrounding circumstances in the same way as words or writing. For example, a patient making and attending an appointment for a dental examination impliedly consents to non-invasive inspection, but explicit consent would be required for unanticipated tooth extraction. See further Q22.
- (iv) *Where consent to aspects of care or research can be implied.* If explicit consent is obtained, it will rarely (if ever) cover all aspects of what is to follow. In light of the patient’s needs and preferences, a judgement is required as to the content of consent, and care must be taken not to exceed the scope of the authority given by a patient.¹³⁵ Such a judgement becomes more complicated when treating a patient whose beliefs or values might make component parts of treatments unacceptable. So, for example, it might be necessary to explain the presence of animal products to a vegan before gaining their consent to a treatment or supportive measure. See further Q23.

In our responses to Q21–23, we explore these factors in more detail.

The need to obtain voluntary consent

The law of battery provides one of several reasons for obtaining explicit consent to care that involves physical contact. It is a basic tenet of the law that to treat an adult patient with capacity in a non-emergency situation, their valid consent is required. Consent is a defence to what would otherwise constitute a battery and so the onus is on the doctor to show that consent was obtained and that it was valid.

Consequently, while the law does not (except in limited situations) dictate the *form* consent should take, it does limit the situations in which consent can be deemed; and provides reasons both to mitigate potential misunderstandings between doctor and patient as to what is agreed, and to document the consent obtained.

The law is supported by ethical considerations. The process whereby we gain explicit and written/recorded consent protects patient autonomy because it emphasises the need for information provision, understanding, and agreement. It supports a shared decision-making model of medical care and challenges the paternalistic notion of ‘doctor knowing best’.

But to require express and written consent to every medical interaction would be excessive, time-consuming, bureaucratic and contrary to patient needs. In some circumstances implied consent, and sometimes alternatives to consent, can give sufficient protection to patient dignity and autonomy in light of the minimal risk to the patient or the benefits of a procedure to others.

¹³⁴ Organ Donation (Deemed Consent) Act 2019.

¹³⁵ See, for example, GMC. *Seeking Patients’ Consent: The Ethical Considerations*. 1998, para 7.

Consent forms

Post-*Montgomery*, it is clear that healthcare professionals should engage in dialogue with the patient to enhance understanding of the risks and alternatives, and to discharge the duty of care: a signature on a consent form is not enough.¹³⁶ Consent discussions should be recorded in patient notes or a consent form.¹³⁷

In the past, consent forms were more central to the consent process for serious interventions such as operations, but the quality of the consent form varied, and signed consent forms did not necessarily render a consent explicit.

In 1971, the Medical Defence Union (MDU) advised against multipurpose consent forms which could confuse the patient. It also acknowledged that very broad consent forms were in use in some hospitals: 'It seems that it is still the practice in some hospitals to ask a patient on admission to sign a consent form which is in the nature of a blank cheque.' The MDU objected forcefully to their use on the ground that it 'is extremely doubtful if, by itself, it would afford any protection to the surgeon or his employing authority in the event of a claim for damages for assault'. It is apparent from this guidance that in 1971 consent to surgical operations was not always explicit enough to satisfy the requirements of the law. The MDU was clear that practice should change.

The MDU issued model consent forms that enabled hospitals to stipulate the nature and purpose of the operation and agreement from the patient and doctor that this had been explained. The 1971 general form included consent to 'further or alternative operative measures as may be found to be necessary during the course of the operation and to the administration of ... anaesthetic ...'.¹³⁸ Specific forms were provided for parental consent in the case of operations on children, and agreement of the spouse in the case of gynaecological and sterilisation operations. Model consent forms are still used today though they tend to be more detailed and specific to certain patient groups and procedures. A signature on the consent form is not proof of valid consent, but can contribute to a useful record of the process.

Consent to research

(See also response to Q30)

The distinction between therapy and research is becoming increasingly blurred in some areas of modern medicine, e.g. paediatric oncology, genomics, however, traditionally we have seen a particularly important role for explicit consent in a research setting. This is in part due to historical morally unacceptable practices carried out in the name of medical research, but it is also because of the important differences of experience between being a patient and a research participant/subject, a treating doctor and a medical scientist.

The 1975 version of the Declaration of Helsinki advised that in clinical research 'The doctor should ... obtain the subject's freely-given informed consent, preferably in writing'.¹³⁹ Specific legal rules apply to clinical trials of investigational medicinal products. UK Regulations

¹³⁶ *Montgomery v Lanarkshire HB* [2015] UKSC 11, [90].

¹³⁷ GMC. *Consent: Patients and Doctors making Decisions Together*. 2008, para 51.

¹³⁸ MDU. *Consent to Treatment*. 1971, appendix.

¹³⁹ WMA. *Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects*. 1975, I.9. <https://www.wma.net/wp-content/uploads/2018/07/DoH-Oct1975.pdf>. We return to the issue of informed consent to clinical research in Q23 below.

now require the informed consent of the participant in a clinical trial or their proxy.¹⁴⁰ The EU Clinical Trials Regulation (at the time of writing, in force but not yet applicable) defines informed consent in a manner that requires it to be explicit.¹⁴¹

There are many types of research that pose different types and levels of risk to patients. Some carry exceptions to the requirement of consent to research. For example, some information, such as disease surveillance, is collated for research purposes under a public health mandate and individual consent is not required. Research on data that has been stored and anonymised so that it is not linked to individuals might also be permitted.

Where consent is required, there are exceptions to the need for it to be explicit. For example, deferred consent, advance agreement, and generic consent may exceptionally be acceptable if utility is high, risk to the patient is low, and approval has been obtained from a recognised research ethics committee.¹⁴²

Where consent to research is required, must it be specific?

Consent is generally specific to a certain procedure or research project. The UK is not a signatory to the Council of Europe Convention on Human Rights and Biomedicine, but its provisions have relevance to the debate as to whether consent to research must be specific. Article 5 requires that ‘interventions in the health field’ must not be carried out without ‘free and informed consent’ and Article 16 adds that if the intervention constitutes research, ‘the necessary consent as provided for under Article 5 has been given *expressly, specifically and is documented*’. (our italics)

Some research utilises stored data or samples. The practical need created by the formation of health registries and biobanks has led to adaptation of the ethical and legal requirements of informed consent. The current approach in the UK is to allow *generic* and enduring consent in some circumstances, for example in relation to health registries, or biobanks which store genetic data for research purposes. Health registries allow comprehensive information to be gathered about a population and facilitate advances to public health. Nonetheless, the adaptations to informed consent requirements, so as to allow generic consent, remain contentious and internationally variable.¹⁴³

Generic consent is not specific and therefore the participant does not control their research samples. For this reason, issues of trust and governance become crucially important with the need for clear and detailed policy on how samples could be used, by whom and with what assurances. Given what we now know about the power and potential of big data, the NHS has an interest in capturing and utilising patient records in order to advance research and improve treatments. Data is also a commodity that can be traded and sold to commercial bodies. It is against this background that scientists/policymakers have to defend any move away from a specific and explicit consent model towards one which allows those who end up holding the data more control over its use.

¹⁴⁰ Medicines for Human Use (Clinical Trials) Regulations 2004, Sched 1, Part 2, para 9; Clinical Trials Regulation EU No 536/2014, article 28.

¹⁴¹ Clinical Trials Regulation EU No 536/2014, Art 2(2)(21): “‘Informed consent’ means a subject’s free and voluntary expression of his or her willingness to participate in a particular clinical trial, ...”

¹⁴² See discussion in Dal-Ré R, Avendaño-Solà C, Bloechl-Daum B, de Boer A, Eriksson S, Fuhr U et al. Low risk pragmatic trials do not always require participants’ informed consent. *BMJ* 2019; 364: 1092.

¹⁴³ Caulfield T, Murdoch B. Genes, cells, and biobanks: Yes, there’s still a consent problem. *PLoS Biol* 2017; 15(7): doi:10.1371//pbio.2002654.

A wider exception to the requirement of consent has been advised by the Council for International Organizations of Medical Sciences.¹⁴⁴ The Council has issued guidance that allows written informed consent to be *waived* if the research has scientific and social value, would be impractical if consent was required, poses no more than minimal risk to participants, and is approved by a research ethics committee. It is envisaged that this provision will be rarely utilised and is particularly relevant to data stored in health registries.

Research on human tissue

As discussed in response to Q20, the Human Tissue Act 2004 (in England, Wales and Northern Ireland) requires 'appropriate consent' for the storage and use of human tissue from living patients, including blood. The form of consent depends on how it will be used. Consent does not need to be in writing, though the Code of Practice states that if it is not in writing it should be clearly documented, for example, in the patient's notes.¹⁴⁵ Nor does the Act limit the *scope* of consent, which can be generic and enduring so that separate consents are not necessarily required for future research projects where tissue is stored. Furthermore, consent for research is not required if tissue from living patients is released to the researcher in a non-identifiable form, and the research has been approved by an accredited research ethics committee. For example, this applies to blood obtained for diagnostic or screening purposes which is then stored in a diagnostic archive.¹⁴⁶

Question 22. What do you understand by the concept of implied consent?

Supplemental Q10. When, if ever, is it permissible for a clinician to rely on the concept of implied consent?

It has long been accepted in law that the defence of consent to unlawful battery can sometimes be implied. In an 1891 American case, it was found that a person who bared his arm and held it out to a doctor administering vaccinations consented, notwithstanding the absence of an explicit verbal agreement.¹⁴⁷

A statement issued by the Medical Defence Union (MDU) in the *British Medical Journal* in 1960 stated:

Treatment administered without the patient's *express or implied* consent constitutes an assault which may lead to an action for damages under the civil law or a prosecution under the criminal law.¹⁴⁸ (our italics)

In 1971, the MDU pamphlet on *Consent to Treatment* also acknowledged that consent may be express (whether written or spoken) or implied. While both are effective as a defence to battery, the MDU cautioned that from a legal perspective:

An express consent is in every respect more desirable than an implied one and a written consent is preferable to an oral consent, because it can more easily be proved to have been given.¹⁴⁹

¹⁴⁴ CIOMS, International ethical guidelines for health-related research involving humans. 2016, Guideline 10. <https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/>.

¹⁴⁵ Human Tissue Authority, *Code of Practice A: Guiding Principles and the Fundamental Principle of Consent*. 2017, para 59.

¹⁴⁶ Human Tissue Authority, *Code of Practice E, Research*. 2017, para 30.

¹⁴⁷ *O'Brien v Cunard SS Co* (Mass 1891) 28 NC266.

¹⁴⁸ Addison H. Parental consent to treatment. *BMJ* 1960; 26:1(5177): 976.

¹⁴⁹ MDU. *Consent to Treatment*. 1971, p 3.

Today it is recognised that consent might not always be explicit and might sometimes be ‘implied’, though use of the term ‘implied consent’ is increasingly rare (an issue that is explored further below) and we prefer the term ‘implicit consent’. Two such instances are:

- i. When one process is a necessary part of another process to which the patient has given explicit consent

‘Explicit’ means clear and unambiguous, but even when oral or written consent to care is obtained, expression is unlikely to be given to every aspect of what will follow. There are implicit factors to most explicit consents and judgement and sensitivity to the particular patient’s needs is required to determine how much to cover and in what detail.

Where treatment involves multiple components, explicit and written consent to each constituent part could be unfeasible. So, for example, the consent of a patient to undergo surgery might encompass consent to nursing care afterwards, and examination of a patient may be a part of diagnosis or treatment to which the patient has consented. In such cases, the patient might indicate consent to the ancillary activity by complying with requests that have been explained by the healthcare professional.

However, care must be taken to define the scope of consent. In 1998, the GMC advised that doctors should not exceed the authority given by patients. This was particularly important where the treatment is delivered in stages or is subject to adjustment; where different investigations and treatments are involved; when different doctors will provide different elements of treatment; and when diagnosis is uncertain.¹⁵⁰

- ii. When a process is minor, low risk, and the patient signals agreement

In 2008, the GMC recognised that patients:

may imply consent by complying with the proposed examination or treatment, for example, by rolling up their sleeve to have their blood pressure taken.¹⁵¹

For minor or routine investigations, implied consent may be sufficient, but the higher the risks involved, the more important it is to obtain express and documented consent.¹⁵²

Having said this, it is important to ensure that medical/nursing interventions do not become routinised to the extent that practitioners assume implicit consent to interventions that ought to be presented as optional, and patients find themselves on a conveyor belt it is difficult to step off.

In both (i) and (ii), there remains a risk that signals can be misinterpreted. The patient might have been rolling up his sleeve because he was hot, or accepting nursing care because she did not understand that it is her right to say no.¹⁵³ A patient might consent to a treatment and then discover it entails a component they are unable to accept for moral reasons, e.g. animal products, blood products. In deciding whether to act on implicit consent, a judgement is required. The greater the likelihood that the signals could be misinterpreted and the greater the potential harms that would befall the patient (including harms to their autonomy interests)

¹⁵⁰ GMC. *Seeking Patients’ Consent: The Ethical Considerations*. 1998, para 7. <https://www.gmc-uk.org/-/media/documents/patient-consent-1998---2008-55678021.pdf?la=en>.

¹⁵¹ *Ibid*, para 45.

¹⁵² *Ibid*, paras 46 and 47.

¹⁵³ *Ibid*, para 31: ‘You should be careful about relying on a patient’s apparent compliance with a procedure as a form of consent. For example, the fact that a patient lies down on an examination couch does not in itself indicate that the patient has understood what you propose to do and why.’

if the signals have been misinterpreted, the more important it is that the doctor obtains explicit consent and that accurate records are kept. Equally, even in a familiar setting, the more unfamiliar or unknown the current encounter, the more important it is that consent is explicitly negotiated.

Problems with the term ‘implied consent’

The term ‘implied consent’ carries a risk of misinterpretation in practice. Implicit consent might be restricted to cases where a non-verbal signal of agreement is given, but it might erroneously be extended to cases where no such signal is given. While we have set out examples where deemed consent might be considered acceptable in law and ethics (such as opt-out organ donation), it is important to note that deemed consent is different in character to implicit consent, and that it is only acceptable exceptionally. The following examples indicate the dangers of extending the concept of ‘implied’ consent to encompass ‘imputed’, ‘deemed’, ‘inferred’ or ‘assumed’ consent:

- Consent should not be ‘implied’ because a particular option is considered logical or obviously beneficial from the doctor’s perspective. It cannot be assumed that the clinically indicated option is the route the patient would choose. To do so would deny patient individuality and the relevance of their values and preferences.
- Consent should not be implied because a particular option is best for patients generally, even if it is not necessarily best from the individual patient’s point of view. The doctor has obligations both to the individual and to public health, but doctors’ first concern is with their patients.

In relation to professional guidance, it has long been considered that paternalistically imputed consent fails to protect patient autonomy. In 1980, the BMA in their medical ethics booklet required consent to be freely given by a patient who understands the nature and consequences of what is proposed: ‘Assumed consent or consent obtained by undue influence is valueless’ (para 1.8).

Professional guidance has recognised that implicit consent is sometimes acceptable and offered some practical guidance as to how to make the judgement. The GMC’s 1988 guidance on *HIV Infection and AIDS: The Ethical Considerations* states:

A patient’s consent may in certain circumstances be given implicitly, for example by agreement to provide a specimen of blood for multiple analysis. In other circumstances it needs to be given explicitly, for example before undergoing a specified operative procedure or providing a specimen of blood to be tested specifically for a named condition (para 12).

Question 23. Is it ever acceptable, from an ethical perspective, to treat a person with capacity without their express and informed consent?

This question considers the informational component of consent.

The limits of informed consent

Onora O’Neill argued in 2003 that there are natural limitations to consent. She pointed out that consent is a propositional attitude: a response to a description of action to be performed. Information disclosed by the doctor can be specific to different degrees and limits have to be

drawn on the detail that is divulged. Too much detail and the patient will be overwhelmed. Too little and they will not understand. It is difficult if not impossible to get this balancing exercise exactly right:

I may consent to A, and A may entail B, but if I am blind to the entailment I need not consent to B. ... I may consent to C, and it may be well known that C causes D, but if I am ignorant of the causal link I need not consent to D.¹⁵⁴

The issue is not limited to treatment decisions. For example, a patient may consent to her general practitioner referring her to a specialist. But precisely what sensitive information should be shared with the specialist is unlikely to be explicitly discussed by the patient and GP. Yet too much sharing might impact on the patient's privacy; too little and there is potential risk to the patient's health.¹⁵⁵ The patient has explicitly agreed to a treatment or process, but the necessary information to make an autonomous choice has not been made explicit.

Efforts to make consent express or explicit will almost always leave some elements of the decision implied or implicit. The opacity of consent can be mitigated by ensuring that consent is specific to and guided by the patient. Trust, dialogue and responsiveness are key.

How specific does consent have to be?

Where explicit consent is obtained, a judgement is required as to the detail divulged. If a patient complains that the information was not sufficient to enable them to make a valid consent, they might look to the law of battery for a remedy.

What has the law to say? In 1981, it was held in *Chatterton v Gerson*¹⁵⁶ that someone who is informed in broad terms of what is planned, but is not told of the risks inherent in a procedure, cannot claim that there is no consent, though they might argue that the doctor was negligent in obtaining their *informed* consent. Misleading advice, on the other hand, can leave a patient unclear as to the nature of the procedure and open the way to a battery claim.¹⁵⁷

Margaret Brazier, in the 1992 edition of *Medicine, Patients and the Law*, applied this legal distinction to the testing of a patient for HIV, in order to illustrate its likely application. The example is pertinent to the Inquiry and so we repeat it in full:

Consider the example of a patient tested for HIV without his consent. He agrees to a blood test preparatory to surgery. He is never told that among the tests to be carried out on his blood is a test for HIV. Did he understand the nature and purpose of the test? He understands what would be done to him and that several tests would be carried out on his blood. It is difficult to say that he did not understand in broad terms what was going on. Of course, had some ruse been employed to obtain his consent the picture might be different. A doctor suspects a patient is HIV positive and wants a test for that sole purpose. Fearing that the patient would refuse consent if asked outright, the doctor uses a pretext for the test, for example a suspicion of anaemia. The patient falls within the *Chatterton v Gerson* test, for his consent was obtained by fraud or misrepresentation. The line between battery and negligence is a fine and often illogical line.¹⁵⁸

¹⁵⁴ O'Neill O. Some limits of informed consent. *J Med Ethics* 2003; 29: 4-7.

¹⁵⁵ See, for example, Adams K. Routine referral letters share clinical data without patients' consent. *BMJ* 2014; 348: g2419.

¹⁵⁶ *Chatterton v Gerson* [1981] 1 All ER 257.

¹⁵⁷ *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871.

¹⁵⁸ Brazier, M. *Medicine, Patients and the Law*. London: Penguin, 1992, 80.

If a patient is informed of the nature of the procedure, they are unlikely to have a claim in battery unless they have been misled. Instead, they must look to negligence for a remedy. The limited remedy offered by law is not reflected in principles of medical ethics which support a greater focus on patient autonomy. Explicit consent is of dubious value if it does not give the patient scope to understand what it is that they are agreeing to.

Treatment, diagnosis and examination

Where implicit consent is considered acceptable, it is still necessary that consent is informed. The information must be sufficient for the patient to make a choice, in addition to the requirements of free and voluntary consent referred to above. Where consent is signalled (e.g. opening the mouth to have the throat examined) it is because the patient anticipates a certain action (the doctor looking at the throat) and they are comfortable with this. This should be an informed decision. In some circumstances the information might be gleaned from previous experience or general knowledge but otherwise it should flow from an explanation from the doctor.

This is reflected in some professional guidance. For example, the Department of Health 2001 guidance on consent recognises that a person who 'holds out an arm for their blood pressure to be taken' can give valid non-verbal consent provided they have the requisite voluntariness *and understanding*.¹⁵⁹

But what *is* the requisite understanding? As we discussed above (Q20), the law on informed consent has developed incrementally and the consequences of not providing sufficient information differ according to the laws of battery and negligence. To avoid a claim in battery, basic information must be provided so that the patient understands what they are agreeing to. A failure to inform a patient of material risks and reasonable alternatives is governed by the law of negligence and, unlike the law of battery, the onus is on the patient to show that consent was not sufficiently informed. Furthermore, the duty to inform in negligence is subject to certain exceptions.

From a legal perspective, it is sometimes acceptable to treat a person with capacity with their express consent that is not fully informed. This may be in line with the patient's wishes. Preserving one's autonomy may at times be consistent with handing over an element of control to another person, someone who is better equipped at that point to support your goals and secure your best interests. Consent allows one to delegate power to another so that they can apply their expertise to your ends and in your interest, while at the same time ensuring that the person remains on track with your way of thinking, and your plans and projects. Alternatively, gaps in information may be appropriate in an emergency or if the therapeutic exception and previously the therapeutic 'privilege' applies (see response to Q20 above).

Informed consent to research

As referred to above, informed consent is generally a requirement in clinical research, though some claim that the heightened level of information required for research projects can be 'needlessly cruel' with potential to undermine therapeutic approaches to information giving.¹⁶⁰ Exceptionally, accredited research ethics committees might approve research in which consent is not fully informed. For example, a patient might not be told the purpose of a procedure, because the knowledge would cause them to change their behaviour and

¹⁵⁹ DH. *Reference Guide to Consent for Examination or Treatment* 2nd ed. 2009, para 35. <https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition>.

¹⁶⁰ Tobias, JS, Souhami RL. Fully informed consent can be needlessly cruel. *BMJ* 1993; 307: 1199.

so limit the scientific validity of the study. If possible, the participants should be informed that there will be certain gaps in the information they will be given. Where that too would limit validity, participants should be informed after the research has ended.¹⁶¹ Social or behavioural research which deceives participants might exceptionally be approved, provided it exposes participants to no more than minimal risk.¹⁶² The gold standard of medical research is the double-blind randomised- controlled trial, where it is of crucial importance that neither participant nor researcher knows who receives which treatment (or indeed a placebo). In this case it is key to informed consent that the participant understands the study design and the concept of randomisation.

Consent to research combined with medical care

The current version of the Declaration of Helsinki states that medical care should only be combined with medical research ‘to the extent that this is justified by its potential preventive, diagnostic or therapeutic value’ and if there is ‘good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects’.¹⁶³ In common with today’s version, the 1975 version of the Declaration recognised that combining medical research and care in order to acquire new knowledge was acceptable, provided the research is ‘justified by its potential diagnostic or therapeutic value for the patient’ (II.6).

What information must be given to a patient whose medical care is combined with research? Today, the participant should be informed of the research component:

31. The physician must fully inform the patient which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient’s decision to withdraw from the study must never adversely affect the patient-physician relationship.

Historically, the principle that patients should be fully informed was less clear. The 1975 version of the Declaration of Helsinki¹⁶⁴ set out a general principle that research participants should be informed of the aims, methods, risks and benefits of the research and give ‘freely-given informed consent’ (I.9). However, it was considered that medical research combined with professional care blurred the boundaries between research and treatment. The need to tell the patient they were part of a research project was not made explicit. In fact, the 1975 Declaration considered that it might even be possible to dispense with informed consent ‘if the doctor considers it essential not to obtain’ it,¹⁶⁵ subject to the approval of a research ethics committee (II.5). This advice was reiterated in the 1983, 1989 and 1996 versions. In 2000,¹⁶⁶ the Declaration made clear for the first time that:

When medical research is combined with medical care, additional standards apply to protect the patients who are research subjects (para 28). ... The physician should fully inform the patient which aspects of the care are related to the research (para 31).

¹⁶¹ CIOMS, *International Ethical Guidelines for Health-Related Research Involving Humans*. 2016, Guideline 10. <https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/>.

¹⁶² CIOMS, *ibid*.

¹⁶³ WMA. *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*. 2018, para 14.

¹⁶⁴ WMA. *Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects*. 1975 <https://www.wma.net/wp-content/uploads/2018/07/DoH-Oct1975.pdf>

¹⁶⁵ *Ibid*: ‘If the doctor considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee.’ Para II.5.

¹⁶⁶ WMA. *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*. 2000. <https://www.wma.net/wp-content/uploads/2018/07/DoH-Oct2000.pdf>.

One reason for not obtaining informed consent where the research is combined with treatment would be because the therapeutic privilege applied. We have argued that its role in relation to treatment is now limited. Ethically, its acceptability in relation to research is even more controversial.

Unproven therapeutic interventions

With regard to unproven interventions administered outside of a research project, the 1975 version of the Declaration of Helsinki gave freedom to doctors to use 'new diagnostic and therapeutic measure(s)' if they had potential to save life, improve health or alleviate suffering (II.1). Today, the Declaration of Helsinki adds to this requirement of explicit and informed consent, and requires that such interventions should be made the object of research:

In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorised representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available.¹⁶⁷

Supplemental Q11. Please consider where it is ever acceptable to treat a child without their or their parent's express and informed consent.

To avoid a claim in battery in non-emergency treatment, a valid consent is required. In response to Q20 we stated that young people aged 16 and over are presumed able to consent to treatment. Children under the age of 16 can consent if they are *Gillick* competent.¹⁶⁸ Exceptions to the requirement for consent apply in an emergency and the therapeutic exception may apply so that certain information can be withheld if it would cause serious harm to the patient. These exceptions apply to children as well as to adults.

Where a valid and informed consent is obtained from the child, there is no legal obligation to also seek the express and informed consent of a parent. However, it is good practice to involve parents in the decision-making process if the child agrees.

If the child cannot consent to treatment, then consent should be obtained from someone with 'parental responsibility',¹⁶⁹ but there are good reasons for informing and involving the child in the decision-making process.¹⁷⁰

Emergencies

If a child is unable to consent due to emergency but a parent or guardian is available, then parental consent should be sought. However, in *Gillick* in 1985 it was made clear that parental rights are held to enable them to fulfil their responsibilities to their children and should be exercised in the child's best interests. If a parent refused to consent to treatment that clinicians

¹⁶⁷ WMA. *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*. 2018, para 37. <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>.

¹⁶⁸ *Gillick v W Norfolk & Wisbech AHA* [1985] 3 All ER 402.

¹⁶⁹ Children Act 1989, s 3(1): 'In this Act "parental responsibility" means all the rights, duties, powers, responsibilities and authority which by law a parent of a child has in relation to the child and his property.'

¹⁷⁰ See Shaw M. Competence and consent to treatment in children and adolescents. *APT* 2001; 7: 150-159.

consider necessary to protect the life and health of the child, court authorisation might be sought, if time allows. According to the Children Act 1989, the welfare of the child is the court's paramount consideration. If time is of the essence, the doctrine of necessity is likely to protect treating clinicians acting without consent.¹⁷¹

The doctrine of necessity is now relatively well developed,¹⁷² but has not always been thus. Problems may have been exacerbated by the facts that parents were not always able to stay with their children in hospital and could not be contacted with the ease with which that is generally possible today.¹⁷³ The BMA in its 1974 guidance recognised that a 'common problem' existed whereby patients under 16 needed treatment and no parent or guardian was available to give consent. The BMA advised:

Emergencies should not wait for consent and there can be little doubt that a court, having regard to parents' duty to provide medical care for their child will uphold the doctor's action in providing such care as might reasonably anticipate the parents' consent. For patients who need treatment for illnesses of lesser urgency the doctor must balance the need for treatment against the difficulty of contacting the parents (paras 1.11–1.12).

The 1980 guidance repeated this advice and also addressed what might happen if no relatives are available at all:

If no relatives are available a minor may have to be placed under legal guardianship of the police or Social Services in order that consent may be obtained (para 3.25).

In 1988, the GMC considered that it could sometimes be appropriate to test a child for HIV without parental consent, where the child is not competent to consent, and testing is considered to be in the child's best interests. It was considered that 'the possibility that the child may have been infected by a parent may, in certain circumstances, distort the parent's judgement so that consent is withheld in order to protect the parent's own position'.¹⁷⁴ Today, not only would the justification be considered dubious in the extreme, but the situation is unlikely to constitute an 'emergency' and therefore consent of the child, parent or court should be sought. The 1988 advice implies greater latitude on the part of clinicians when acting in the best interests of children in circumstances where they think the parent might object.

Refusals of consent

In a series of cases in the 1990s it was held that parental consent can supply the doctor with the necessary permission notwithstanding a child's (competent) refusal.¹⁷⁵ Today, the autonomy rights of the child, protected under Article 8 of the Human Rights Act 1998, would make it preferable to seek a determination of best interests by the court rather than overriding a child's competent refusal.

¹⁷¹ *Gillick v W Norfolk & Wisbech AHA* [1985] 3 All ER 402, p 424 and p 435.

¹⁷² *Re S* [1994] 2 FLR 416, at 420.

¹⁷³ Sainsbury CPQ, Gray OP et al. Care by parents of their children in hospital. *Archives of Disease in Childhood* 1986; 61: 612-615.

¹⁷⁴ GMC. *HIV Infection & AIDS: The Ethical Considerations*. 1988, 14.

¹⁷⁵ *Re R (A Minor) (Wardship: Consent to Treatment)* [1992] Fam 11 (CA); *Re W (A Minor) (Consent to Treatment)* [1993] Fam 64 (CA). Discussed in response to Q24i.

Where a child who has competence/capacity refuses treatment that is life-sustaining, their decision can be overridden by the court.¹⁷⁶ This might be particularly pertinent to the discussion above regarding risk and side-effects. For example, if a child refuses life-sustaining treatment due to a fear of the side-effects of treatment, a doctor might seek to override that concern. However, where a child has long term experience of a particular treatment and the attendant side-effects, a doctor might well support the child in reaching a decision to move to a more conservative treatment, etc.

Where a proxy makes a decision that clinicians do not consider compatible with a child's best interests then the dispute can be brought before the courts to determine best interests. This could entail parents wishing not to treat a child, e.g. blood products refused for religious reasons, or it could entail parents wanting treatment to continue beyond a point deemed to be in the child's best interest by the medical team. The court will not necessarily follow the parental view. Instead, the court makes an objective assessment of the child's best interests, taking into consideration the relevant views. For example, in a 1999 case¹⁷⁷ an HIV-positive mother became pregnant and gave birth to a girl. The local authority applied to the High Court arguing that it would be in the girl's best interests to test for her HIV status and, if found to be positive, to treat her. The court held that, even if reasonably held, the parental view could be overridden because the welfare of the child is the paramount consideration.

Supplemental Q12. When a patient is given treatment (such as a blood transfusion or the administration of blood products) in emergency circumstances what ethical principle and obligations should guide the clinician's actions at the time of, and following such treatment? Would this be different, and if so how if a patient is unconscious or under general anaesthetic?

We have alluded several times to the fact that in an emergency, consent may be modified or waived. The GMC's 2008 guidance states (as referred to above) that written consent should be obtained in certain circumstances. It recognises that this requirement might be waived in an emergency or if the patient is in serious pain or distress:

But you must still give the patient the information they want or need to make a decision. You must record the fact that they have given consent, in their medical records.¹⁷⁸

Consent might also be waived where it is not possible to obtain consent or wait for such a time that the patient will be able to provide it as, for example, if the patient is unconscious and treatment is urgently required. The GMC made clear in its 1998 guidance (that applied until 2008) that emergency treatment without consent should be 'limited to what is immediately necessary to save life or avoid significant deterioration in the patient's health'.¹⁷⁹ Sometimes the need for emergency treatment might be anticipated in which case, advance care planning should include discussions about what might happen in an emergency so the patient's wishes can, as far as possible, be followed.¹⁸⁰

¹⁷⁶ Ibid.

¹⁷⁷ *Re C (HIV Test)* [1999] 2 FLR 1004.

¹⁷⁸ GMC. *Consent: Patients and Doctors Making Decisions Together*. 2008, para 50.

¹⁷⁹ GMC. *Seeking Patients' Consent: The Ethical Considerations*. 1998, para 18.

¹⁸⁰ GMC. *Consent: Patients and Doctors Making Decisions Together*. 2008, para 58.d.

We have dealt with emergency treatment of children in our response to Supplemental Q11. With regard to adults, section 5 of the Mental Capacity Act 2005 gives doctors a general authority to act in the care or treatment of a person provided they have taken reasonable steps to establish that the person lacks capacity, and reasonably believe that it is in the person's best interests for the act to be done.

With regard to the *scope* of permissible treatment, the GMC's 2008 guidance on consent states:

79. When an emergency arises in a clinical setting and it is not possible to find out a patient's wishes, you can treat them without their consent, provided the treatment is immediately necessary to save their life or to prevent a serious deterioration of their condition. The treatment you provide must be the least restrictive of the patient's future choices. For as long as the patient lacks capacity, you should provide ongoing care on the basis of the guidance in paragraphs 75–76. If the patient regains capacity while in your care, you should tell them what has been done, and why, as soon as they are sufficiently recovered to understand.

Section 2: Treatment

Question 24. What ethical principles should inform decision-making about the treatments to offer a patient?

In particular, and from a medical ethics perspective:

24a. What factors should a clinician consider when determining whether a treatment is clinically indicated and so can be offered to a patient?

Guidance regarding the relevance of patient preferences to the selection of treatment options has changed over time. The BMA's 1970 booklet on medical ethics sets out a procedure for examination in consultation, in which the practitioner and consultant would examine the patient and then 'the diagnosis, prognosis and treatment should be discussed by the practitioner consulted and the attending practitioner in private' and 'The opinion on the case and the treatment as agreed should be communicated to the patient ... where practicable by the practitioner consulted in the presence of the attending practitioner'.¹⁸¹ Though consultation with the patient would allow consideration of his or her preferences, the focus of the guidance was on agreeing the relevant clinical factors between generalist and specialist professionals.

2001 guidance from the GMC also emphasised the relevance of clinical considerations, requiring doctors to provide treatment 'based on your clinical judgement of patients' needs and the likely effectiveness of the treatment'.¹⁸² From 2008, however, GMC guidance supported the view that *non-clinical* considerations are also relevant to treatment selection. It stated that patients should have information they want or need around options for treatment.¹⁸³ Accordingly:

The doctor uses specialist knowledge and experience and clinical judgement, *and the patient's views and understanding of their condition*, to identify which investigations or treatments are likely to result in overall benefit for the patient.¹⁸⁴ (our italics)

Consequently, decisions about tests, treatment and procedures ideally flow from a combination of best available evidence, patient preferences and clinical judgement. Yet even today this balance is not always maintained.¹⁸⁵ Patient preferences are sometimes disregarded for a range of possible reasons including inadequate understanding of the importance of patient autonomy and its therapeutic benefits, lack of time, poor communication on the part of clinicians, and the impact of cultural norms on patients. Progress has been made since the 1970s and 1980s, during which period there was potential overreliance on scientific evidence, and a failure to adjust appropriately to situations where such evidence was lacking or unclear: the failure was in part due to the assumption that clinical judgement could operate independent of information about patient preferences and/or robust scientific evidence.

¹⁸¹ BMA. *Medical Ethics*, BMA 1970, para 5.

¹⁸² GMC. *Good Medical Practice*. 2001, para 5.

¹⁸³ GMC. *Consent: Patients and Doctors Making Decisions Together*. 2008, para 9.

¹⁸⁴ *Ibid*, para 5.

¹⁸⁵ See Community Research, *Doctors' Attitudes to Informed Consent and Shared Decision Making: Full Research Report for the GMC*. June 2017. https://www.gmc-uk.org/-/media/documents/Doctors_attitudes_to_consent_and_shared_decision_making_FINAL_research_report.pdf_72137875.pdf.

It is worth acknowledging that having an accurate sense of what a patient wants, and a clear sense of what medicine can offer does not necessarily mean that a doctor can proceed to providing that thing. The scope of what can be offered by clinicians is determined to some extent by non-clinicians. Governments make decisions about how and to what degree to fund healthcare costs. At a local level, commissioners and administrators make decisions about resource allocation and cost containment; research ethics committees may determine the acceptability of clinical trials involving particular patient profiles; and hospital ethics committees or, indeed, the courts may be involved in ethically charged treatment decisions particularly when the treating clinicians and patients or parents disagree. It is therefore the case that an individual doctor's options for treating a particular patient may be limited to a degree that the patient may not understand. The question then arises regarding what responsibility, if any, the doctor has to lay bare the limiting factors.

Current guidance from the GMC sets out what they expect of doctors providing clinical care.

'you must:

- prescribe drugs or treatment, including repeat prescriptions, only when you have adequate knowledge of the patient's health and are satisfied that the drugs or treatment serve the patient's needs
- provide effective treatments based on the best available evidence
- take all possible steps to alleviate pain and distress whether or not a cure may be possible
- consult colleagues where appropriate
- respect the patient's right to seek a second opinion
- check that the care or treatment you provide for each patient is compatible with any other treatments the patient is receiving, including (where possible) self-prescribed over-the-counter medications
- wherever possible, avoid providing medical care to yourself or anyone with whom you have a close personal relationship.¹⁸⁶

More specifically, the considerations relevant to whether a particular treatment is clinically indicated will include some of the following:

- (i) How certain is the diagnosis?
Should further tests be undertaken?
Should treatment be delayed pending greater certainty?
- (ii) What treatments are licensed for the condition?
How effective are they according to available evidence?
What are their risks, burdens, benefits and side-effects?
- (iii) Which are suitable to and for this patient?
Are there contraindications?
Which treatments are feasible?
What does the patient want?

¹⁸⁶ GMC. *Good Medical Practice*. 2013, Domain 1. <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice/domain-1---knowledge-skills-and-performance>.

- (iv) Which of the potential treatments are available to this patient?
 Will the treatment be privately funded?
 If the treatment is funded by the NHS, is allocation of resources to this patient justified?
- (v) Are relevant clinical trials available?
 How relevant are they to this patient's needs?
 Is it practical for the patient to access them?
 What are the potential risks and benefits to this patient?
- (vi) Is innovative treatment/accelerated access available?
 If a treatment is not licensed is there reason to think it might be efficacious?
 Are there alternative licensed treatments of similar efficacy?
 What are the potential risks and benefits?

24b. How should a clinician weigh those factors?

Three ethical principles in particular guide decision-making in this context:

- (i) Protect life, health and wellbeing

The clinician's first duty is to their patient. Clinicians are expected to use their knowledge and skill to protect (and where appropriate save and prolong) life and health and promote wellbeing. A claim in negligence may arise if it is alleged that the treatments selected were inappropriate and harm to the patient results. Clinicians are required to act on sufficient information. Ethically, a clinician will be expected to serve a patient's interests in a manner that respects their autonomy and dignity, while ensuring that the patient benefits in an appropriate manner from their expertise.

Their expertise is founded in part on their general, specialist and continuing medical education, which is overseen by the GMC. Clinicians are required to keep abreast of developments, with current guidance from the GMC requiring doctors to be competent in all aspects of work and to 'keep your professional knowledge and skills up to date'. Doctors must also be 'familiar with the law and with guidelines and developments that affect your work'.¹⁸⁷ They may be found negligent if they have not followed general and approved current practice, though they are not expected to know of every published research paper in their field.¹⁸⁸ In line with this expectation, the GMC requires that medical education engenders an understanding and application of clinical, basic, behavioural, and social sciences on which medical practice is based.¹⁸⁹

The National Institute for Clinical Excellence (NICE)¹⁹⁰ was established in 1999 to provide patients and clinicians with evidence and guidance on best practice. This is to be taken into account by clinicians when exercising clinical judgement but does not override individual responsibility to the patient to take decisions according to the particular patients' needs:

The considered judgement of NICE, or the profession itself, will be evidence of what constitutes responsible practice. Does this mean any doctor departing from official guidelines will be proven negligent? Some doctors fear guidelines will ... lead to a 'tick-box' approach to patient care. Doctors will cease to exercise professional judgement based on the needs and circumstances of the individual patient. This

¹⁸⁷ GMC. *ibid.* Similar provisions were outlined in GMC. *Good Medical Practice*. 1995, paras 3, 5, 7.

¹⁸⁸ *Whiteford v Hunter* (1950) 94 Solicitor's Journal 758, HL.

¹⁸⁹ GMC. *Tomorrow's Doctors*. 1993, para 13.

¹⁹⁰ Now the National Institute for Health and Care Excellence. <https://www.nice.org.uk>.

should not happen. Where departure from the guidelines can be justified in the interests of the patient, the doctor discharges his duty of care. Blind adherence to guidelines or protocols would itself be negligent.¹⁹¹

The very existence of NICE tells us that a modern doctor is required to contextualise the treatment decisions relating to particular patients, but this does not mean they can, or should, ignore factors which might be overlooked were they to demonstrate ‘blind adherence to guidelines or protocols’.

The art of medicine is to combine the scientific knowledge which can be tested and verified with an understanding of the social and biographical reality of particular patients and in some cases groups of patients.

(ii) Treat justly

Like all health systems the world over, the NHS has finite resources and consequently if resources are allocated to one purpose or service they are, by definition, not available to another. In allocating resources fairly, a balance must be made between overall benefit to this patient and the duty to other patients. Wherever resources are limited, an assessment is required of the extent to which treating a particular group of patients with a particular drug, for example, might mean that other groups or individuals have to be deprived of something from which they would benefit. The NHS sets priorities and shares its budget with commissioners. Since 1999, NICE makes recommendations about the efficacy and application of treatments, but decisions must still be taken as to whether such treatments are justifiable in each case. For example, NICE evidence-based clinical guidelines currently state that eligible women should be offered three full cycles of IVF, but very few clinical commissioning groups fund three rounds and some do not fund any.

Managers may have to make decisions at Trust level, but this must be balanced with the clinician’s duty to their patients. In 1999 the GMC advised:

Conflicts may arise when doctors are called upon to make decisions about the use of resources and about patients’ care, when the needs of an individual patient and the needs of a population of patients cannot both be fully met. Dilemmas of this kind have no simple solution. When taking such decisions, doctors should take into account the priorities set by Government and the NHS and/or their employing or funding body. But they must also be clear about their own role. As clinicians, doctors must make the care of their patients their first concern, bearing in mind the effects of their decisions on the resources and choices available for other patients. As managers, doctors must allocate resources in the way that best serves the interests of a community or population of patients. In both roles, doctors should use evidence from research and audit to make the optimum use of the resources available.¹⁹²

Clinicians are sometimes often called upon to prioritise treatment between individuals. Guidelines and/or long standing and ethically justifiable medical conventions may assist in some situations. For example, in a busy emergency department, a system of triage usually operates to determine who has the greatest need; an available heart for donation will trigger an assessment of which patient on the waiting list is most likely to benefit. In both these cases the relevant factors to be considered are forward looking and clinically based. A

¹⁹¹ Brazier M, Cave E. *Medicine, Patients and the Law*. Manchester: MUP, 2016, p 208.

¹⁹² GMC. *Management in Health Care – The Role of Doctors*. May 1999, para 7. <https://www.gmc-uk.org/-/media/documents/management-in-health-care-1999---2006-55679495.pdf?la=en>.

scarce resource will be used in the manner most likely to bring about the most certain and/or substantial benefit. While some regard will be given to issues of desert, such as waiting time to be treated, the promise of clinical benefit is paramount. It is even possible that someone's access to treatment will be jeopardised by behaviours which make that benefit less secure, such as smoking in the context of a heart transplant or failing to lose weight prior to IVF.

It is important to stress that a justice-based approach to medicine is non-judgemental and non-discriminatory in the sense that issues such as smoking or obesity are only relevant if and when (and because) they undermine treatment. The issue is not one of blame or social censure, but rather a variant of the triage approach set out above. In this case when distributing a scarce resource, it might be necessary to overlook an individual whose behaviours are detrimental to a good outcome. This becomes particularly difficult for practitioners in the face of evidence relating to health inequalities and the impact of low income, etc., on such behaviours.

(iii) Respect autonomy

The law distinguishes between the clinician's duty in selecting treatment options, which is a matter of clinical judgement taking into consideration the needs of the particular patient, and their duty to explain the risks and benefits of those options to the patient and enter into dialogue to enable the patient to make an informed choice whether to accept one of them.¹⁹³

In practice and in medical ethics, partnership and dialogue are relevant to both the selection of treatment and choice between available options. For example, the patient may seek guidance as to which of several treatment options is most suitable and the clinician should take into consideration the patient's preferences and values when selecting treatment. This is reflected in GMC guidance that requires that doctors:

Work in partnership with patients. Listen to, and respond to, their concerns and preferences. Give patients the information they want or need in a way they can understand. Respect patients' right to reach decisions with you about their treatment and care.¹⁹⁴

While partnership, or 'shared decision-making', is relevant to both selection of treatments and the choice between them, the power balance in each case is dissimilar.¹⁹⁵ Clinicians cannot require a patient with capacity to accept a certain treatment, even if it is life-sustaining. And while a patient can request and suggest treatment, the clinician is not obliged to treat if the option is not clinically indicated.

Not all patient choices must be honoured. One reason for this is the ethical imperative not to undertake actions expected to do more harm than benefit. Jonathan Montgomery frames "objection" as a key professional role [whereby] the professional is expected to object to "inappropriate" access to the treatments sought.¹⁹⁶ The World Medical Association has produced international guidance promoting healthcare professionals' freedom from undue external interference. It 'supports physicians if they refuse demands by patients and family

¹⁹³ *Montgomery v Lanarkshire HB* [2015] UKSC 11, [82]: There is a 'fundamental distinction between, on the one hand, the doctor's role when considering possible investigatory or treatment options and, on the other, her role in discussing with the patient any recommended treatment and possible alternatives, and the risks of injury which may be involved.'

¹⁹⁴ GMC. *Good Medical Practice*. 2013.

¹⁹⁵ See Cave E. Selecting treatment options and choosing between them: delineating patient and professional autonomy in shared decision-making. *Health Care Analysis* 2020; 28: 4-24.

¹⁹⁶ Montgomery J. Conscientious objection: Personal and professional ethics in the public square. *Med Law Rev.* 2015; 23(2); 200-22.

members for access to inappropriate treatments and services'.¹⁹⁷ So, while an informed decision by a competent patient to refuse treatment is sufficient grounds for non-treatment, a patient's preferences are never, in and of itself, a sufficient ground for treatment. Although, importantly, it is sufficient grounds for non-treatment.

Accordingly, the GMC in 2008 advises that clinicians should:

- Determine what treatment options are clinically indicated
- Explain the options to the patient, setting out their risks and benefits
- Potentially, and particularly if requested, make a recommendation
- Allow the patient to decide whether they want any of the options.¹⁹⁸

Supplemental Q13. When answering questions 24a and 24b, please consider whether there is an ethical obligation or responsibility on the clinician to explain to the patient the factors that he/she has weighed and/or an obligation or responsibility to explain to the patient how he/she has weighed those factors.

The principle of autonomy underlies the requirement of informed consent discussed in response to Q20. We have set out the information that should be disclosed about alternatives, risks and benefits, and the importance of dialogue. The dialogue should encompass the 'reasonable' alternatives selected by the clinician, and we have opined that today the selection will be responsive to the particular patient, their goals and values. Clinicians should engage with the patient in dialogue to determine what is in the best overall interests of the patient.¹⁹⁹ It follows that an explanation of some of the relevant factors weighed by the clinician in selecting treatment options will be encompassed within the informed consent process. As stated above, some patients might make clear that they do not require, nor desire, such an explanation.

Additionally, the clinician should respond to questions raised by the patient as to options that they do not consider reasonable and also to treatments that are routinely used but are not clinically indicated in the patient's case.

Historically, a more paternalistic attitude dominated, and less emphasis was placed on explaining possible alternatives or how decisions as to the best treatment option had been made. In 1989, Silverman lamented the narrow scope of informed consent and the limited protection it gave to patients' autonomy:

'Daily consent' is reviewed, if at all, only in retrospect. Doctors are merely exhorted to obtain informed consent; they often minimise uncertainties about 'best' treatment and they feel duty-bound to provide patients with an unequivocal recommendation for action.²⁰⁰

¹⁹⁷ WMA. *Declaration on Professional Autonomy and Clinical Independence*, Adopted by the 59th WMA General Assembly, Seoul, Korea. 2008, amended 2018, para 8. See also paras 1-2 and para 12.

¹⁹⁸ GMC. *Consent: Patients and Doctors Making Decisions Together*. 2008, para 5.

¹⁹⁹ See Savulescu J. Rational non-interventional paternalism: why doctors ought to make judgements of what is best for their patients. *J Med Ethics*. 1995; 21: 327-31; 155; Savulescu J. Liberal rationalism and medical decision-making. *Bioethics* 1997; 11: 115-129.

²⁰⁰ Silverman WA. The myth of informed consent: in daily practice and clinical trials. *J Med Ethics*. 1986; 15: 6-11.

24c. What obligation or responsibility does the clinician have to identify and offer the best treatment for a patient?

There is an ethical obligation to offer the patient the best available treatment. This did not happen in the case of breast surgeon Ian Paterson, who performed inappropriate and unnecessary procedures on thousands of patients from the mid-1990s and was convicted of wounding with intent in 2017 (see Q20 above). The 2020 independent inquiry found that this was not simply the case of a rogue surgeon, but of system failure: ‘This capacity for wilful blindness is illustrated by the way in which Paterson’s behaviour and aberrant clinical practice was excused or even favoured’.²⁰¹ The obligation to identify and offer the best treatment is not merely one that is attached to the treating clinician, but is the responsibility of the profession and regulators.

Identifying the best treatment for a patient

‘Best treatment’ can only be assessed against the knowledge that exists at the time. It shifts as medicine advances and more becomes known about conditions and potential treatments.

What is ‘best’ for one patient will not necessarily be best for another: a clinician must balance known evidence of efficacy, burdens and benefits with the clinical presentation of the patient and with the patient’s values, wishes and preferences.

For these reasons the decision as to which is best may be finely balanced between two or more options, or there may be genuine uncertainty as to the most clinically beneficial treatment, or what is best might change over time due to changes in the patient’s condition or advances in science and available evidence. Sometimes, what is best for a patient will not offer them the best or indeed any possibility of cure. Sometimes the best option is not to treat. This is a decision which a doctor may reach and/or voice before a patient or vice versa.

Offering the best treatment for a patient

When resource constraints apply, clinicians (and also the NHS and managers) must balance overall benefit to this patient and the duty to other patients. It is not always feasible in a system of finite resources to give patients what they want or even what they need. Where it is important to establish the cost-effectiveness and feasibility of a treatment alongside its clinical efficacy there is potential for patients to want something which could feasibly benefit them, but which as yet has not been accepted as a fundable option within the NHS.

There may also be a delay in treatment, diagnosis or referral that flows from pressure on the system. Balancing demand and capacity while driving quality, value and productivity is the responsibility of the NHS, managers and clinicians. It is important that this is communicated clearly and realistically. The independent inquiry into Ian Paterson’s conduct revealed that he exploited the fear of waiting for treatment for cancer in order to persuade patients to opt for treatment in the independent sector. He did not explain the reality of how long they might have to wait for NHS treatment.²⁰²

²⁰¹ James G. Rev’d (Chair). *Report of the Independent Inquiry into the Issues raised by Paterson*. 2020 HC 31.

²⁰² *Ibid*, 114.

24d. What obligation or responsibility does the clinician have to identify and offer alternative treatments for a patient?

Treatment versus no treatment

There is always an alternative to the treatment clinicians identify as optimal for the patient, and that is not to have the treatment. Patients should be given the option to say ‘no’ and be assured of compassion and continuing care in that event. A decision to stop active treatment is not and should never be understood as the end of the caring relationship, although the primary responsibility for care could shift to different parties.

If a patient makes an informed choice to refuse a treatment because a clinician has explained the risks involved and the patient decides they do not wish to run those risks, then no harm has been done. If a patient accepts a treatment unaware of the known risks involved, then that person has in the first place been wronged and may subsequently be harmed. The distinction between these two cases holds, even if the negative consequences of the treatment refusal are more serious than those of the treatment.

How should treatment alternatives be selected?

Sometimes there will be more than one clinically indicated treatment option, in which case commitment to patient autonomy requires that the options are put to the patient. In the 2015 Supreme Court case of *Montgomery*, it was recognised that patients should be informed not just of a recommended treatment, but also of ‘reasonable alternatives’ and their risks.²⁰³ Though this is the clearest statement of this principle to date, it was recognised by the courts prior to *Montgomery* that there is a need to discuss ‘the possible methods of treatment’²⁰⁴ with patients. The duty is particularly strong if the alternative is as efficacious as the recommended treatment, but carries fewer burdens or risks.

The duty to inform the patient of ‘reasonable alternatives’ should not be confused with a duty to refer to every alternative. Offering diagnoses or treatments that are not clinically justified carries adverse consequences both to the system and the patient. In Scotland, the Chief Medical Officer has produced a series of annual reports promoting ‘realistic medicine’:

Realistic Medicine encourages us to recommend investigations and treatments that add value, minimise waste and to personalise our approach to each patient, involving them fully in decision making.²⁰⁵

Realistic medicine requires selection and communication of alternatives in a responsible manner that reflects what can be achieved or expected. A similar approach has been set out in Wales.²⁰⁶

Post-*Montgomery* it is unclear what legal standard applies when choosing treatment options to put to the patient. ‘Reasonable’ alternatives should be selected, but how is reasonableness to be determined? Lords Kerr and Reed distinguished the context of *selecting* proposed

²⁰³ *Montgomery v Lanarkshire HB* [2015] UKSC 11, [89].

²⁰⁴ *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] AC 871, p 904 per Lord Templeman and see *Birch v University College London Hospital NHS Foundation Trust* [2008] EWHC 2237 (QB).

²⁰⁵ Healthcare Quality and Improvement Directorate. *Practising Realistic Medicine: Chief Medical Officer for Scotland annual report*. 2018, Ch 3. <https://www.gov.scot/publications/practising-realistic-medicine/pages/2/>.

²⁰⁶ Welsh Government. *Making Prudent Healthcare Happen*. 2014, updated 2016. <http://www.prudenthealthcare.org.uk/>.

treatment alternatives and the *disclosure* of the treatment options to the patient.²⁰⁷ The latter is governed by the *Montgomery* test and what the reasonable/actual patient would consider relevant.²⁰⁸ *Bolam* and *Bolitho*²⁰⁹ may still be relevant when determining which options are clinically relevant, as this involves clinical expertise. The matter is unsettled as the test may depend on the relevance of risk to the reasonableness of the alternatives: if the procedure is elective, then even small risks may be relevant; if treatment is novel and less certain then comparisons with available standard options are relevant.

In terms of medical ethics, the clinician should consider the patient's perspective as well as the relative risks when selecting and discussing possible treatment options. It is important to understand what gives a patient's life value, and what bodily and cognitive functions they are therefore most keen to protect and maintain. Drugs may secure improvement in some symptoms at the cost of others, and the patient could have firm views regarding which symptoms they wish to prioritise treating because of their understanding of how they have an impact on their quality of life.

24e. In broad terms what kind of information should a clinician provide to a patient about possible treatments?

Lords Kerr and Reed in *Montgomery* set out three focuses to the information required to protect a doctor from a claim in negligence: (1) the seriousness of the condition, (2) the risks and benefits of proposed treatment, and (3) reasonable alternatives and their risks and benefits.²¹⁰ This information must be comprehensible:

The doctor's duty is not therefore fulfilled by bombarding the patient with technical information which she cannot reasonably be expected to grasp, let alone by routinely demanding her signature on a consent form.²¹¹

Dialogue is required to enhance the patient's understanding and help them make a decision whether or not to accept treatment, or, more realistically in some circumstances, accept the treatment this clinician is willing and able to offer. Setting out alternatives might in some situations entail presenting evidence-based alternatives not as yet available in the NHS or in this country. This is an ethically challenging demand on doctors who might worry about the additional burden placed on patients and their families by introducing the possibility of treatments they cannot provide.

Information on risk should as a minimum include 'material' information, as defined in *Montgomery* from the perspective of the reasonable and/or actual patient (see Q20). It is clear from *Montgomery* and subsequent case law that what is material cannot be reduced to percentages. In general, the less urgent or necessary the intervention to maintain life or health,

²⁰⁷ *Montgomery v Lanarkshire HB* [2015] UKSC 11, [82] making 'a fundamental distinction between, on the one hand, the doctor's role when considering possible investigatory or treatment options and, on the other, her role in discussing with the patient any recommended treatment and possible alternatives, and the risks of injury which may be involved.'

²⁰⁸ *Montgomery v Lanarkshire HB* [2015] UKSC 11, [87]: 'The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.'

²⁰⁹ *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582. The selection of alternatives will be considered reasonable if it was in accordance with a responsible body of doctors of the relevant specialism, even though others may have selected different alternatives, provided that the advice had a logical basis (*Bolitho v City and Hackney Health Authority* [1998] AC 232).

²¹⁰ *Montgomery v Lanarkshire HB* [2015] UKSC 11, [90]: 'the doctor's advisory role involves dialogue, the aim of which is to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision.'

²¹¹ *Ibid*, [90].

the greater the imperative to disclose even small risks. Communication of risk should include information about the magnitude of the risk, including the chances of them occurring and the range of consequences if they occur. Today, percentages are often used to communicate risk (e.g. ‘there is approximately a 10% risk of numbness if you have this procedure’) as this is less likely to be misinterpreted than more subjective terms such as ‘small’ or ‘moderate risk’. But this is not always possible and has not always been so. Whether the risk should have been set out as a percentage will depend on what was considered responsible practice at the time.²¹² There should be adequate time and space for meaningful dialogue²¹³ and care should be taken not to rely overly on leaflets in place of meaningful discussions.²¹⁴ The 2020 independent inquiry into Ian Paterson’s conduct (referred to above) made recommendations to improve the consent process including:

We recommend that it should be standard practice that consultants in both the NHS and the independent sector should write to patients, outlining their condition and treatment, in simple language, and copy this letter to the patient’s GP, rather than writing to the GP and sending a copy to the patient. ...

We recommend that there should be a short period introduced into the process of patients giving consent for surgical procedures, to allow them time to reflect on their diagnosis and treatment options. We recommend that the GMC monitors this as part of ‘Good Medical Practice’.²¹⁵

The law of negligence does not capture the entirety of the ethical duties to inform. Today, it is clear that information requirements are responsive to the situation and patient. From 1998, too, the GMC’s guidance on consent required doctors to inform patients of the following wide range of factors:

- details of the diagnosis, and prognosis, and the likely prognosis if the condition is left untreated;
- uncertainties about the diagnosis including options for further investigation prior to treatment;
- options for treatment or management of the condition, including the option not to treat;
- the purpose of a proposed investigation or treatment; details of the procedures or therapies involved, including subsidiary treatment such as methods of pain relief; how the patient should prepare for the procedure; and details of what the patient might experience during or after the procedure including common and serious side effects;
- for each option, explanations of the likely benefits and the probabilities of success; and discussion of any serious or frequently occurring risks, and of any lifestyle changes which may be caused by, or necessitated by, the treatment;
- advice about whether a proposed treatment is experimental;
- how and when the patient’s condition and any side effects will be monitored or re-assessed;

²¹² For example, in *Ollosson v Lee* [2019] EWHC 784 (QB), ‘The GP experts ... agree that in 2012 most people would consider 1-2% to be a small risk.’ [103].

²¹³ *Thefaut v Johnson* [2017] EWHC 497 [58].

²¹⁴ *Ollosson v Lee* [2019] EWHC 784 (QB).

²¹⁵ James G. Rev’d (Chair). *Report of the Independent Inquiry into the Issues raised by Paterson*. 2020 HC 31, 218-219.

- the name of the doctor who will have overall responsibility for the treatment and, where appropriate, names of the senior members of his or her team;
- whether doctors in training will be involved, and the extent to which students may be involved in an investigation or treatment;
- a reminder that patients can change their minds about a decision at any time;
- a reminder that patients have a right to seek a second opinion;
- where applicable, details of costs or charges which the patient may have to meet.²¹⁶

The challenge posed by this guidance is a challenge common within modern medicine – that of communicating uncertainty and complexity as opposed to providing definitive answers to medical problems. It also requires doctors to respect their commitment to patient-centred care by informing people about the processes they will be part of, much more than might have been expected in the past. This helps to manage patient expectations and ensure that they understand their responsibilities but it means that the doctor’s responsibilities extend far beyond writing a prescription or ordering a test.

24f. What obligation or responsibility does the clinician have to inform the patient of the risks of a particular treatment that is being recommended or considered?

(See also Q20a)

A claim lies in negligence if a patient is not given sufficient information about the proposed treatment to allow them to make a decision as to whether or not to accept it. There has, since the 1950s, been recognition of a legal duty to inform patients of material risks, but what is considered ‘material’ has changed significantly.

As we explored in response to Q20, the reasonable professional standard adopted in the 1950s required clinicians to inform the patient of the risks of treatment, but reasonableness then was determined on the basis of what other competent doctors considered appropriate. This made it hard for patients to prove negligence and both responded to and exacerbated medical paternalism in practice. Two qualifications to the doctor-centred standard were set out in the House of Lords case of *Sidaway* in 1985. If the patient themselves raised questions, then the doctor was duty-bound to answer them. But this gave little assistance to patients who did not know to ask the question due to their lack of expertise or were too intimidated to question the doctor’s authority due to the imbalance of power. The second qualification related to disclosures ‘so obviously necessary to an informed choice on the part of the patient that no reasonably prudent medical man would fail to make it’, for example, ‘if there was a substantial risk of grave adverse consequences, as, for example, the ten per cent risk of a stroke’.²¹⁷

We have discussed the development of the law and guidance on informed consent in response to Q20 which we refer to only in brief here. From 1998, the GMC set out clear guidance on communicating information: ‘Patients must be given sufficient information, in a way that they can understand, to enable them to exercise their right to make informed decisions about their

²¹⁶ GMC. *Seeking Patients’ Consent: The Ethical Considerations*. 1998, para 5. <https://www.gmc-uk.org/-/media/documents/patient-consent-1998---2008-55678021.pdf?la=en>.

²¹⁷ *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] AC 871, p 900 (Lord Bridge).

care.²¹⁸ In 2004, the patient right to information about risks was recognised as ‘an important right which must be given effective protection whenever possible’²¹⁹ and in 2008 the GMC adopted a patient centred standard that was approved and emulated by the Supreme Court in the 2015 *Montgomery* decision. In *Montgomery* the ‘reasonable professional’ test used to determine what risks are material was replaced with a nuanced ‘reasonable patient’ test. According to the patient-centred approach in *Montgomery*:

The doctor’s duty of care takes its precise content from the needs, concerns and circumstances of the individual patient, to the extent that they are or ought to be known to the doctor.²²⁰

The decision is borne of a realisation that patients are ‘now widely regarded as persons holding rights, rather than as the passive recipient of the care of the medical profession’.²²¹ Furthermore, this change entails a responsibility on the part of the doctor to develop a heightened awareness of the rights that such a person enjoys, and a commitment to identifying the best way to protect them within the medical encounter.

Unknown risks of treatment alternatives

Supplemental Q14a. Please consider not only well-known and widely accepted risks, but also risks that are beginning to be suspected or known as a result of developing medical and scientific understanding.

Supplemental Q14b. Please consider whether, in circumstances where there is no reliable data to indicate that a product or treatment is safe, there is an ethical obligation to inform the patient of this.

Supplemental Q17. Is there an ethical obligation or responsibility on clinicians to keep themselves informed and up-to-date with current knowledge relating to the risks and benefits of products or treatments they are prescribing?

Montgomery was concerned with the communication of known risks that a reasonable or actual patient would want to know. What of unknown risks? When it comes to identifying the risks, the courts have determined that whether a certain risk should be known by the clinician is a matter of clinical judgement, to be determined by reference to *Bolam* and *Bolitho*²²²: there is no duty to warn of risks that a responsible clinician would not have known about, even if that risk would be particularly relevant to the patient.

This would appear to leave the medical profession with the task of assessing whether a particular clinician knew enough about an emerging risk given what was, or is, known more generally at the time. This may be so, but as mentioned above (Q19; Q24b) the modern doctor, both individually and as a profession, is frequently reminded of their responsibility to keep abreast of medical knowledge and this is particularly true in relation to risks associated with their own area of practice.

²¹⁸ GMC. *Seeking Patients’ Consent: The Ethical Considerations*. 1998, para 1. <https://www.gmc-uk.org/-/media/documents/patient-consent-1998--2008-55678021.pdf?la=en>.

²¹⁹ *Chester v Afshar* [2004] UKHL 41, [17] per Lord Steyn.

²²⁰ *Montgomery v Lanarkshire HB* [2015] UKSC 11, [73].

²²¹ *Ibid* [74].

²²² *Duce v Worcestershire Acute Hospitals NHS Trust* [2018] EWCA 1307.

Sometimes risks are unknown because the treatment is an unproven therapeutic intervention or is given as part of a clinical trial. We discuss the requirements for informed consent regarding such cases in response to Q20 where we opine that when research was combined with care, the ethical imperative to inform the patient of the fact that the treatment was unproven is more explicitly framed today than was the case in the 1970s and 1980s.

Issues also arise when there is still a degree of uncertainty around the harms associated with particular treatments despite them having been subject to appropriate research and licensing. For example, after a few years of use evidence might start to emerge of an unexpected risk or side-effect. While this should trigger a responsible response in terms of collection of evidence and further research, it also requires a thoughtful and measured response to sharing the information with patients. This is particularly true where the treatment has provided substantial benefit which would not otherwise be available, and for which no alternative approach exists as yet. It is important to assess the extent to which certain benefits should be balanced against as yet unproven harms and importantly, this needs to be done in an open and transparent manner involving those who have been taking the treatment as well as those who have been prescribing or supplying it.

In some cases, risks will come to light during the course of a person's treatment which might require the clinician to consider alternatives. This is particularly so if the clinician is aware that the patient is experiencing difficulties with the current treatment regime.²²³

24g. Where there is a risk (even a small one) of exposure to a serious infection, is it always incumbent upon the clinician to inform the patient of that risk so that the patient can take an informed decision for themselves?

The legal approach governing when a failure to disclose risk associated with treatment is actionable in negligence has changed over time. As we described in response to Q24f, the approach in the 1980s was that substantial risks, such as a 10% risk of stroke, should be disclosed, and questions should be honestly answered, but the relevance of other risks should be judged according to the standard of the reasonable doctor. In other words, whether non-disclosure was negligent would depend on what was considered responsible and reasonable practice at the time.

As a patient centred standard has become more widely accepted in practice and firmly adopted in law in 2015, so the advice as to disclosure of risk has changed. The GMC advised from 2008:

You must tell patients if an investigation or treatment might result in a serious adverse outcome, even if the likelihood is very small. You should also tell patients about less serious side effects or complications if they occur frequently, and explain what the patient should do if they experience any of them (para 32).

In *Montgomery v Lanarkshire HB*, Lords Kerr and Reed said:

The assessment of whether a risk is material cannot be reduced to percentages. The significance of a given risk is likely to reflect a variety of factors besides its magnitude: for example, the nature of the risk, the effect which its occurrence would have upon the life of the patient, the importance to the patient of the benefits sought

²²³ *Kennedy v Frankel* [2019] EWHC 106 (QB), [39].

to be achieved by the treatment, the alternatives available, and the risks involved in those alternatives. The assessment is therefore fact-sensitive, and sensitive also to the characteristics of the patient.²²⁴

In conclusion, the emphasis on disclosing even small risks of serious infection has been clarified and emphasised in recent times, but even today it cannot be said that small risks of serious infection should *always* be disclosed.

- Firstly, as we have seen, the duty to inform is subject to exceptions including necessity (where the disclosure might be delayed in an emergency) and the therapeutic exception (in which case it would be important to balance the serious harm associated with information disclosure with potential harms flowing from not informing the patient).
- Secondly, it is acknowledged in *Montgomery* that the duty to disclose risks is dependent on multiple factors. In most cases a small risk of serious infection should be disclosed as this offers clear benefits to the patient that might include seeking tests, treatment, taking precautions that protect themselves and others, and preparing for what might come. Very occasionally disclosure of risk might be withheld until a later date. For example, in another context it has been recognised that adult onset conditions revealed in genomic screening of children should generally not be disclosed until there is a clinical justification.²²⁵ Doing otherwise potentially interferes with the child's right to an open future (discussed Q19).

24h. What obligation or responsibility does the clinician have to inform the patient of the possible side-effects, or possible health complications, of a particular treatment that is being recommended or considered?

Supplemental Q15. Please also consider what obligations or responsibility a clinician has to offer other treatment or medication to mitigate such side-effects or complications.

The side-effects or health complications are aspects of the risk and burden of a particular treatment that should be explained as part of the informed consent process. See Q24f and Q20a above.

We can all think of treatments where the potential side-effects are well known even before a doctor discusses them with a particular patient – nausea and fatigue in response to certain chemotherapy regimens would be an obvious example. In this case the doctor still needs to discuss the side-effects, but part of the task will be to counter misunderstandings and tell the patient about measures that can be taken to mitigate some side-effects. In this case, an open discussion about side-effects could be reassuring and might help a patient to cope more effectively with their treatment.

In other situations, side-effects of treatment will not be known either because they are novel and unfamiliar outside specialist settings, or because the disease being treated gets little public attention or exposure. Clearly it is very important in these situations for doctors to be honest and open about the side-effects, even if they are extremely serious and debilitating. As previously stated, if the communication is sensitively handled, the clinician should not feel responsible for a patient's decision to refuse a treatment on the grounds of not wishing to experience the side-effects of treatment, particularly if it is a treatment they have undergone

²²⁴ *Montgomery v Lanarkshire HB* [2015] UKSC 11, [89].

²²⁵ British Society for Human Genetics. *Report on the Genetic Testing of Children*. 2010.

before. The clinician should seek to understand the basis for the patient's decision and check that they have given them accurate and appropriate information and the time to consider it and come to an informed decision.

24i. Does it make a difference if the patient is a child? If so, how and why?

We have discussed the special arrangements that might apply with regard to consent in the case of children (Q20). In relation to the treatments that might be offered to patients, one consideration is that many treatments licensed for use in adults are not licensed for use in children. Though medicines used to treat adults might be used 'off-label' for children, this poses additional risks which it will be important to discuss with the child (if they consent or are capable of taking part in the decision) and parents/carers (if they consent or are party to the decision-making process).

Ethically we know that the way in which we treat children in a medical context is complex and subject to all sorts of social, psychological and moral influences. For many years, children were seen as vulnerable beings who needed to be protected and shielded from the many harms that medicine could visit upon them. More recently, led in part by children and young people themselves, we understand that age, in and of itself, should not determine how a patient is treated. Nor should it deny anyone rights which are taken for granted in the adult world such as the right to access evidence-based medicine.

Best interests is a primary consideration and a 'universal theme of the various national and international instruments' relating to the treatment of children.²²⁶ The treatment options relevant to young patients are therefore governed by the principle of best interests. The danger lies in the perpetuation of a belief that best interests is purely a clinical matter.²²⁷ Clinicians are required to consider best interests broadly, including children's emotional and autonomy interests and in order to do so they should seek the views of children able to provide them.²²⁸

As discussed above (Q19) medicine has historically been prone to paternalism, that is the imposition of medical judgement upon patients who could be quite capable of making important medically-related decisions for themselves. One might balk at extending a discussion of paternalism to the treatment of children, given the appropriateness of a paternal relationship in many situations. However, it is increasingly understood that there is a potential for inappropriate paternalism even in relation to the treatment of quite young children.

Treatment of young people is managed better than in the past, thanks to the development of specialist adolescent services which help with the transition to adult services.

What information must be disclosed about risks and alternatives when the patient is a child?

Notwithstanding that *Montgomery* refers to 'adult person(s) of sound mind', the principles of informed consent are equally relevant when the patient is a child.²²⁹ Whether the proxy or the child is the decision-maker, they will require information upon which to base their decision.

²²⁶ *ZH (Tanzania) v Secretary of State for the Home Department* [2011] UKSC 4, [45] (Lord Kerr).

²²⁷ *Re T (A Minor) (Wardship Medical Treatment)* [1997] 1 WLR 242 (CA), 250-251 (Butler-Sloss LJ).

²²⁸ Children Act 1989, s1(3); UN Convention on the Rights of the Child, Article 12.

²²⁹ Cave E, Purshouse P. Think of the children: liability for non-disclosure of information post-Montgomery. *Med Law Rev* 2019. <https://doi.org/10.1093/medlaw/fwz023>.

While the common law provides a reason to inform the person who provides the consent, ethical principles and the UN Convention on the Rights of the Child also requires that the child who is unable to consent, is helped to participate to the best of their abilities. This requirement is reiterated by the GMC:

You should provide information that is easy to understand and appropriate to their age and maturity about:

- a. their conditions
- b. the purpose of investigations and treatments you propose and what that involves, including pain, anaesthetics and stays in hospital
- c. the chances of success and the risks of different treatment options, including not having treatment
- d. who will be mainly responsible for and involved in their care
- e. their right to change their minds or to ask for a second opinion.²³⁰

Supplemental Q16. Is there an ethical obligation or responsibility on clinicians to share information they have about the risks and benefits of products or treatments, with professional colleagues?

In relation to treatment there is an obligation to record information and discussions accurately in the patient's records. A failure to do so might raise questions as to the adequacy of information given to the patient and it might also obfuscate what has been carried out and compromise patient care.²³¹

Medical progress is based on research on the causes and development of diseases and the improvement of interventions. There is an ethical obligation to share new knowledge so that others might benefit from it. The Declaration of Helsinki 2018 promotes the registration, publication and dissemination of research results (para 36). Though the ethical obligation has historic relevance, guidance has traditionally focused on research conduct rather than dissemination. The 1975, 1983 and 1996 versions of the Declaration clearly anticipated that results should be reported in relevant medical journals and exhorted researchers to 'preserve the accuracy of the results' in publications. From the 2000 version, it was made clear that both negative and positive results should be made publicly available.

²³⁰ GMC, *Guidance 0-18 Years: Guidance for All Doctors*. 2007, para 8. https://www.gmc-uk.org/guidance/ethical_guidance/children_guidance_index.asp.

²³¹ James G. Rev'd (Chair). *Report of the Independent Inquiry into the Issues raised by Paterson*. 2020 HC 31, 116-118.

Section 3: Testing for infection

Question 25. What ethical principles should inform the approach to testing a patient to determine whether they have been infected with a disease?

Decisions should be made on the basis of the best interests of the patient and consistent with distributive justice. While a patient's wishes regarding testing should be considered, they may not be decisive in every case.

The best interests of the patient are determined by weighing benefits and risks. This is determined by the clinician and patient in turn. The clinician brings to bear clinical expertise, knowledge of epidemiology and other relevant disciplines, while the patient brings their own values, experiences, perspectives and needs.

In the past, interests relevant to medical decisions were more narrowly defined. For example, in 1968 Sir Roger Ormrod suggested it was a requirement that patients were informed 'in broad terms of the risks to life or future health or of pain and discomfort involved in the contemplated procedure or to a frank admission that in the given circumstances these cannot be assessed with any accuracy'.²³² This explanation of the information required suggests relevant interests were limited to medical interests, primarily the treatment and prevention of disease, understood in narrow biomedical terms. This may be contrasted with even the earliest advice from the General Medical Council (GMC) on *HIV Infection & AIDS: The Ethical Considerations*, which recognises the importance of considering the 'serious social and financial consequences'.²³³ Today, best interests determinations consider the broad benefits of knowledge, diagnosis, prognosis, treatability and risks of the test.²³⁴ Testing is now performed for the purposes of life planning but in the past it was more focused on therapeutic intervention, either treatment or prevention.

In practice, the appropriateness of testing is determined by both societal and individually focused considerations. For a programme of testing to proceed, policymakers would consider the probability and severity of disease, the reliability of the test, the medical and non-medical actionability (what action might be possible as a result of the test), the cost and the opportunity cost (i.e. the benefits that might be lost as a result of choosing this option over others), the acceptability of the test to society and to the patient, and any risks posed by the test and the resulting information.

Distributive justice will determine whether the utility of a test in the patient's interests is sufficient to warrant public funding. This should not preclude private funding, but has typically within the NHS.

The need to respect the patient's autonomy means it should be up to the patient to determine whether they will accept or reject the test.²³⁵

²³² Compare Ormrod Sir R. Medical ethics. *BMJ* 1968; 19(2): 7-10.

²³³ GMC. *HIV Infection & AIDS: The Ethical Considerations*. 1988, 13.

²³⁴ GMC. *Consent: Patients and Doctors Making Decisions Together*. 2008, 1-5; Wilkinson D, Herring J, Savulescu J. *Medical Ethics and Law; A curriculum for the 21st century*, third edition, Elsevier: London, 2020, 41-53.

²³⁵ GMC. *Consent: Patients and Doctors Making Decisions Together*. 2008, 1-5.

25a. In particular and from a medical ethics perspective, when should a clinician or health body inform a person they may have been exposed to an infectious risk?

In general, there are few arguments against informing someone if they have been infected.²³⁶ If there is any reason to believe the condition is significantly burdensome, they should be informed. While there is a strong reason in favour of disclosure, the mode may differ according to context. Non-disclosure may be justifiable only rarely if the risk is small, the burden to individuals is small, or if the test is associated with significant costs (financial or other).²³⁷

In addition to the principles above and outlined in our preamble to this question, the risk to others of an individual passing on infection constitutes a further reason for disclosure.

There will be a value judgement about what level of confidence or credence (level of evidence) is sufficient to warrant informing and testing and employing risk management. In general, the greater the burden of disease which can be prevented or treated, the lower the threshold for confidence.

25b. What factors should a clinician consider when deciding whether or not to offer a patient a test?

In deciding whether to offer a patient a test, a clinician should consider the factors listed above (Q25 preamble) in relation to determining the patient's best interests and balancing them against considerations of public good and benefit and detriment to others. In response to Q24 we considered the ethical principles that should inform decision-making about the treatments to offer a patient and many of those principles are also relevant to the offer of testing.

The reliability of the test is important – the test should have suitable sensitivity, specificity, and predictive value. This determination involves value judgements by the clinicians based on the statistical properties of the test, such as judgements about what constitutes an acceptable level of reliability. In the past, this decision was made purely by the clinician but more recently this has been made jointly with the patient. These decisions should again be guided by the best interests of the patient and resource constraints (distributive justice), as well as the patient's values and preferences. The decision should be informed by the best evidence of the time, including evidence which ought to be available.

When a clinician is deciding whether to offer a patient a test, their decision must be based on the best interests of the patient. Consideration of broader public interests should usually occur at higher levels, such as government departments, colleges, NHS, etc. Determinations of public interest should generally not be made at the bedside by individual clinicians.

In the past, clinicians made a paternalistic judgement about whether testing was appropriate but today the value of testing is established as a part of a broad discussion about the goals of care. For example, the General Medical Council's 1988 *HIV Infection & AIDS: The Ethical Considerations* recognises the importance of consent to testing but includes no guidance on

²³⁶ Hodkinson K. The need to know—therapeutic privilege: A way forward. *Health Care Analysis* 2013; 21: 105-129, 106-109; Gallagher T. Levinson W. Disclosing harmful medical errors to patients *Archives Internal Medicine* 2005; 165: 1819-1824, 1822; Higgs R. Truth-telling. In Singer P, Kuhse H. (ed) *A Companion to Bioethics*. New York: John Wiley & Sons, 2009; Sokol D. A commentary on Ethics of HIV testing in general practice without informed consent: a case series. *J Med Ethics* 2005; 31(12): 701-702; Fraser J. Ethics of HIV testing in general practice without informed consent: a case series. *J Med Ethics*. 2005; 31(12); 698-702.

²³⁷ GMC. *Consent: Patients and Doctors Making Decisions Together*. 2008, 13-17.

making decisions about when testing may be appropriate.²³⁸ The General Medical Council's 1998 *Seeking Patient's Consent* recognises the importance of maintaining a 'continuing dialogue' about treatments and proposed investigations.²³⁹ While the 2008 *Consent: Patients and Doctors Making Decisions Together* provides a more fulsome discussion of shared decision-making and sharing information with patients to inform future decisions.²⁴⁰

25c. How should a clinician weigh those factors?

In the past, those factors were weighed by the clinician alone or in consultation with colleagues, and informed by professional guidelines.²⁴¹ Increasingly, this weighing occurs today in discussion between clinicians and patients.²⁴² The weighing of risks and benefits was traditionally informed by medical values associated with treatment and prevention of disease. Today they are informed by more global values related to wellbeing and the patient's own values.²⁴³

In the past, doctors believed there were uncontroversial metrics for weighing benefits and harms. Today there is greater recognition of value pluralism²⁴⁴ and these determinations are often more grey than black or white. There is greater recognition of the wider array of evidence that can be brought to bear on policy and clinical decision-making.²⁴⁵ This shift is reflected in the development of guidelines and other documents. Previously biomedical experts and the government provided authoritative guidance based on medical evidence. Now there are more democratic fora (e.g. NICE) that allow greater public involvement and input.

In the past, determinations about the appropriateness of testing were viewed as medical factual judgements (see Q20 above) but today the unavoidable value judgements informing these decisions are recognised.

25d. In broad terms what information should a clinician provide to a patient prior to the patient deciding whether or not to be tested?

(See also response to Q25e)

The clinician should provide information relevant to making the decision about whether or not to be tested. Broadly, this should include the possible outcomes, the value of these outcomes, and the probability of each course of action (including no action). The clinician should also provide the confidence assigned to those values or probabilities.²⁴⁶

In practice, this will include the major benefits and risks in terms of wellbeing, their probabilities, alternative courses of action (including doing nothing) and their risks and benefits. If a risk has a low probability but is nonetheless significant it should be disclosed. The appropriateness

²³⁸ GMC. *HIV Infection & AIDS: the ethical considerations*. 1988, 13.

²³⁹ GMC. *Seeking Patients' Consent: The Ethical Considerations*. 1998, 13.

²⁴⁰ GMC. *Consent: Patients and Doctors Making Decisions Together*. 2008, 7-26.

²⁴¹ Faden R, Beauchamp T, King N. *A History and Theory of Informed Consent*. Oxford: Oxford University Press, 1986, 55-113; Will J. A brief history and theoretical perspective on patient autonomy and medical decision making; Part I: The beneficence model. *Chest*. 2011; 139(3): 669.

²⁴² GMC. *Consent: Patients and Doctors Making Decisions Together*. 2008.

²⁴³ See, for example, Royal College of General Practitioners, *RCGP Curriculum – 3.3 Ethics and Value-based Practice*, 2 April 2010, <https://www.gponline.com/rcgp-curriculum-33-ethics-value-based-practice/article/869298>.

²⁴⁴ Value pluralism is the recognition of there being several values (beliefs that guide actions) that may be equally correct and relevant even though they sometimes conflict.

²⁴⁵ Parker M. Overstating values: medical facts, diverse values, bioethics and values-based medicine. *Bioethics*. 2013; 27(2): 97-104.

²⁴⁶ GMC. *Consent: Patients and Doctors Making Decisions Together*. 2008, 9.

of a disclosure in the past was determined by reference to the *Bolam* principle – that the disclosure is in accordance with a practice accepted by a responsible body of practice by relevant doctors at the time. In response to Q20 we referred to recent changes in the law which judge disclosure of risk, benefits and reasonable alternatives in accordance with what the reasonable or actual patient would need.

We discuss the information that should be provided in relation to treatment in response to Q20a. In the context of testing for infection, information should be provided about:

- The nature of the test and its implication for wellbeing, whether experimental/unproven.
- Information relating to both the test and the condition for which it is done. This includes medical indication, utility of the test, risks of the test, the value of the knowledge, alternatives to testing (e.g. wait for symptoms), cost of the test, who does the testing, and who will deal with the information. Information should also be provided about the implications of testing, for example, for insurance and employment.
- The voluntary nature of the testing and ability to withdraw consent.
- Obligations flowing from test, such as the obligation to inform others.
- Confidentiality and its limits.
- Public health and interest justifications for testing.
- Any costs to the patient.
- The opportunity to ask questions and time to make a decision.

25e. Are there any circumstances in which it would be ethical for a clinician to test a person with capacity without their knowledge or consent? If so, what are they?

In general, it is not ethical to test a person with capacity without their consent.²⁴⁷ Existing consent could cover future uses where it is consistent with the patient's intentions (e.g. further testing for the same purposes, for example, more accurate testing).²⁴⁸ Even in instances in which samples have been collected previously, new testing should not be conducted unless people have been warned in general terms about the possible future use of their biological specimens or samples.²⁴⁹ As we discussed in response to Q20, consent for research may not be required if tissue from living patients is released to the researcher in a non-identifiable form, and the research has been approved by an accredited research ethics committee.

In the past, blood and tissue were tested for research, audit and quality assurance purposes if those specimens had already been obtained for clinical purposes, and more latterly with ethics committee approval.²⁵⁰ Quality assurance and laboratory practice may involve testing without consent and has no benefits or risks to the patient.

²⁴⁷ GMC. *ibid*, 5.

²⁴⁸ Medical Research Council, *Human Tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines*, 2014, 11. <https://mrc.ukri.org/publications/browse/human-tissue-and-biological-samples-for-use-in-research/>.

²⁴⁹ MRC. *ibid*, 11.

²⁵⁰ See, for example, the famous case of Lacks H, Rao R. Informed consent, body property, and self-sovereignty. *Journal of Law, Medicine & Ethics*. 2016; 44: 437-444.

Information can be withheld if the clinician judges it would cause serious harm – this is called the therapeutic exception (see Q20a above).²⁵¹ The therapeutic exception has always been controversial, and questions remain about what constitutes serious harm and when it is sufficient to justify withholding information.²⁵² Claims of serious harm are a weak justification for withholding information.

In some, rare circumstances, emergency legislation might set out a public interest exclusion to the requirement to obtain consent to examination, monitoring or isolation, etc., such as in a public health emergency. For example, the Coronavirus Act 2020 gives public health officers powers to detain potentially infectious persons for certain purposes.²⁵³ It is possible, but uncertain, that the court could authorise treatment of a non-consenting adult with capacity in a public health emergency.²⁵⁴

25f. What obligation or responsibility does the clinician have to inform the patient of the result of the test?

Once the test has been done there is an obligation to inform the patient of the results. In rare circumstances in the past, therapeutic exception might have justified non-disclosure where there was a genuine belief it would be harmful and provide no benefit.²⁵⁵ We discuss this in response to Q20a above and Q26b below. However, in the case of infections, there is always a risk to others which provides a reason to disclose the results to the patient in order to avoid further infection.

There are circumstances where failure to contact patients implies normalcy of the results and so non-disclosure may also be misleading.²⁵⁶

25g. Are there any circumstances in which it would be ethical for a clinician to withhold a test result from a person with capacity? If so, what are they?

See above (Q25f). Generally, respect for autonomy would require disclosure of test results even if there was perceived limited utility for the patient in receiving the information.

In the past, clinicians judged patients' interests and gave weight to psychological harm (and sometimes did not disclose terminal cancer diagnoses).²⁵⁷ However, there has been a shift in the locus of power to the patient to evaluate the utility of information and make decisions.²⁵⁸ It is also now recognised that the clinician is not usually in a position to accurately assess the potential psychological harm or determine that it would be better for the patient not to receive this information.

²⁵¹ GMC. *Consent: Patients and Doctors Making Decisions Together*. 2008, 16.

²⁵² GMC. *Seeking Patients' Consent: The Ethical Considerations*. 1998.

²⁵³ See Schedule 21. In addition, Regulations can be made under the Public Health (Control of Disease) Act 1984, s 45 and the Civil Contingencies Act 2004 gives powers to make emergency regulations by Order in council (i.e. legislation made under the Royal Prerogative).

²⁵⁴ See *Secretary of State for the Home Dept v Robb* [1995] 1 All ER 677 discussed in Herring J. *Medical Law and Ethics*. Oxford: OUP, 2018, 169.

²⁵⁵ GMC. *Seeking Patients' Consent: The Ethical Considerations*. 1998.

²⁵⁶ See, for example, Albrecht, E, Frascarolo P, Meystre-Agustoni G, Farron A, Gilliard N, Darling KEA, and Cavassini M. An analysis of patients' understanding of 'routine' preoperative blood tests and HIV screening. Is no news really good news? *HIV Medicine* 2012; 13: 439-443.

²⁵⁷ Goldie L. The ethics of telling the patient. *J Med Ethics* 1982; 8(3): 128-133.

²⁵⁸ Sokol D. How the doctor's nose has shortened over time; a historical overview of the truth-telling debate in the doctor-patient relationship *Journal of the Royal Society of Medicine* 2006; 99(12): 632-636.

Having said this, there may be rare cases where disclosure is not considered appropriate – for example where a test has been undertaken very close to the end of a patient’s life. If the result would offer neither psychological reassurance or treatment possibilities, and the lack of knowledge of the result poses no risk to others, then it might be withheld. If it is decided that it is unnecessary or unwise to burden the patient with further information in the final days of life, what becomes relevant is if and how to inform the patient’s relatives in a sensitive and timely manner.

25h. Is it ethical for a clinician or hospital to store samples (e.g. of a patient’s blood), for later testing and/or for research, without their knowledge or consent?

It is not ethical for clinicians or hospitals to do this now. As we discuss in response to Q19 and Q20, this occurred in the past and it was considered to be acceptable practice.

In the past, hospitals, laboratories and other providers retained samples for many years, without knowledge and consent. Tissue and data were used for quality assurance and these stored samples could be used for other secondary use, such as teaching, audit or research. This secondary use has raised challenges and led to policies requiring ethics committee approval and more recently consent. It is now common practice to inform patients of potential future use and to seek consent for this.

Even in the past, where stored samples were subsequently tested without consent, those results should have been disclosed if they had relevance for the patient’s care or interests.

25i. Does it make a difference if the patient is a child? If so, how and why?

Today, someone must consent to testing (see response to Q20 above) or research with children (see response to Q30g below). This may be a child with decision-making capacity or someone with parental responsibility.²⁵⁹

In the past, clinicians were more inclined to act in what they perceived to be the child’s interests without parental consent. For example, the 1988 General Medical Council guidance suggests that in instances in which a parent may have infected a child, it may be appropriate to proceed with testing in the child’s best interests because the parent may be concerned with protecting their own position.²⁶⁰

25j. To what extent if at all is it legitimate to test the likelihood that a particular therapy may give rise to infection by administering it to a patient?

It is not acceptable to administer a particular therapy to test the risk of infection without the patient’s consent to this risk.²⁶¹ People should not be subjects of research which involves risk without consent. This has been clear in numerous guidance documents on research ethics.²⁶² There is not a justification for imposing a risk on a competent patient without their consent, except perhaps in the most urgent, extreme public health emergency.

²⁵⁹ GMC. *Consent: Patients and Doctors Making Decisions Together*. 2008; *Gillick v West Norfolk AHA* (28) [1985] UKHL 7; (1986) AC 112, 189; Family Law Reform Act 1969, s 8.

²⁶⁰ GMC. *HIV Infection & AIDS: The Ethical Considerations*. 1988, 14.

²⁶¹ World Medical Association, *Declaration of Helsinki; Ethical Principles for Medical Research Involving Human Subjects*, 9 July 2018. <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>, 25-32.

²⁶² *Ibid.*

There is a difference between testing the likelihood and documenting the risk and outcome of an established therapy. It may be reasonable to give a therapy with risk of infection if the treatment is in the patient's best interests and is administered to meet the patient's needs. This may be particularly true where the treatment is the best available option.

A treatment with potential benefit but with risk of infection could be given to the patient with valid consent, if the risk was reasonable (proportionate and minimised). A risky therapy could be given to an incompetent patient if it were in that patient's best interests, for example, because the alternative was death or serious morbidity which the treatment might avert. If this is to be done, it should be a part of a properly designed trial with publication of results.

In all cases the intention should be to provide the patient with the best available treatment allowing for the fact that in some cases this might entail the risk of infection as a known and unavoidable side-effect.

Supplemental Q19. When answering question 25j of the initial letter of instruction, please also consider whether (and if so why) it makes a difference if the patient is an adult or a child, and whether (and if so why) the patient's existing state of health makes a difference.

Whether (and if so why) it makes a difference if the patient is an adult or a child

The fact that the patient is a child does not remove the requirement to get consent. Consent may be given by a child with decision-making capacity, a parent or legal guardian. Decisions about appropriate therapy should be made on the basis of the best interests of the child.

Whether (and if so why) the patient's existing state of health makes a difference

A patient's existing state of health may be part of clinical determinations about an appropriate course of action and will inform an understanding of the risks and benefits posed to an individual. The value of a patient's life should not be diminished just because they are in an advanced state of disease. It may, however, be acceptable to the patient themselves to be exposed to a greater level of risk when their only alternative is death, or where there are no other available treatments to remedy a grave condition. While a clinician might offer such a treatment, decisions should always be made by the patient, following the provision of all available relevant information.

Supplemental Q18. When answering question 25 of the initial letter of instruction (which asks about the ethical principles informing the approach to testing a patient for infection), please also consider the following:

a. In what circumstances should the clinician give advice about the testing of spouses, partners and others?

Advice should be given when there is a medical indication to do so. This should be identified through a determination of whether the ratio of benefits to risk suggest it is in the interests of the persons affected and is generally consistent with the autonomy of patient. Those giving advice should also be mindful of sociocultural and/or personal factors which might mean that the sharing of information and the suggestion of testing could place a patient in a vulnerable position vis a vis their spouse, partner or other close associates.

In the first instance the clinician should advise their patient to inform relevant others to be tested, counselled or otherwise offered management. Today, there is a duty to warn of the risk to others and, in some situations, where there is demonstrable risk, the clinician may reasonably contact these individuals for testing or counselling.²⁶³

Where there is a genuine threat to the wellbeing of others and the disclosure is necessary to avoid that threat, doctors should disclose directly to at-risk parties. This disclosure is necessary under a duty of rescue.²⁶⁴ We discuss this duty further in response to Q28b and Q28c.

b. Are there any circumstances in which it is ethical for a clinician to take blood from a patient (with capacity) without the patient (or, in the case of a child, the parent) being informed about what it is being taken for?

No. See our response to Q25e above.²⁶⁵

However, consent might be sought or implied in broad terms for diagnosis, without the patient being aware of the specifics of testing. The focus in the past was diagnosis and management of disease, with less attention to broader psychosocial consequences of testing, diagnosis or management.

c. Are there any circumstances in which it is ethical for a patient's test results to be shared with any third party without the consent of the patient (or, in the case of a child, the parent)?

(See also response to Q28b and Q28c)

There are three different circumstances in which disclosure of results to a third party without the consent of the patient may be ethical:

- Where it is mandated by law, e.g. reportable disease, coronial inquiry.
- Where it is in the best interests of the patient.
- Where third parties, such as siblings, parents or spouses, are directly affected and there is a risk of serious harm if they are not informed, in circumstances where notwithstanding counselling, the patient refuses to consent to disclosure.

In each of these cases the decision to disclose will follow a careful consideration of patient confidentiality and privacy.

²⁶³ GMC. *Disclosing Information about Serious Communicable Diseases*. 2017, paras 12-15. <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/confidentiality---disclosing-information-about-serious-communicable-diseases>; Gibson E. Medical confidentiality and protection of third party interests. *American Journal of Bioethics* 2006; 6(2): 23-25; Bozzo A. A Challenge to unqualified medical confidentiality. *J Med Ethics* 2018; 44(4): 248-252.

²⁶⁴ GMC. *Disclosing Information about Serious Communicable Diseases*. 2017, 12-15.

²⁶⁵ GMC. *Consent: Patients and Doctors Making Decisions Together*. 2008, 37-43.

d. Is there an ethical obligation on clinicians to offer pre-test counselling to patients and if so in what broad circumstances?

In 1989, the Council of Europe recommended a policy of voluntary testing as the most effective public health response to HIV infection.²⁶⁶ It recommended that testing is 'always accompanied by counselling' subsequent to appropriate training, and that counselling is provided on a consensual and confidential basis.

More generally, pre-test counselling may be necessary to ensure both that consequences of consenting to a test are fully understood and that the patient is in a frame of mind to make a full autonomous decision about whether to go ahead with testing. Patients should give valid consent to all procedures, including testing, performed upon them. Where the consequences of testing are particularly grave and there is a possibility that they might not be well understood, pre-test counselling would be in the patient's best interests and facilitate a fully autonomous decision. As a condition becomes better understood it is possible that approaches such as self-testing could remove the possibility of counselling, but such changes would only be introduced on the basis of appropriate research.

²⁶⁶ Council of Europe, Committee of Ministers, *Recommendation No. R (89) 14 on the Ethical Issues of HIV Infection in the Health Care and Social Settings* (Oct. 24, 1989), reprinted in 41 *International Digest of Health Legislation* 39 (1990). <http://hrlibrary.umn.edu/instree/coerecr89.html>.

Section 4: Informing people of infections

The principles that applied in Section 3 on testing for infection are also relevant to informing people of infections. In particular, there are close connections between Questions 25f and 25g, and Questions 26a and 26b. Test results may, but do not always, establish a diagnosis. In this section we build and expand on our response to those questions.

We consider the ethical issues related to sharing information once a patient has been tested for an infectious disease. We begin with the assumption that there is a *prima facie* moral case for informing a patient of their test results in order to respect their autonomy and to place them in a better position to make life choices consistent with their welfare and best interests. We will also consider how to respond to those who do not wish to know the results of tests undertaken, and how to manage situations where others could benefit from being told the results, or could be at risk of harm if they do not know them.

Given the sensitive nature of the infections discussed here, it is important to ensure that access to information is controlled and managed in the interests of the patient. Other than in rare and specified situations, requests for disclosure of diagnoses should be subject to the patient's consent. However, there will be instances where we have to consider what will happen when consent is not forthcoming.

In the context of blood-borne diseases, the standard precautionary clinical advice (which we discuss below) would be to proceed as if *any* patient is or could be infected, taking appropriate steps to self-protect and minimise risk, irrespective of what is known in a particular case. In theory, this means that knowing a particular patient's (or indeed clinician's) status need not be seen as decisive in terms of preventing risks to others and therefore affords protection where either a test is unavailable or take-up is low.

If we can reliably assume that everyone is practising medicine safely, and avoiding unsafe behaviours more widely, a patient can be afforded privacy and confidentiality without increasing the risk of harm. This option is particularly valuable where sharing information could be stigmatising and/or lead to the person being discriminated against. It is against this background that much of the guidance cited below prefers an approach of encouraging rather than forcing disclosure of test results.

However, we also understand that the emergence and/or spread of infectious diseases is challenging to a healthcare system and to society more generally; and there may be circumstances in which it becomes ethically acceptable, or even mandatory, to impose duties to inform, and/or to take action when persuasive measures fail. This may be for very direct practical reasons in terms of preventing direct and immediate harms, or it may have more to do with maintaining trust in the system of public health.

Question 26. What ethical principles should inform the approach to telling a patient that they have been infected with a serious disease?

Supplemental Q20. When answering questions 26 and 27 of the initial letter of instruction, please read ‘serious disease’ as incorporating potentially serious diseases or infections.

26a. In particular and from a medical ethics perspective: What obligation or responsibility does the clinician have to inform the patient of their diagnosis?

In general, if an individual has been tested for a range of possible conditions, then they are entitled to know what those tests reveal. This might not entail a thorough run through of all conditions that have been excluded, rather it should concentrate on the elimination of the most serious possibilities and a clear account of what the patient has tested positive for. Some results might be relatively inconsequential but where a serious disease/infection is identified this clearly needs to be shared with the patient to ensure that they understand and concord with any treatment or management proposed. Without accurate and transparent information about the diagnosis and prognosis, the patient is unable to make an informed decision about treatment.

Even if there is no link to clinical treatment, for example, because no treatment yet exists, the right to know is an integral part of the trust between doctor and patient.²⁶⁷ As set out above (Q19), until the 1970s, withholding information from patients was characteristic of the era of paternalism where a clinician would often substitute their judgement for that of the patient. Gradually, patient autonomy and patients’ rights became central to medical ethics and challenged the position of paternalism. The GMC’s guidance on *Good Medical Practice* 1995 (valid until 1998) required doctors to:

give patients the information they ask for or need about their condition, its treatment and prognosis (para 11).

From 1998 (until 2008), the GMC’s guidance on consent required doctors to inform patients of a wide range of factors, including:

- details of the diagnosis, and prognosis, and the likely prognosis if the condition is left untreated;
- uncertainties about the diagnosis including options for further investigation prior to treatment ...²⁶⁸

The Nursing and Midwifery Council *Code of Professional Conduct* 2002 said:

3.1 All patients have a right to receive information about their condition. You must be sensitive to their needs and respect the wishes of those who refuse or are unable to receive information about their condition. Information should be accurate, truthful and presented in such a way as to make it easily understood.

The duty to inform patients of their diagnosis is supported by principles of truth-telling, autonomy, best interests, bodily integrity and privacy. As we discussed in response to Q24g, the right to know is connected to a right not to know (and to an ‘open future’) which might

²⁶⁷ Hodkinson K. The Need to Know—Therapeutic Privilege: A Way Forward. *Health Care Analysis* 2013; 21: 106.

²⁶⁸ GMC. *Seeking Patients’ Consent: The Ethical Considerations*. 1998, para 5. <https://www.gmc-uk.org/-/media/documents/patient-consent-1998---2008-55678021.pdf?la=en>.

occasionally delay the duty to disclose information about a diagnosis where there is no clinical or overall benefit to imparting the knowledge at a particular point in time. Respect for autonomy does not necessarily require that all the information is given at one time.

Some patients might not want to know certain information about their diagnosis (see response to Q28b), for example, they might be willing to be told that they have X condition but do not want (at this stage) to know their prognosis. If a patient does not wish to know whether they have a particular condition it could be in their interest not to be tested for it, as once the results are available it may be difficult to avoid learning about them either directly or indirectly. If a clinician is open about which tests they plan to carry out, the consent process prior to testing should provide the opportunity to refuse consent and avoid an unwanted diagnosis. Once testing takes place and information is available it is far harder to respect a right not to know, particularly where clinicians feel that openness would ensure benefit to the patient and others. One of the contexts in which common medical practice respects the right not to know is in the genetic testing for diseases such as Huntington's Disease.

The right of patients to access their medical records has been recognised in various statutory provisions. A right of access was established in the Access to Medical Reports Act 1988 in relation to medical reports supplied by clinicians for employment or insurance purposes, and the Access to Health Records Act 1990 and then the Data Protection Act 1998²⁶⁹ set out a right for patients to access their health records. In *KH v Slovakia*,²⁷⁰ the European Court of Human Rights held that the right to respect for private and family life under article 8 ECHR should be interpreted in a way which also protects a person's right to access their medical records.

As in many areas of life, it took time for a formal legal right to translate into common practice. Patient-held notes, end-of-bed notes, and the copying of referral and follow-up letters to patients are a recent phenomenon, as is the attempt to avoid unduly technical language and medical acronyms for the benefit of patients.

Previously, medical notes were written by doctors for doctors, with little consideration of whether a patient should or would see them. As a result, there might have been a gap between what had been communicated verbally to a patient and what was recorded in the notes, with the possibility that greater openness and clarity was evident in the latter.

Supplemental Q21. Does it make a difference, and if so what, to your answers to Q26 if the disease or infection is understood by the clinician to be less serious or relatively minor?

Where the issue is relatively minor despite a clear risk of infection, for example the spread of lice among primary school children, a resource-based decision might result in the removal of formal preventative measures, leaving the responsibility to detect and inform to teachers or possibly parents. In the same setting, a pupil diagnosed with a childhood infectious disease may never see a healthcare professional, but parents and teachers should be aware of the appropriate steps that should be taken to avoid infecting others once they have recognised the condition in their child. Both cases demonstrate the possibility of shifting responsibility away from formal authorities, relying instead on a sense of common good and general will

²⁶⁹ The Data Protection Act 2018 now enshrines the EU General Data Protection Regulation into UK law.

²⁷⁰ Application no 32881/04, ECtHR, 29 April 2009.

to contain the potential for harm. Having said this, a similar approach will become important where a pandemic threatens to overwhelm a healthcare system, and containment and safe practice become the responsibility of citizens at large.

Supplemental Q22. Please also address with what speed or urgency the clinician should inform the patient of the diagnosis.

Timeliness is a virtue in medical practice, with the issue of when and how to impart information being ethically and clinically important. On some occasions, a clinician might be wise to delay sharing the full implications of a test result or diagnosis until a patient is in a better position to understand and process the results. On other occasions, a patient might be too unwell to receive results before urgent and potentially life-saving treatment must commence. However, in a situation where a competent patient has been tested while receiving on-going care, clinically relevant results should be shared as soon as practicably possible to allow treatment and/or infection control measures to proceed as necessary. It will also save the patient from the moral burden of having unintentionally risked infecting others at a point when they could have been advised to change their behaviour and minimise risk.

The strongest imperative to inform promptly will arise where a disease is serious and the risk of infecting others is high. Where a disease is amenable to treatment it will be important to ensure that test results are secured, communicated, and acted upon within the relevant therapeutic window. Where a condition is new and relatively unknown, it should be assumed that prompt action will be beneficial until proven otherwise. Where clinical trials are on-going, an early diagnosis and sharing of results may facilitate entry to a trial which would be unavailable at a later stage.

26b. Are there any circumstances in which it would be ethical for a clinician to withhold a diagnosis from a person with capacity? If so, what are they?

Therapeutic exception

A clinician can withhold a diagnosis from a person with capacity to protect their best interests, but only if disclosure would cause the patient serious harm, or if the patient refuses to have that information. The harm caused to the patient as a result of being told of a diagnosis may be physical, psychological or emotional. The decision to withhold a diagnosis from a patient with capacity should be patient-specific and the clinician should take account of the welfare of that particular patient and their personal circumstances.²⁷¹

The therapeutic exception has been recognised in the English case law on informed consent (discussed in response to Q20).²⁷² This can only be invoked if the clinician believes that disclosure of the material information would cause the patient ‘serious harm’. Where information about diagnosis is central to informed consent (e.g. where a patient would not have consented to particular treatment had they known of the diagnosis and they subsequently suffer harm) the patient might claim in negligence if the therapeutic exception has been inappropriately invoked by clinicians. Otherwise, the operation of the therapeutic exception rests on ethical principles.

²⁷¹ Hodkinson K. The Need to Know—Therapeutic Privilege: A Way Forward. *Health Care Analysis* 2013; 21: 107.

²⁷² *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871; *Montgomery v Lanarkshire Health Board* [2015] UKSC 11.

It has been argued that informing a patient of a diagnosis is a fundamental right which allows the patient to make choices.²⁷³ Justifications for disclosing diagnosis of serious conditions include respect for the patient's autonomy, and the need to know the patient's views about the diagnosis, and the patient's wishes about any future treatment for their condition.²⁷⁴ The doctor has a duty of candour (see responses to Supplemental Q26 and to Q32 below) and to tell the truth.

The importance of truth-telling has developed over time. An 1878 English *Code of Medical Ethics* said:

A practitioner should not be prone to make gloomy prognostications ... at the same time, he should not fail to give to the friends of the patient timely notice of actual danger, and even to the patient himself, if absolutely necessary.²⁷⁵

But in the 1980s several studies debunking this paternalistic stance showed that most patients wished to be told the truth by their doctor, even if they were diagnosed with a fatal condition.²⁷⁶ One empirical study found that:

The vast majority of patients stated that they want to know about their condition (99%). They also thought that physicians had an obligation to inform patients of their condition (99%), and they would want to be told if they had a life-threatening illness (97%).²⁷⁷

The duty to tell the truth must be balanced with other ethical principles, including those of beneficence and non-maleficence. Maclean suggests that a therapeutic exception may apply where 'disclosure would harm the patient or make them so distressed that a rational decision is no longer possible'.²⁷⁸

The GMC recognises the patient's right to information, and takes a narrow interpretation of the therapeutic exception in its 2008 guidance on consent:

You should not withhold information necessary for making decisions for any other reason, including when a relative, partner, friend or carer asks you to, unless you believe that giving it would cause the patient serious harm. In this context 'serious harm' means more than that the patient might become upset or decide to refuse treatment.²⁷⁹

Where information is withheld, the GMC advises that the clinician record their reason for doing so in the patient's medical records and be prepared to explain and justify their decision (para 17). Additionally, the clinician must 'regularly review [their] decision, and consider whether [they] could give information to the patient later, without causing them serious harm'.

²⁷³ Johnston C, Holt G. The legal and ethical implications of therapeutic privilege – is it ever justified to withhold information from a competent patient? *Clinical Ethics*. 2006; 1(3): 146-148.

²⁷⁴ Gillon R. Telling the truth. *BMJ* 1985; 291: 1556.

²⁷⁵ De Styrap J. A Code of Medical Ethics: With Remarks on the Duties of Practitioners to Their Patients, and the Obligations of Patients to Their Medical Advisers: Also on the Duties of the Profession to the Public, and the Obligations of the Public to the Faculty. J. & A. Churchill, 1878
<https://archive.org/stream/acodemedicaeth00styrgoog?ref=ol#page/n4/mode/2up>.

²⁷⁶ Gillon R. Telling the truth. *BMJ*. 1985; 291: 1557; Reynolds PM, Sanson-Fisher RW, Desmond Poole A, Harker J, Byrne MJ. Cancer and communication: information-giving in an oncology clinic. *BMJ* 1981; 282: 1449.

²⁷⁷ Sullivan RJ, Menapace LW, White RM. Truth-telling and patient diagnoses. *J Med Ethics* 2001; 27: 193.

²⁷⁸ Maclean A. *Autonomy, Informed Consent and Medical Law*. CUP: 2009, 183.

²⁷⁹ GMC. *Consent: Patients and Doctors Making Decisions Together*. 2008, 12.

Where the patient refuses information

The GMC recognises the importance of information on diagnosis when making decisions about treatment and care. This can be particularly difficult if the patient declines such information. The GMC advises:

13. No one else can make a decision on behalf of an adult who has capacity. If a patient asks you to make decisions on their behalf or wants to leave decisions to a relative, partner, friend, carer or another person close to them, you should explain that it is still important that they understand the options open to them, and what the treatment will involve. If they do not want this information, you should try to find out why.

The GMC provides that it is for the patient to decide whether or not they wish to receive information about their condition and possible treatment, subject to the information needed to understand broadly what is proposed and so to give a valid consent to treatment. A decision to refuse detailed information on diagnosis should therefore be respected, but some basic information may be necessary if treatment (and thus consent) is sought by the patient.²⁸⁰

26c. Are there any circumstances in which a clinician should inform a patient of their diagnosis (for example, on public health grounds) contrary to the patient's expressed wish? If so, what are they?

Even after consenting to being tested for a serious infection, a patient should generally have the right not to be told of the result of the test. The UK has not signed or ratified the Council of Europe Convention on Human Rights and Biomedicine, but it is noteworthy that Article 10 provides that:

Everyone has the right to respect for private life in relation to information about his or her health. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.

However, the right not to be told of the results of a test for a serious infection may infringe on another important interest: the protection of third parties from serious harm. In these circumstances the clinician may need to make a decision between two competing interests: the right to autonomy and privacy of the patient (the right not to be told) and the protection of third parties from serious harm. A broad approach to the right to autonomy and privacy of the patient would imply that the clinician should not inform the patient of their diagnosis if they refused to be told of the diagnosis or result of the test, even if the failure to do so would cause harm to the patient or a third party.²⁸¹ However, a clinician may choose to give more weight to the protection from serious harm. A utilitarian approach would suggest that the clinician should inform the patient of their diagnosis even if the patient refuses to accept that it is in their best interest, the reason being to protect others from becoming infected.²⁸²

²⁸⁰ GMC. *ibid*, para 14: 'If, after discussion, a patient still does not want to know in detail about their condition or the treatment, you should respect their wishes, as far as possible.' Paragraph 15: 'If a patient insists that they do not want even this basic information', the clinician will need to explain 'the potential consequences of them not having it, particularly if it might mean that their consent is not valid'.

²⁸¹ Temmerman M, Ndinya-Achola J, Ambani J, Piot P. The right not to know HIV-test results. *The Lancet* 1995; 345: 969.

²⁸² Kwong Chan T. HIV status: the prima facie right not to know the result. *J Med Ethics*, 2016; 42: 101-102.

26d. What factors should a clinician consider when deciding when, how and in what setting to inform a patient that they have contracted a serious disease?

Information given to the patient should be tailored to their needs, wishes, nature of their condition, complexity of the treatment, and nature and level or risks associated with the treatment.²⁸³ BMA guidance in the 1980s recognised that good communication between doctor and patient was of fundamental importance,²⁸⁴ and it is particularly relevant in cases of serious medical conditions.²⁸⁵ However, as recognised in the *Expert Report to the Infected Blood Inquiry on Psychosocial Issues*, best practice in communication has changed from a paternalistic to a more collaborative model.²⁸⁶ Guidance and training on good communication has improved since the 1980s and there is less reliance on the patient asking the ‘right’ questions.

The GMC’s 2008 guidance on consent emphasises the importance of how matters of diagnosis, prognosis and treatment options are discussed. It advises clinicians to:

- ‘1. share information in a way that the patient can understand and, whenever possible, in a place and at a time when they are best able to understand and retain it
2. give information that the patient may find distressing in a considerate way
3. involve other members of the healthcare team in discussions with the patient, if appropriate
4. give the patient time to reflect, before and after they make a decision, especially if the information is complex or what you are proposing involves significant risks
5. make sure the patient knows if there is a time limit on making their decision, and who they can contact in the healthcare team if they have any questions or concerns.’²⁸⁷

The clinician should try to enhance the patient’s understanding of relevant information (discussed in Q20a, Supplemental Q8b). Information should be given in a private setting whenever possible unless the patient consents to other people (such as a relative or translator) being present, and ‘strenuous efforts should be made’ to meet the needs of non-English speaking patients.²⁸⁸ The medical team should pay particular attention to the patient’s physical and emotional state and the ‘suitability of the occasion when he is to be given information’.²⁸⁹ The ways in which information is communicated can have serious psychological impact on patients.

Communication must be managed within the constraints of time and space in a hospital setting or clinic as sensitively as possible. It is clear that, even today, it is not always managed appropriately; sometimes private information is given to the patient in a non-private setting, for instance in corridors, elevators, or in rooms of more than one patient, and this is sometimes

²⁸³ GMC. *Consent: Patients and Doctors Making Decisions Together*. 2008.

²⁸⁴ BMA. *The Handbook of Medical Ethics*. 1981, 19-20.

²⁸⁵ Reynolds PM, Sanson-Fisher RW, Desmond Poole A, Harker J, Byrne MJ. Cancer and communication: information-giving in an oncology clinic. *BMJ* 1981; 282: 1449.

²⁸⁶ Infected Blood Inquiry. *Expert Report to the Infected Blood Inquiry: Psychosocial Issues*. January 2020, 13.4.3.

²⁸⁷ GMC. *Consent: Patients and Doctors Making Decisions Together*. 2008.

²⁸⁸ Dunkelmann H. Patients’ knowledge of their condition and treatment: how it might be improved. *BMJ* 1979; 2: 312.

²⁸⁹ *Ibid.*

done carelessly, or even maliciously.²⁹⁰ The 2020 inquiry into surgeon Ian Paterson revealed that some consultations were so rushed that there was no chance to ask questions, some patients were given inaccurate and misleading information and there was a distinct lack of care in his approach: 'In some cases, patients reported that they were told they had cancer immediately as they came into the consulting room.'²⁹¹

We refer to the *Expert Report to the Infected Blood Inquiry on Psychosocial Issues*, which reported many instances of poor and insensitive communication of HIV and Hepatitis C test results and the psychological impact of ethical breaches.²⁹²

26e. What are your views on clinicians providing information to patients about the possibility (or fact) of infection with a serious disease in a group setting, with other patients present?

Generally, disclosing confidential information about a patient's diagnosis in a group setting would go against well-established ethical principles regarding confidentiality and the protection of patients' interests. It is important to protect the confidentiality of individual patients, even where they have allowed a conversation to begin despite the presence of others or when they have agreed to participate in group activities which could be seen to be suggestive of a particular diagnosis, e.g. a patient support group.

Where a doctor can reasonably anticipate that information will be difficult to receive, or where they understand the social sensitivities around particular information, there is a strong imperative to prioritise privacy, and to signal to the patient that they need to consider who they wish to be present.

Where the physical environment makes complete privacy difficult, e.g. screened cubicles in outpatient settings or open wards, clinicians must make every effort to ensure that information is provided as discreetly as possible and that patients are protected from intrusion while processing difficult news.

The common law duty of confidentiality is subject to exceptions if disclosure is in the public interest, required by law or a court order, or where the patient consents to the disclosure. Confidentiality is also now protected in various instruments, including the Human Rights Act 1998 which transposes the European Convention of Human Rights into UK law. Article 8 protects the right to respect for private and family life, which extends to confidential information about an individual. This is explained in *Z v Finland*:

The protection of personal data, not least medical data, is of fundamental importance to a person's enjoyment of his or her right to respect for private and family life as guaranteed by article 8 of the Convention ... Without such protection, those in need of medical assistance may be deterred from revealing such information of a personal and intimate nature as may be necessary in order to receive appropriate treatment and, even, from seeking such assistance thereby endangering their own health and, in the case of transmissible diseases, that of the community.²⁹³

²⁹⁰ Beltran-Aroca CM et al. Confidentiality breaches in clinical practice: what happens in hospitals? *BMC Medical Ethics* 2016; 17: 52, 9.

²⁹¹ James G. Rev'd (Chair). *Report of the Independent Inquiry into the Issues raised by Paterson*. 2020 HC 31.

²⁹² Infected Blood Inquiry. *Expert Report to the Infected Blood Inquiry: Psychosocial Issues*. January 2020, 13.4.4.

²⁹³ *Z v Finland*, Application no. 22009/93 (1998) 25 EHRR 371, [95]-[96].

The GMC issued specific guidance on confidentiality in 1995, 2000, 2004, 2009 and 2017.²⁹⁴ There was also a number of guidelines on HIV and AIDS from the 1980s.²⁹⁵ Guidance in the 1980s and 1990s did not, as far as we are aware, directly address the issue of informing patients of sensitive information in a group setting. However, the duty of confidentiality was a strong feature of good medical practice, and this was emphasised in BMA guidance.²⁹⁶ In 1986, the BMA provided that ‘the traditional confidentiality of the doctor-patient relationship must be upheld in the case of patients suffering from AIDS and HIV seropositive individuals’.²⁹⁷ The BMA statement also provided that:

According to DHSS guidelines, unless the patient has given consent personal health data should not be disclosed to anyone for any purpose other than the health care of that patient, except where disclosure is necessary to prevent the spread of infection.

The statement adds: ‘if breaches of confidentiality occur this will deter others at risk of HIV infection from coming forward for testing or treatment’.²⁹⁸

In 1989 the Council of Europe addressed the question of whether those infected with HIV have the same rights to confidentiality as other patients and concluded that they do. It recommended that in relation to the patient-doctor relationship:

– strongly support respect for confidentiality, if necessary by introducing specific policies, and by promoting educational programmes for health care workers to clarify confidentiality issues in relation to HIV infection.²⁹⁹

Today, the GMC’s 2017 guidance on confidentiality explains when a clinician can disclose personal information about a patient to a third party. This includes when:

- The patient consents, whether implicitly or explicitly for the sake of their own care or for local clinical audit, or explicitly for other purposes (paras 13–15).
- The patient has given their explicit consent to disclosure for other purposes (paras 13–15).
- The disclosure is of overall benefit to a patient who lacks the capacity to consent (paras 41–49).
- The disclosure is required by law (see paragraphs 17–19), or the disclosure is permitted or has been approved under a statutory process that sets aside the common law duty of confidentiality (paras 20–21).
- The disclosure can be justified in the public interest (paras 22–23).³⁰⁰

²⁹⁴ GMC. *Confidentiality: Good Practice in Handling Patient Information*. 2017. And see <https://www.gmc-uk.org/ethical-guidance/archived-ethical-guidance#confidentiality> for previous versions.

²⁹⁵ GMC guidance on *HIV infection and AIDS* in 1988, 1993 and 1995; BMA Board of Science and Education *Statements on AIDS* in 1985, 1986, 1986 and *Statement on AIDS and HIV* 1991 and a *Statement on HIV testing and Related Issues* in 1992; also First report of the RCN AIDS working party. *Nursing Guidelines on the Management of Patients in Hospitals and the Community Suffering from AIDS*. RCN 1985.

²⁹⁶ Barrister A. Confidentiality, The legal aspects. *BMJ*. 23 June 1973: 701; Asbury AJ. Confidentiality of personal health information. *BMJ* 1984; b289: 1559.

²⁹⁷ BMA. *Third BMA statement on AIDS*, London: BMA, 1986, 13; Gillon R. AIDS and medical confidentiality. *BMJ* 1987; 294: 1675.

²⁹⁸ BMA. *Third BMA statement on AIDS*. London: BMA, 1986, 13.

²⁹⁹ Council of Europe, Committee of Ministers, *Recommendation No. R (89) 14 on the Ethical Issues of HIV Infection in the Health Care and Social Settings* (Oct. 24, 1989), reprinted in 41 *International Digest of Health Legislation* 39 (1990). <http://hrlibrary.umn.edu/instreet/coecr89.html>.

³⁰⁰ GMC. *Confidentiality, Good Practice in Handling Patient Information*. 2009.

Outside the rules of confidentiality and breach of privacy rights, there is also the consideration of the emotional harm that might be associated with informing people in a group setting. Not only might the patient suffer from being informed in a public manner, but there might be people within the group, such as children, who would benefit from a much more carefully managed approach to information sharing. Compassion is an important component of ethical medical practice. Some patients may prefer to bring a friend or relative with them for support, others wish to protect their family and/or their privacy, but it is important to choose a time and place that allows for the patient's reasonable preferences to be respected and for dialogue.³⁰¹ Today, breaking bad news is part of the reflective practice expected of doctors³⁰² but historically, there was less emphasis on communication skills.³⁰³

26f. What obligation or responsibility does the clinician have to inform the patient that they may have contracted, or did, contract the disease as a result of their medical treatment?

Supplemental Q26. What ethical principles should inform the approach a clinician should take to answering reasonable questions from a patient about how they became infected and about their previous treatment? Please set out in broad terms the kind of information a clinician should provide to a patient in such circumstances.

Some ethical principles discussed in response to Q26a are also relevant here. The patient's right to be informed, the trust between doctor and patient, and the patient's right to autonomy, suggest that patients should be informed when they have contracted a disease following a medical treatment. Furthermore, clinicians have a well-recognised duty of candour and honesty towards patients, and members of the public (see response to Q32). This duty implies that the physician must:

tell the patient (or, where appropriate, the patient's advocate, carer or family) when something has gone wrong; apologise to the patient (or, where appropriate, the patient's advocate, carer or family); offer an appropriate remedy or support to put matters right (if possible); explain fully to the patient (or, where appropriate, the patient's advocate, carer or family) the short and long term effects of what has happened.³⁰⁴

It is reasonable that a person who learns that they have been infected will want to understand how this has happened. This desire could result in the wish for both a medical scientific explanation of transmission/infection and/or a more personalised account of who or what is thought to have led to infection in their particular case.

A clinician should be prepared to have an open and frank discussion bounded by the state of current knowledge and mindful of any uncertainties that exist. It is possible that at an early stage of a disease being identified routes of infection remain unclear, so the conversation should be on-going as further details and/or understanding emerges.

³⁰¹ Medical Defence Union. *Breaking Bad News*. 2019. <https://www.themdu.com/guidance-and-advice/guides/breaking-bad-news>.

³⁰² GMC. *Reflecting on an Experience: Breaking Bad News*. 2019. <https://www.gmc-uk.org/education/standards-guidance-and-curricula/guidance/reflective-practice/breaking-bad-news>.

³⁰³ Miller SJ, Hope T, Talbot DC. The development of a structured rating schedule (the BAS) to assess skills in breaking bad news. *British Journal of Cancer* 1999; 80(5/6): 792-800.

³⁰⁴ GMC. *Openness and Honesty When Things Go Wrong: The Professional Duty Of Candour*, July 2015, updated June 2019, 1.

A clinician's first duty is to their patient, and this must not be clouded by concerns such as protecting their own reputation or that of their professional group. If there is any possibility that the infection was due to an element of medical treatment, this should be acknowledged, and the patient's questions answered as far as that is possible. Similarly, if a delay in identifying the disease/infection and testing for it has resulted in a higher rate of infection this should be acknowledged.

Where an iatrogenic cause of infection has been ruled out or deemed highly unlikely, a clinician should help the patient to understand and identify other possible routes of infection, both in the interests of fulfilling their need for information but also in order to take appropriate steps regarding that person's needs and future infectivity. In discussing matters with the patient, it will be important to manage expectations and be clear about what may or may not be available in terms of formal contact tracing, etc.

In the vast majority of cases, it is important to avoid the language of 'blame' when discussing how someone has been infected. However, this may not be possible in cases where a systems failure has been identified but not acted upon, or where an individual has knowingly infected others, despite being given clear advice about their condition and the risk some behaviours could entail.

When a patient has (or potentially has) been infected by a disease as a result of their medical treatment, a clinician should explain to the patient the circumstances in which the patient was infected; apologise where there is fault; explain the possible effects of the disease; and should offer relevant treatment, or an appropriate remedy. More generally, errors should be reported to encourage a learning culture in a healthcare setting.³⁰⁵

In the past, the duty of candour was less well defined and it was feared that apologies to patients would open the clinician to the possibility of legal action. A climate of secrecy has gradually been dismantled, and new mechanisms have been put in place to help investigate complaints and incidents, improve learning from incidents so they are not repeated, and provide better apologies and redress to the extent that NHS Resolution now advises that:

Saying sorry meaningfully when things go wrong is vital for everyone involved in an incident, including the patient, their family, carers, and the staff that care for them.³⁰⁶

26g. In broad terms, what categories of information should a clinician provide to a patient when informing them that they have been infected with a serious disease?

GMC guidance on *Serious Communicable Diseases* from 1997 advised that clinicians explain to the patient:

- (a) The nature of the disease and its medical, social and occupational implications, as appropriate.
- (b) Ways of protecting others from infection.
- (c) The importance to effective care of sharing information with relevant healthcare professionals, such as general practitioners.³⁰⁷

³⁰⁵ Ibid, 4.

³⁰⁶ NHS Resolution. *Saying Sorry*. 2017. <https://resolution.nhs.uk/wp-content/uploads/2017/07/NHS-Resolution-Saying-Sorry-Final.pdf>.

³⁰⁷ GMC. *Serious Communicable Diseases*. October 1997, para 18.

In addition, and in light of our response to Q26f, we would add that the information should include the probable causes of infection but with an emphasis on scientific causes as opposed to moral blame.

The GMC recognised the right of patients to refuse to allow other healthcare workers to be informed of the diagnosis, unless the failure to disclose that information would ‘put a health care worker or other patient at serious risk of death or serious harm’ (para 19). Paragraph 19 also makes clear that information should be given to the patient in a balanced way, and the clinician must refrain from putting pressure on the patient to accept their advice. The clinician may need to support these ‘discussions with patients by using [accurate and up to date] written material, or visual or other aids’ (para 20).

26h. What kind of counselling or support should be offered to a patient by a clinician who is informing them that they have contracted a serious disease?

The GMC’s 1997 guidance stated that the clinician:

must make sure, wherever practical, that arrangements are made to give the patient any necessary support. This might include, for example: using an advocate or interpreter; asking those close to the patient about the patient’s communication needs; or giving the patient a written or audio record of the discussion and any decisions that were made (para 21).

Furthermore, the BMA *Third Statement on AIDS* 1986 provided that people found to be HIV-positive should be counselled and advised appropriately ‘to avoid transmitting the virus’, and ‘in dealing with the fear of developing AIDS itself, and with social stigma or difficulties with family, friends, employment, insurance, etc.’³⁰⁸ The Statement also stated that specialist nursing within a hospice or in the community was the most appropriate form of care at the later stages of AIDS.³⁰⁹ Similar guidelines were given in relation to patients found to be infected with Hepatitis C.³¹⁰

26i. Does it make a difference if the patient is a child? If so, how and why?

We have discussed the special arrangements that might apply in the case of children with regard to consent (Q20) and treatment (Q24i) and testing for infection (Q25i). Informing children of infection will depend on their age, their ability to understand the information and what is considered in their best interests in all the circumstances. Information given to child patients should be as open and honest as possible and should be appropriate for their age and maturity.³¹¹ When assessing what is in the best interests of the child, the clinician must consider:

‘the views of the child or young person, so far as they can express them, including any previously expressed preferences; the views of parents; the views of others close to the child or young person; the cultural, religious or other beliefs and values of the child or parents; the views of other healthcare professionals involved in providing care

³⁰⁸ BMA. *Third BMA statement on AIDS*. London: BMA, 1986, 18.

³⁰⁹ BMA. *ibid*, 19.

³¹⁰ BMA. *Transfusion-Transmitted Hepatitis C: Guidelines for Counselling Patients*. 1995.

³¹¹ GMC. *0-18 years: Guidance for All Doctors*. 2007, 9.

to the child or young person, and of any other professionals who have an interest in their welfare; which choice, if there is more than one, will least restrict the child or young person's future options'.³¹²

We have seen that children over the age of 16 can consent to treatment, and for this they will need to understand their diagnosis. Similarly, children under 16 who are competent to consent or assent to treatment need to know why they are being treated.

If a child cannot consent, someone with parental responsibility can consent to medical treatment, and also to disclosure of medical information about the child patient. The GMC provides that children and young people should be involved 'as much as possible in discussions about their care, even if they are not able to make decisions on their own'.³¹³ As seen above, a clinician may choose to withhold information about diagnosis from a patient if information disclosure is likely to cause them serious harm, and this also extends to child patients. In that case, there is potential to inform those with parental responsibility of the diagnosis and proceed on the basis of their consent; but values of truth-telling and the need to foster trust and protect patient autonomy mitigate against hiding from a child the purpose of their treatment.

Occasionally, disputes about information disclosure to a child patient about their diagnosis can arise and if the disagreement cannot be resolved, the court could make a determination of what is in the best interests of the child.

A child patient might choose not to be told of the diagnosis. In the case of a *Gillick* competent child or a young person of 16 or 17, this right should generally be respected, but there are strong ethical arguments for openness in relation to child patients, including promoting 'some degree of involvement in decision-making', avoiding 'restriction of future autonomy', 'respect for the child as a person', improving wellbeing, and encouraging truthfulness and fidelity.³¹⁴ When a child patient has been diagnosed with a serious condition, information about the diagnosis communicated in age-appropriate terms can render them 'better prepared to deal with the future' and enhance trust between the child, the parents and clinicians.³¹⁵ Even where a cure/effective treatment is not currently available, understanding their health condition could assist the child in understanding why it is important that they co-operate with their treatment, lead a healthy life style, avoid infection, etc., and thereby remain as well as possible in the hope of future advances addressing their underlying problem.

With regard to confidentiality, the GMC is clear that: 'The same duties of confidentiality apply when using, sharing or disclosing information about children and young people as about adults'.³¹⁶ This might be particularly important in the context of schooling where the adoption of safe practices and the child's own awareness of risk should allow for their confidentiality to be protected (see further response to Q28a).

As in the case of adults, a clinician has the right to disclose information about the child patient to a third party if there is a public interest in the disclosure, if disclosure would be in the best interests of the child, or if disclosure is required by law.³¹⁷

³¹² GMC. *ibid*, 7.

³¹³ GMC. *Consent: Patients and Doctors Making Decisions Together*. 2008, para 54.

³¹⁴ Hudson N, Spriggs M, Gillam L. Telling the truth to young children: Ethical reasons for information disclosure in paediatrics. *Journal of Paediatrics and Child Health* 2019; 55: 14-15.

³¹⁵ Woolley H, Stein A, Forrest GC, Baum JD. Imparting the diagnosis of life threatening illness in children. *BMJ* 1989; 298: 1625-6.

³¹⁶ GMC. *0-18 Years: Guidance For all Doctors*. 2007, para 43.

³¹⁷ GMC, *ibid*, para 46.

26j. Does it make any difference to the decision as to whether, when and if so how to inform the patient, if the disease is one for which there is no available and/or effective treatment? If so, how and why?

The patient should generally be informed of the diagnosis regardless of whether the disease is one for which there is no available and/or effective treatment. This is justified on the grounds of patient autonomy, and self-determination. Withholding that information would be a very paternalistic move on the part of the clinician. The patient should be informed and should be able to choose how to live their life and how to administer their affairs after they have been informed of the diagnosis, unless of course, the patient refuses to be informed.

However, when and how the patient should be informed of the diagnosis may be affected by the fact that the disease is one for which there is no available and/or effective treatment. A patient may choose not to know about a diagnosis which will affect their future life and which can have grave psychological and emotional repercussions, or the clinician may elect not to immediately inform a patient of a diagnosis of a disease for which there is no available or effective treatment, if the information is likely to cause the patient serious harm. As made clear above, timely and effective disclosure is extremely important if the patient has potential to infect others.

As set out in Q26h above, patients should be assisted, when a diagnosis has been made of a disease for which no treatment is available, with appropriate counselling and support, including psychological and emotional support.

Question 27. What ethical principles should inform the approach to telling a patient that they may have been, or have as a matter of fact been, exposed to the risk of a serious disease for which there is no diagnostic test?

Supplemental Q23. Please consider whether it makes a difference if the disease is an infectious one.

Supplemental Q24. If a patient is told that they have been or may have been exposed to the risk of a serious disease for which there is no diagnostic test, what categories of information, in broad terms, should be provided to them?

Principles such as the protection of public health, prevention of infectious diseases, and spreading of contamination would guide the decision whether or not to inform someone they may be at risk of being infected with a serious disease for which there is no diagnostic test. This was the case, for instance, for patients who had been at risk of contamination with Variant Creutzfeldt-Jakob disease (vCJD) after receiving blood products in the 1990s. There was no test available for vCJD and for reasons of public safety, certain patients who were at risk of having been infected were informed of the risk and were told not to give blood in 2004.³¹⁸ They were also asked to reveal this risk when undergoing future procedures which carried a risk of passing on the infection, such as dental treatment or surgery. However, as in previous cases, society's strongest protections lay in treating all dental patients as if they were potentially carrying the disease, and sterilising or disposing of all surgical equipment as if it had been exposed to prion disease.

³¹⁸ Kmietowicz Z. Patients informed of increased risk of vCJD contact. *BMJ* 2004, Sep 25; 329(7468): 702.

If a patient is told that they have been or may have been exposed to the risk of a serious disease for which there is no diagnostic test, open and honest information should be given about the type of disease the patient may have been infected with, the circumstances in which the patient may have been infected, possible ways to infect others, and ways to prevent contamination from spreading to other people, as well information about possible available treatment, ongoing research, and relevant counselling and support.

Clearly, the emotional costs to individuals can be high in such circumstances, and the stigma associated with a poorly understood condition will add to this. It is also important to acknowledge that the lack of a definitive test carries with it the added burden of uncertainty, and the inability to make the sorts of choices discussed at length in this section of the report.

Question 28a. What ethical principles should inform decision-making about whether, and if so in what circumstances, a clinician could or should disclose confidential information about a patient's health to a third party (e.g. a partner who might themselves be at risk of being infected or a public health authority)?

Patient confidentiality and public health considerations are guiding principles which should inform decision-making about whether, and if so in what circumstances, a clinician could or should disclose confidential information about a patient's health to a third party (see above). It is important to note that the duty of confidentiality applies even after a person has died.³¹⁹

Healthcare professionals have the strongest responsibility to be involved in informing and managing risk of harm to others where infection is serious and possibly rare. However, even in this case, the responsibility to prevent transmission must be considered alongside the rights of the person who has been diagnosed in terms of their privacy, liberty and bodily integrity.³²⁰

In 1989 the Council of Europe issued guidance on the ethical issues of HIV infection, strongly supporting respect for confidentiality.³²¹ This approach was broadly emulated in guidance in the UK.

Partner notification

In relation to managing the wider implications of test results, any infectious or transmissible condition can result in risk or harm to others, and where this harm is avoidable there will be good reason and a prima facie ethical responsibility to inform, and the possibility of taking steps to prevent infection.

The Council of Europe guidance took the view that, as a general rule, partner notification should not take place without the patient's consent. Though informing (known) at-risk third parties was not ruled out; counselling, support and explanations were the primary responses recommended in cases of reluctance to consent.³²² One proposed measure of support was a confidential provider referral which would not necessarily identify the patient.

³¹⁹ GMC. *Professional Conduct and Discipline*. 1979, p 16; GMC. *Serious Communicable Diseases*. October 1997, para 21: 'a patient's death does not of itself release a doctor from the obligation to maintain confidentiality. But in some circumstances disclosures can be justified because they protect other people from serious harm or because they are required by law'; *Lewis v SoS for Health* [2008] EWHC 2196.

³²⁰ *ABC v St George's Healthcare NHS Trust & Ors* [2020] EWHC 455 (QB).

³²¹ Council of Europe, Committee of Ministers, *Recommendation No. R (89) 14 on the Ethical Issues of HIV Infection in the Health Care and Social Settings* (Oct. 24, 1989).

³²² CoE, *ibid*.

The GMC's 1988 guidance on HIV and AIDS took a similar view, preferring a consensual approach:

15. Doctors are familiar with the need to make judgements about whether to disclose confidential information in particular circumstances, and the need to justify their action where such a disclosure is made. The Council believes that, where HIV infection or AIDS has been diagnosed, any difficulties concerning confidentiality which arise will usually be overcome if doctors are prepared to discuss openly and honestly with patients the implications of their condition, the need to secure the safety of others, and the importance for continuing medical care of ensuring that those who will be involved in their care know the nature of their condition and the particular needs which they will have. The Council takes the view that any doctor who discovers that a patient is HIV positive or suffering from AIDS has a duty to discuss these matters fully with the patient.

The 1998 guidance did, however, recognise the potential to lawfully breach patient confidentiality in the public interest where 'there is a serious and identifiable risk to a specific individual who, if not so informed, would be exposed to infection.'³²³

GMC guidance on *Serious Communicable Diseases* from 1997 added that information can be disclosed to close contacts, 'in order to protect a person from risk of death or serious harm' (para 22). The guidance provides that a clinician:

may disclose information to a known sexual contact of a patient with HIV where [they] have reason to think that the patient has not informed that person, and cannot be persuaded to do so. In such circumstances [the clinician] should tell the patient before [making] the disclosure, and [the clinician] must be prepared to justify a decision to disclose information.

The guidance makes clear that information should not be disclosed to others, 'for example relatives, who have not been, and are not, at risk of infection' (para 23).

Very recently, the courts in England and Wales considered the duty of doctors to inform at-risk third parties with whom they have a close relationship, of confidential information the patient wishes to keep secret. In *ABC v St George's Healthcare NHS Trust & Ors*³²⁴ it was acknowledged that clinicians must perform a careful balancing exercise between the interests of those parties. Though the case concerned a genetic risk (the risk that the gene for Huntington's Disease might be passed on), the precedent extends to other confidential information.

Disclosure to other healthcare professionals

Where the patient is diagnosed with a serious disease in a specialist setting, the question arises as to whether the patient's general practitioner (GP) or other practitioners involved in their ongoing care should be informed. As in relation to partner notification, the approach adopted in the 1980s focused predominantly on providing the patient with explanations and support in the hope that this would lead to consensual disclosures.

The Council of Europe advised 'strongly supported respect for confidentiality' and the GMC, in its 1988 guidance on HIV and AIDS, advised that the patient should be made aware of the advantages to their health of an integrated and supportive approach from their GP. If, having

³²³ GMC. *HIV infection and AIDS: The Ethical Considerations*. May 1988, para 19.

³²⁴ [2020] EWHC 455 (QB).

considered the matter carefully in the light of counselling and support, the patient still refuses to allow their GP to be informed, then the patient's request for privacy should be respected. The only exception to that general principle arose where the doctor judged that the failure to disclose would put the health of any of the healthcare team at serious risk, in which case the doctor must be able to justify their action.

The GMC's 1988 guidance adopted a similar approach in relation to sharing information with other specialists:

18. Similar principles apply to the sharing of confidential information between specialists or with other health care professionals such as nurses, laboratory technicians and dentists. All persons receiving such information must of course consider themselves under the same general obligation of confidentiality as the doctor principally responsible for the patient's care.

With regard to the prevention of infection in healthcare settings, the Council of Europe recommended a routine approach for all patients whereby standards are adopted to protect health workers exposed to blood, tissue and body fluids:

health care workers should consider all patients as potentially infectious and should adhere rigorously to precautions concerning blood, body fluids and tissues or other control of infection procedures.³²⁵

Schools

The Council of Europe also issued advice on the disclosure of information to schools when a child has HIV:

- school health staff, teachers and other educational staff should all strictly respect the principles of confidentiality;
- decisions on whether to inform the school of the presence of an HIV infected child or adolescent should be taken only when in the interest of the person in question on a case by case basis and after a consultation among, if possible the infected person, the parents, the teachers and the health care staff.³²⁶

Supplemental Q25. Is there an ethical obligation or responsibility on a clinician to advise a person who has contracted an infectious disease, of the risks of infecting others such as family and friends?

A failure to warn of risks inherent in treatment can lead to a claim in negligence. The same is not necessarily true of a failure to warn of risk *to others*. Having said this, it would not be in the best interests of a patient to undermine their ability to protect their significant others. There is, therefore, an ethical duty to inform of the risk to others notwithstanding that the doctor's primary responsibility is to his or her patients. As we stated in our introduction: given the social nature of both illness and healthcare, healthcare professionals are obliged to consider what is ethically owed not only to individual patients, but also to their families and loved ones and to the local and global communities in which they live.

³²⁵ Council of Europe, Committee of Ministers, *Recommendation No. R (89) 14 on the Ethical Issues of HIV Infection in the Health Care and Social Settings* (Oct. 24, 1989).

³²⁶ CoE, *ibid.*

28b. What obligations does a clinician have in the public interest to protect others when a patient has been informed they may have contracted an infectious disease?

28c. How should a clinician weigh those factors when making a decision?

We take Questions 28b and 28c together. The duty to protect a patient's confidentiality comes from the common law and is both a private and a public interest. Today, its development is heavily influenced by human rights law. It is a duty that is subject to certain (and limited) exceptions. In some circumstances, disclosures are required by law. For instance:

the appropriate authority must be informed where a notifiable disease is diagnosed. Where a communicable disease contributed to the cause of death, this must be recorded on the death certificate. [The clinician] should also pass information about serious communicable diseases to the relevant authorities for the purpose of communicable disease control and surveillance.³²⁷

It is also subject to an exception in the 'public interest'. In *X v Y*³²⁸ a health authority employee breached confidentiality and informed a newspaper of the identity of two general practitioners who were HIV positive. The newspaper argued that this information was in the public interest. The judge disagreed and granted an injunction: The doctors had received counselling regarding safe practice and the risk to patients was negligible. The risk that people with infectious diseases who could not rely on confidential medical treatment might avoid medical assistance was, however, considerable. Contrast this case with *W v Egdell*³²⁹ where it was in the public interest for a psychiatrist to release confidential information about a patient in a secure unit to certain officials to warn them of the potential risks to the public should he be released.

As we discussed in response to Supplemental Q18a, there is potential to lawfully breach a patient's confidentiality in the public interest where there is a serious risk to others,³³⁰ but as we have stated in response to Q28a, the preferable way forward is counselling, support and consensual notification. In response to Supplemental Q25 above, we considered the ethical duty to inform patients of the risk of infecting others and of the precautions a patient might take to prevent this.

³²⁷ GMC. *Serious Communicable Diseases*. October 1997, para 20.

³²⁸ [1988] 2 All ER 648.

³²⁹ [1990] 1 All ER 835, CA.

³³⁰ GMC. *Disclosing Information about Serious Communicable Diseases*. 2017, paras 12-15. <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/confidentiality---disclosing-information-about-serious-communicable-diseases>; Gibson E. Medical confidentiality and protection of third party interests. *American Journal of Bioethics* 2006; 6(2): 23-25; Bozzo A. A Challenge to unqualified medical confidentiality. *J Med Ethics* 2018; 44(4): 248-252.

Section 5: Research

Scientifically robust research is essential to maintaining global health and wellbeing. Such research becomes particularly important in the context of serious and transmissible disease, where the human and financial costs associated with non-evidence-based practice will be particularly high. There is a moral imperative in medicine to protect individuals and societies through the development and implementation of appropriate evidence-based practice, and research is crucial to this end.

However, we are well aware that the drive for scientific and medical progress has sometimes led to individuals being subject to unacceptable risks and/or experiencing unacceptable levels of harm. It is therefore unsurprising that ethical commentators have often emphasised the importance of protecting patients from research. We prefer to work with a narrative which entails protecting individuals *through* research.³³¹ We therefore proceed on the basis that medical research is a good thing and that our moral responsibilities in this area would not be served by being research averse.

A further important point before proceeding to answer the questions below relates to the use of language. Historically it has been common to refer to those taking part in research as 'research subjects' and to some extent this persists. We prefer the term 'research participant', as it reminds us to think about how we can protect people who volunteer to be involved in research by treating them as active participants rather than passive subjects. We will however leave the language of guidance intact and largely uncommented upon.

Question 29. What is the difference between audit of practice and research? What different ethical principles apply to each?

(See also response to Q20 which sets out the principles of consent, including consent to research).

The primary aim of research is to derive new knowledge and evaluate new interventions, whereas audit and service evaluation measure levels of existing care against existing standards, and then by way of an audit cycle confirm or amend those standards. Audit is a kind of quality assurance. It is important in order to define any gaps between evidence-based practice and patient care, and to improve the effectiveness and safety of care. The Declaration of Helsinki explains that:

The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.³³²

The distinction between research and audit is not always clear and some projects, such as research on the quality improvement process, fall in-between the two definitions.

³³¹ Nuffield Council on Bioethics. *Children and Clinical Research*. 2015 p vii.

³³² WMA. *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*. 2018, para 6.

Consequently, the distinction between the two types of activity does not always translate into relevant differences in terms of the ethical issues they raise. While there are clearly demarcated governance processes and substantial guidance around research activity, this is less clear in relation to audit. For this reason, there is a strong imperative upon those engaged in audit activities to consider the impact of their activities and seek ethical advice and support where necessary. Any activity that poses a risk of psychological or physical harm to patients requires consideration of the ethical dimensions. It is also important to stress that it is ethically unacceptable to describe a research study as audit or service evaluation in order to avoid the rigorous processes involved in ethical approval of research.

Audit within a clinical setting is a much less visible activity than research, in fact it is largely invisible to patients. This is in part because their consent is often not required in the same way as when recruiting to a research project. However, it remains important to ensure that the ethical interests of those whose treatment is being audited are properly served by, for example, appropriately anonymising data; safely storing and transferring potentially sensitive material; not diverting unreasonable amounts of time from clinical care; and being open about the findings of audit activities, particularly where they reveal problems or shortcomings.

The Healthcare Quality Improvement Partnership (HQIP) has issued a guide to managing ethical issues in clinical audit.³³³ It concludes that: ‘Research requires ethics review and quality improvement requires ethical oversight.’ In relation to audit, it recommends robust processes to screen for ethical issues; involvement of relevant professionals, services and patient groups; designation of accountable persons; oversight of ethical issues; and formal ethical review in cases of research on quality improvement or intervention.

Thus, research and audit could be seen as working together and as being equally subject to the ethical standards that ‘promote and ensure respect for all human subjects and protect their health and rights’.³³⁴ The two activities will remain distinct, and could raise different issues, but where either poses a threat to participants, ethical standards must be maintained.

Question 30. What ethical principles should inform decisions about participation in research?

Research is often referred to as if it is a unitary activity. Clearly this is not the case. Research can take many forms and may be conducted by a range of different professionals. We refer most frequently here to research which involves researchers and participants working together in the bid to establish whether an as yet unproven intervention is safe and beneficial. However, it is also possible to undertake research after a drug or other intervention has been licensed and widely used. An example might be where a much cheaper alternative appears anecdotally to be an acceptable equivalent to an existing standard treatment. In both of these cases the altruism of the participant is engaged. In the first there is the possibility of the research showing that there is no benefit, or maybe even some harm, associated with the new drug/intervention. In the second, there is the possibility that the cheaper drug will be seen as a more cost-effective choice for a state-funded health system, but to prove this, patients may be taken off therapies they have been happy with. A subset of participants may be shown to do ‘well enough’ on the cheaper option but demonstrate a strong preference

³³³ HQIP. *Guide to Managing Ethical Issues in Quality Improvement or Clinical Audit Projects*. 2017. <https://www.hqip.org.uk/wp-content/uploads/2017/02/guide-to-managing-ethical-issues-in-quality-improvement-or-clinical-audit-projects.pdf>.

³³⁴ WMA. *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*. 2018, para 4.

for their more expensive familiar treatment. What is owed in this situation is an obligation to continue to audit the performance of what has now become the standard treatment in order to ensure that lessons are learned as a result of its wider use.

In both these cases, 'standard research participation' and 'post-licensing research', the research participant may not enjoy the direct benefits they had personally hoped for, but in both cases, they will have contributed to a common good by helping to advance knowledge and practice. It is in the very nature of medical research that participants need to understand that direct personal benefit to participants may not be possible or even sought. What is possible within a scientifically and ethically robust study is the opportunity to contribute to a greater good which may, in the longer term, bring benefit to those who took part. This can be a very compelling motivation, particularly for those who identify with the experience of people diagnosed with the same or related conditions, and those who know their medical problems to have a genetic and therefore inherited character.

Against this background it is generally agreed that there are two basic ethical principles which protect participants even where direct benefit is not anticipated: reasonable risk and consent. Participants should only be exposed to reasonable risks and (other than in a few carefully specified cases) this should only be with their consent. In determining whether the risks of participation in research are reasonable, the following factors are relevant:

- (1) Is there a known risk to participants prior to commencing the study and what is its magnitude, based on evidence available at the time?
- (2) Should any non-human or epidemiological research, systematic overview or computer modelling have been performed prior to the study to better estimate the risk to participants or obviate the need for the use of human participants?
- (3) Could the risk have been reduced in any other way? Is it as small as possible?
- (4) Are the potential benefits (in terms of knowledge, improvement of welfare of trial participants or other people) of this study worth the risks?
- (5) Could this research generate knowledge which is likely to significantly harm either participants or others outside the research, now or in the future?³³⁵

If the risks of research are reasonable, competent participants should give informed consent. In the case of children, appointed decision-makers should give consent on their behalf.

The activities and risks involved will vary across different types of research, as will the burdens placed on participants. The risks involved in injecting novel compounds into sick patients or asking healthy volunteers to trial new vaccines are very different to those arising when we ask young people to take part in focus group discussions on sensitive issues. But it would be wrong to assume they are different in terms of complexity or importance. We must therefore think carefully about the sorts of protections that people might need in all three situations, but similarly we must appreciate the value of their participation in such research, both individually and societally. Ultimately individuals will need to decide what they will and will not do in the name of research, be they researchers or participants, but it is clear that there can be no half measures. Conducting research effectively requires strict adherence to study protocols by both researcher and participant (although withdrawal is always an option in the latter case,

³³⁵ Savulescu J, Hope, T. Ethics of research. In Skorupski J. (ed.) *The Routledge Companion to Ethics*. Abingdon: Routledge, 2010, 781-795.

as is calling a halt to the study in the former). This is why the philosopher Hans Jonas was so clear back in the late 1960s that research should only ever rely on volunteers as opposed to conscripts.³³⁶

The legal landscape affecting research has developed significantly since the late 1990s with the introduction of the Data Protection Act 1998 (and subsequently the EU General Data Protection Regulation), the Medicines for Human Use (Clinical Trials) Regulations 2004 (and subsequently an EU Clinical Trials Regulation) and legislation on mental capacity and human tissue in the devolved administrations. From the 1990s regulation was heavily influenced by European law. Today, law is supplemented with extensive guidance from the GMC, BMA, the Medical Research Council, Royal Colleges and the Department of Health and Social Care emphasising the safety, dignity, and wellbeing of participants.³³⁷

Our response to Q20 outlined the development of guidance from the 1960s, including some of the many gaps and limitations. The BMA set out the Declaration of Helsinki in its 1970 and 1974 guidance on medical ethics. In its 1980 edition, the BMA included a more detailed section on 'Research in Human Subjects' warning that:

Medical advances have always depended upon the public's confidence in those who carry out investigations on human subjects. The confidence will be maintained only if the public believes that such investigations are submitted to rigorous ethical scrutiny and self-discipline. It is unethical to conduct research which is badly planned or poorly executed.³³⁸

The Royal College of Physicians filled a lacuna in practical guidance in the 1980s, issuing advice on the responsibilities of ethics committees and the conduct of research on patients and healthy volunteers.³³⁹ This was particularly important given the lack of a legislative framework at the time.

Research in global health emergencies raises particular issues due to the urgency of the situation. In 2020 the Nuffield Council on Bioethics (NCOB) published a report into the ethical issues.³⁴⁰ It set out three core principles of fairness, equal respect and helping reduce suffering. From this 'ethical compass' the working group extrapolated recommendations to duty bearers such as researchers, funders, organisations and governments. Among its recommendations was a call for global collaboration and engagement of the relevant community when designing the research. With regard to informed consent of research participants, the report acknowledges that difficulties in explaining complex research studies with their inherent uncertainties exist in relation to non-emergency research and can be exacerbated in an emergency setting where there may be heightened risk and uncertainty. The working group was clear that 'respectful consent processes that demonstrate equal respect for participants are as important in emergencies as in any other context.' Ethics committees should ensure that consent processes are appropriate and as sensitive as they can be in the circumstances. Researchers should feedback results and conclusions to participants and communities.

³³⁶ Jonas, H. Philosophical reflections on experimenting with humans. *Daedalus* 1969; 98: 219-247.

³³⁷ See for instance, GMC. *Good Practice in Research and Consent to Research*. March 2013. https://www.gmc-uk.org/-/media/documents/Good_practice_in_research_and_consent_to_research.pdf_58834843.pdf.

³³⁸ BMA. *The Handbook of Medical Ethics*. 1980, 4.2.

³³⁹ Royal College of Physicians: *Supervision of the Ethics of Clinical Research Investigations in Institutions*. 1967; *Guidelines on the Practice of Ethics Committees Involved in Medical Research Involving Human Subjects*. 1984; *Research on Healthy Volunteers*. 1986; *Research Involving Patients*. 1990.

³⁴⁰ NCOB. *Research in Global Health Emergencies*. 2020. <https://www.nuffieldbioethics.org/publications/research-in-global-health-emergencies>.

30a. In particular and from a medical ethics perspective: What factors should a clinician take into account when considering whether a patient might take part in a research project or otherwise be the subject of research or study?

There are two prominent relevant factors:

- (1) Are the risks reasonable for this particular patient?
- (2) Can the patient give valid consent, or is there another legally appointed proxy?

Governance

Further to our discussions in response to Q20, governance arrangements now apply to research, including oversight from research ethics committees which will (among other things) consider the trial design; evaluate risks and benefits to participants; ensure that information provided to patients is suitable and sufficient; and consider the suitability of researchers.³⁴¹ Once the research is approved and underway, audit, monitoring and reporting aims to ensure that researchers do as they promised at the application stage. Post-research, emphasis on transparency of results aims to ensure that negative as well as positive results are reported, so reducing publication bias, duplication and incumbent expense and risk. There has also been a growing movement towards involving patients and potential participants more fully in the research agenda through organisations such as the Lind Alliance and through the work of medical charities.³⁴² This is a global phenomenon, and research involvement and engagement are areas of practice in which we have much to learn from practices in resource-poor settings.

Scientific considerations

Prior to undertaking a research project, a clinician researcher has a number of issues to consider. First among these is the need to consider whether the project as proposed should be undertaken at all. This will depend on whether preceding scientific work has established that the study has a realistic chance of providing a positive result, by which is meant a scientifically significant result which will hopefully demonstrate the value of a therapy. Having said this, it could in some cases provide confirmation that a treatment is ineffective, too fraught with side-effects, or no better than standard treatments.

Risks and benefits to the participants

At the same time as considering the timeliness, scientific provenance, and the proposed methodology of the study, the scientist will also need to consider the costs and burdens anticipated, most importantly the risk of harm to participants, but also the opportunity costs to other patients. The Declaration of Helsinki provides that:

All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation. Measures to minimise the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher (para 17).

³⁴¹ See, for example, The Medicines for Human Use (Clinical Trials) Regulations 2004, Reg 15(5).

³⁴² See: The James Lind Alliance, <http://www.jla.nihr.ac.uk>.

Additionally,

Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed.

When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study (para 18).

A clinician will be concerned with the additional risk involved in being part of a research project. In line with our more holistic approach to best interests it is important to appreciate that information pertaining to risk must be individualised, taking into account the patient's view of what matters most to them, and the risks they will be most concerned to understand and weigh up.

This could be for example the risk of physical harm and/or side-effects from new drugs, or the risks and benefits of alternative courses of action, the risk of emotional upset as a result of interview-based studies, or the risk of missing out on activities which give life value as a result of additional hospital visits or inpatient care. In the 1990s concern was raised that the amount of information one was required to impart when recruiting to some trials was 'needlessly cruel' and potentially out of step with what a patient would have been told therapeutically.³⁴³ Clearly the risk of upsetting a patient must not act as a barrier to providing important and relevant information, but there is a need for sensitivity and a willingness to contextualise.

In scientific terms it is desirable if clinical research proceeds from a position of equipoise i.e. a position where there is as yet no good reason for a choice between two or more therapeutic options. This means that it is particularly important the clinician is clear with would-be participants that involvement in the research will not necessarily deliver any direct benefit, indeed it might deprive them of benefit and/or subject them to harm or at the very least inconvenience. In the gold standard randomized control trial, particularly one that incorporates blinding of researcher and research participant, there is no way of knowing who will receive which intervention and there should certainly be no suggestion that allocation to the experimental arm is necessarily better – this is what the research is designed to test. It is therefore safer to proceed on the basis that all research, however well designed and ethically rigorous, entails a degree of uncertainty as to outcome. Communicating this point is an important precursor to recruitment.

It is typically held that research must be stopped when equipoise is disturbed. This is mistakenly thought to be a purely statistical decision. Whether there is sufficient confidence to stop a clinical trial is a complex ethical judgement involving the weighing of the interests of trial participants against future patients and society.

In the Nuffield Council on Bioethics report *Children and Clinical Research* the authors set out the concept of a 'fair offer'.³⁴⁴ The idea is that having done the basic ground work, a clinician should only be prepared to present a study to a patient or healthy volunteer if they believe that, irrespective of the role they are allocated in the study, and/or any risks or burdens involved, participation is consistent with the patient's broader welfare. While this might be

³⁴³ Tobias JS, Souhami RL. Fully informed consent can be needlessly cruel. *BMJ* 1993; 307: 1199.

³⁴⁴ NCOB. *Children and Clinical Research*. 2015. <https://www.nuffieldbioethics.org/publications/children-and-clinical-research>; NCOB. *Research in Global Health Emergencies*. 2020. In global emergencies, ethics committees should consider 'whether, in all the circumstances, what is being asked of participants can be justified as fair.'

possible at the outset of a trial, as data accumulates it usually becomes more likely as the trial progresses that one arm is superior and in a patient's interest. If the trial continues in order to demonstrate more clearly that the positive results are not down to chance, this is more properly seen as being in the interest of future patients.

An ethics committee will endorse this position if it agrees that the offer is one that a patient should be allowed to consider, and if it feels that having made the offer the clinician (or appropriate others) could go on to support potential recruits in deciding whether or not to accept/consent to participate and to continue once preliminary results are available. In some cases, a clinician might feel that a particular trial is not suitable for a patient given their particular circumstances, and that to invite them to participate would not constitute a fair offer, because those circumstances would prevent them from being in a position to make an appropriate choice. In other cases, a combination of scientific and ethical considerations could mean that a trial is halted in the interests of participants before the scientists have amassed the data they originally aimed for.

Suitability of the researcher

Clinicians may also have to consider the suitability of their personal involvement in the project given their workload, expertise, resources or conflicts of interest etc. They should also consider the skills that they need to develop in order to protect their patients when they take on the dual role of clinician and researcher. A clinician researcher faces the unique challenge of balancing the therapeutic interests of specific patients with the benefit of advancing the research agenda. This can be uncomfortable on occasion, for example when one might have to tell a patient desperate for the hope associated with a trial that they do not fulfil the recruitment criteria. Or it might sometimes be the case that what the clinician wants to do therapeutically for a particular patient is not possible within the constraints imposed by a research protocol. It is therefore incumbent upon a clinician researcher to be able to manage the patient's expectations, give a balanced and honest account of the pros and cons of involvement, and other relevant alternatives, and anticipate any difficult choices that might ensue. These examples suggest the particular importance of empathy and effective communication skills and the need to consider therapeutic and scientific considerations alongside one another.

While not exhaustive, this list of considerations indicates the care that needs to be taken before a clinician signs participants up to a study.

Informed consent

Historically clinical research relied heavily on the consent of the research participant as a foundation for legitimacy. This is made clear in the Nuremberg Code and the Declaration of Helsinki (see response to Q20 above). However, it is now appreciated that consent cannot 'do all the work' in relation to ensuring that a research procedure is ethical. Given that researchers must seek to protect the 'life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects',³⁴⁵ other issues such as trust, transparency, public understanding of research etc. are seen as important.

If a clinician decides that they can in good faith recruit to a study, they will become either directly or indirectly responsible for acquiring consent from their patients to do so. The Declaration of Helsinki makes clear that the consent of the research subject must be voluntary

³⁴⁵ WMA. *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*. 2018, para 9.

(para 25), and informed (para 26). Voluntariness might be compromised where participants are offered financial inducements or where their relationship with the researcher makes saying no difficult. The potential research subject must be informed of the ‘right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal’ (para 26). This final point is particularly important in the context of an on-going therapeutic relationship. In such circumstances, consideration should be given to an independent person approaching the potential participant (para 27). This would clearly be important in a situation where clinician and patient have been in a therapeutic relationship over many years and could continue to be so. While out-and-out coercion is unlikely, and would be professionally completely unacceptable, a clinician might subconsciously place pressure on a patient by expressing enthusiasm for a research project or may be seen to be endorsing it simply by asking their patient to consider taking part. As well as the potential for coercion the issue of gratitude or reciprocity might feature with a patient feeling they ‘owe’ it to their clinician to take part in ‘their’ study. A clinician must therefore take appropriate steps to minimise the chance of these possible responses. One important element of all study consent forms is a clear assurance that a patient’s care will not be adversely affected if they decide to withdraw from a study, it is also important to give the same assurance at the recruitment stage.

The clinician must inform the research participant of the risks and benefits of participation and non-participation. They should also disclose the ‘aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study’ (para 26).

Patient information is often provided by means of a Participant Information Sheet (PIS) which will set out the project, the participant’s part in it, the benefits of participation and any potential risks and/or known or anticipated burdens. It should also list any alternatives for diagnosis or treatment if the research is therapeutic in nature. Interested participants could also have access to a full study protocol if required.

As informational documents, PISs have limitations, for example if they are only available in one language, participants have limited reading ability, or they result in information overload if they are introduced in close proximity to a diagnosis or discussion of a complex treatment plan. However, a main task of Research Ethics Committees is to ensure that such documents are readable, use clear language and cover the important ethical issues pertinent to the project and the participants’ involvement. It is also important that the PIS reflects a position of equipoise as set out above, by making clear that research is being conducted precisely because we do not know whether, for example, Drug A is better than Drug B. It is not acceptable to use a PIS to encourage recruitment. It is there to inform in a balanced and open way, and to assist the potential participant in deciding whether they wish to volunteer. Another important element of a PIS is the provision of contact details of someone who could answer any questions or address any concerns during the recruitment process.

Provisions specifically relating to informed consent are exemplified by guideline 9 of the Council for International Organizations of Medical Science (CIOMS) 2016 international guidance:

In summary researchers have a duty to:

- seek and obtain consent, but only after providing relevant information about the research and ascertaining that the potential participant has adequate understanding of the material facts;
- refrain from unjustified deception or withholding of relevant information, undue influence, or coercion ...;

ensure that the potential participant has been given sufficient opportunity and time to consider whether to participate; and

as a general rule, obtain from each potential participant a signed form as evidence of informed consent. Researchers must justify any exceptions to this general rule and seek the approval of the research ethics committee.³⁴⁶

These recommendations support the oft-cited claim that consent is a process as opposed to an event. While there might be strong legal, regulatory and indemnity-related reasons that make it important to secure a signature on a consent form, ethically this is significant if, and only if, it is independently evident that the participant has been given the opportunity to give or withhold their consent in a meaningful way.

30b What obligation or responsibility does the clinician have to inform the patient that they are participating in a research project or are the subject of research or study?

In response to Q20 we discuss informed consent to research and the long-held view that participants of research should give ‘freely-given informed consent’.³⁴⁷ We maintained that today it is clear that participants should generally³⁴⁸ be told when they are participating in research, and, moreover, be given an opportunity to consent to or refuse to participate. In the past, where patients had consented to medical care it was less clear that they should also be told that the care was the subject of research. It was only in the 2000 version of the Declaration of Helsinki that it was made clear that: ‘The physician should fully inform the patient which aspects of the care are related to the research’ (para 31).

30c. In broad terms, what kinds of information should a clinician provide to a patient to enable the patient to give informed consent to participating in a research project or being the subject of research or study?

Information disclosure should focus on important or common risks and benefits of participation and all relevant alternatives. We have discussed the obligations of the clinician to inform research participants in response to Q30a. There is very detailed guidance from CIOMS 2016 (Appendix 2)³⁴⁹ about the content of participant information and the way in which it is communicated. Among the 26 information points set out by CIOMS are the purpose of the research and what it will involve; why the patient is suitable; the voluntariness of participation and right to withdraw; what will happen after the research; what arrangements are made for compensation if injury occurs; potential benefits and detriments; available alternatives; and protection of privacy and confidentiality. As will be apparent from this list, the information is designed to give the participant sufficient information to make an informed decision and also to understand the implications of participation post-research.

The fundamental ethical principles we identified in Q19 apply to research as well as to treatment. Equally, the legal, social and cultural developments of informed consent we referred to in response to Q20 have impacted on research as well as treatment. In the past,

³⁴⁶ CIOMS, *International Ethical Guidelines for Health-Related Research Involving Humans*. 2016. <https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/>.

³⁴⁷ WMA. *Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects*. 1975, I:9.

³⁴⁸ We explore a number of exceptions to the general rule in response to Q20.

³⁴⁹ CIOMS, *International Ethical Guidelines for Health-Related Research Involving Humans*. 2016. <https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/>.

information may have been less comprehensive. Sometimes patients who had consented to certain medical treatment might have been unaware that the treatment was the subject of a research project (as we discuss in response to Qs 20 and 30b). There was also evidence of concern as to the effectiveness of information provision. One prominent study in the 1970s indicated that the retention rate of information given orally to participants was low.³⁵⁰ This realisation led to new efforts to present information appropriately to aid understanding and retention, including the use of Patient Information Sheets (discussed Q30a).

It is important to acknowledge that where the ethical justification for a practice rests heavily on the claim that a person has consented to that practice there is a requirement to ensure that the consent was voluntary and informed, and in the case of research there will be a particularly strong requirement for it to be explicit and appropriately recorded. This is because research involvement falls outside the commonly understood parameters of standard medical treatment where some degree of implied consent might be acceptable.

30d. What obligation or responsibility does the clinician have to tell the patient that information about them is being provided to others for research or monitoring or public health purposes?

Supplemental Q27. When answering Q30d, please also consider whether there is a duty to seek the person's consent for information about them to be shared for research, monitoring or public health purposes.

There is not a single answer to this question as the obligation will depend upon the nature of the information, the form in which it is held, the specificity of any prior consents, and the purposes for which the information will be used.

So, for example, the use of de-identified or anonymised patient data collected in the normal course of events could be approved by an ethics committee for the purposes of public health purposes or monitoring. There would be no requirement to inform or obtain consent from patients.

Similarly, an ethics committee could approve the reuse or secondary analysis of information and/or samples collected within a research project if participants had given general consent to their data being used in future research, or where the study clearly falls within a specific category that the participant consented to. As we discussed in relation to Q20 above, research on residual blood or tissue, left over from clinical or diagnostic procedures, now requires consent unless it is anonymised and approval has been given by an ethics committee, but in the past it may have been deemed 'abandoned' and therefore utilised for research purposes without consent.

However, in the case of a participant providing sensitive and identifiable information for the purposes of a particular study, with no consent to data sharing or reuse, a clinician would have to re-approach the participant and gain their consent to place their data within the new project.

Also, where a patient might be a suitable candidate for a further study run outside the institution caring for them, their details should only be shared with permission. This will ensure that any approaches to participate in a study are consistent with the goals of care for a particular patient e.g. knowledge of diagnosis and prognosis, current treatments etc.

³⁵⁰ Leeb D, Bowers D, Lynch JB. Observations on the myth of 'informed consent'. *Plast Reconstr Surg.* 1976 Sep; 58(3): 280-2. And see Foster C. *The Ethics of Medical Research on Humans*. CUP, 2001, 115-116.

30e. Are there any circumstances in which it would be ethical for a clinician to enrol a patient in a research project, or make them an object of research or study, without the patient’s knowledge or informed consent?

It would be ethical to enrol a patient in research on their data without their consent where their data is anonymised, and the project has been approved by a research ethics committee.

We have discussed the historical differences with regard to information provision and informed consent in our responses to Q20 and Q30b.

Today, it is feasible that a large cohort study could be approved whereby anonymised data was provided over a period of time to inform scientific study of disease prevalence, environmental interactions, and social inequalities of health. Participation might be by virtue of being born in a particular year, or in a particular place, or it could be the result of broader population sampling.

While a particular patient might be unaware of their involvement in research, there should be a general public awareness of the existence of the study; the purposes of such research; the safeguards put in place to protect confidentiality and anonymity; and the way in which the results of research conducted will be utilised and by whom.

Historically patients have taken comfort from the assumption that information about them would ‘stay within the NHS’ even when it is shared for various purposes. We now understand the need for multi-agency care in some cases and with the changing nature of the health economy and greater involvement of private companies etc. public debate has to address the concerns people have about who will be given access to their data and personal information and to what ends.

30f. Are there any circumstances in which it would be ethical for a clinician to provide information about a patient (on a named, de-identified or on an anonymous basis) to others for research or monitoring or public health purposes, without the patient’s knowledge or informed consent?

It is potentially ethical for a clinician to disclose information about a patient where this is in the public interest, where there is appropriate authorisation (e.g. from a court or statute), or where data is anonymised/de-identified and with the approval of a research ethics committee.

A patient’s medical notes will contain personal and sometimes sensitive information which the patient will have an interest in protecting. The information is entrusted to a clinician in order to facilitate the patient’s treatment. If a patient is under the care of a multi-disciplinary team of health care professionals, information will need to be shared between members of the team to ensure that everyone is appropriately informed. The team-based approach to data access should be made clear to the patient and there should be rigorous processes in place to ensure security of personal data and rule out inappropriate access.

With a patient’s consent a clinician could justifiably share named medical data with other non-medical parties involved in multi-agency care, for example educational or housing authorities. Permission could also be given to provide information to bodies such as insurance companies when a patient is pursuing or defending a claim.

Without the patient's knowledge or consent the examples above would be considered unethical, as they betray the trust of the patient and undermine their confidentiality and privacy. Furthermore, the identifiability of the data means that the wrong committed in sharing the data without consent could be propounded by specific harms to the patient, particularly when they have been diagnosed with a stigmatising or poorly understood condition.

This is not to say that medical data can never be shared without consent or knowledge. One possibility is that a patient could give a broad-based consent to data sharing within the context of research which would not require them to be informed of the exact details of how and when their data has been shared. This would be acceptable where the risks associated with doing so were minimal and the potential benefits were clear. Indeed, in the case of rare or newly diagnosed disease the issue of data sharing becomes particularly important, and it may even occur across international boundaries. While this will require appropriate regulation and high standards of governance, such data sharing could be key to making scientific and clinical progress in areas where no one clinician, hospital, or maybe even nation, will see a critical mass of patients.

If and when a patient's data can be fully anonymised and aggregated one could go so far as to say that (subject to sufficient safeguards) there is an ethical imperative to make best use of that data, not just in the interests of the patient, but for other and future patients as well.

30g. Does it make a difference if the patient is a child? If so, how and why?

Research involving children is a fraught and complex issue. The law and professional guidance seek to provide a minimum standard of protection for children's rights and interests, whilst recognising society's interest in the furtherance of research. The 1989 UN Convention on the Rights of the Child recognises children 'have the right to good quality health care—the best health care possible', but persistent exclusion of children from research has meant that many medicines are not licensed for use in children. Children have different physiology to adults and drugs may react differently in them.³⁵¹ Furthermore, socially and psychologically we can no longer think of children and young people as 'small adults.' In 2015 the Nuffield Council on Bioethics issued a report on the ethical issues inherent in research involving children, reiterating that children are rendered more vulnerable, not less, by their exclusion from clinical research.³⁵² And in 2016 the Royal College of Paediatrics and Child Health issued a charter to help guide discussions about enrolling children in research.³⁵³ The Charter emphasises the importance of empowerment, support, engagement and communication. It encourages researchers to actively gain a child's consent/assent and explain the right to withdraw at any time.

Historically, the Declaration of Helsinki in its 1964 version stated that consent of a legal guardian should be obtained before undertaking non-therapeutic clinical research (III.3a). There was no mention of this requirement in relation to 'research combined with professional care', and we have seen (above) that historically the requirement for explicit consent to any research element of medical care was not considered as important at that time. The 1975 and 1983 versions, on the other hand, made the requirement for consent from a legal guardian a basic principle of research on children. Whenever children were too young to consent, then 'informed consent should be obtained from the legal guardian in accordance with national

³⁵¹ CIOMS, *International Ethical Guidelines for Health-Related Research Involving Humans*. 2016, guideline 17. <https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/>.

³⁵² Nuffield Council on Bioethics. *Children and Clinical Research*. 2015.

³⁵³ RCPCH, *Research Charter for Infants', Children's and Young People's Child Health*. 2016. <https://www.rcpch.ac.uk/resources/research-charter-infants-childrens-young-peoples-child-health>.

legislation' and such consent replaced that of the research participant (1.11). The 1989 and 1996 versions added that the minor's consent must be obtained in addition to that of the legal guardian where the child is able to give it (1.11).

Guidance from the BMA in 1981 also set out additional considerations with regard to research on children. It required attention to three points:

- (i) whether 'the project can only be carried out with the use of children';
- (ii) that local ethical committee approval should be obtained;
- (iii) 'for infants, and children under 10 years of age the requirements for informed consent should be particularly stringent. Parents should be aware of their right to withdraw consent at any time if reflection or experience gives them cause for concern. ...'³⁵⁴

From the 1990s more extensive guidance has been available. The Medical Research Council set out guidance in 1991³⁵⁵ updated in 2004³⁵⁶ stating why research on children was important and the principles that apply. The Royal College of Paediatrics and Child Health³⁵⁷ and BMA³⁵⁸ also produced guidance. The Nuffield Council on Bioethics 2015 report called for culture change so that the views of children help shape how research is designed, reviewed and prioritised.³⁵⁹ Today, the Declaration of Helsinki 2013 requires informed consent from a legally authorised representative (para 28) and, to protect child autonomy, that the assent of children capable of providing it is sought (para 29).³⁶⁰

³⁵⁴ BMA. *The Handbook of Medical Ethics*. 1980, para 4.6.

³⁵⁵ MRC. *The Ethical Conduct of Research on Children*. London: MRC, 1991.

³⁵⁶ MRC. *Medical Research Involving Children*. 2004. <https://mrc.ukri.org/documents/pdf/medical-research-involving-children/>.

³⁵⁷ Royal College of Paediatrics and Child Health: Ethics Advisory Committee. *Guidelines for the Ethical Conduct of Medical Research Involving Children*. *Archives of Disease in Childhood* 2000; 82: 177-182. Previously the British Paediatric Association which produced *Guidelines for Research on Children*. 1992 and previously in 1980.

³⁵⁸ BMA. *Consent, Rights and Choices in Healthcare for Children and Young People*. London: British Medical Association, 2001.

³⁵⁹ Nuffield Council on Bioethics. *Children and Clinical Research*. 2015.

³⁶⁰ And see also CIOMS guidance, *ibid*, p 64.

Section 6: Other

Question 31. If a clinician becomes aware of (for example) conduct such as that summarised in paragraph 10 above, what obligation or responsibility does the clinician have, from an ethical perspective, to intervene or take action?

If there is a risk of serious harm to the patient or others, there is a strong obligation to intervene. For example, not informing someone of their HIV status is unethical and risks public health. Other examples of poor conduct – such as insensitive disclosure – involve weaker obligations to intervene. However, persistent failure in this regard should be addressed in order to facilitate training and support.

Where there is clear policy (e.g. General Medical Council (GMC) guidance to disclose HIV status in certain circumstances) and practice is clearly in contravention of this policy, colleagues have an obligation to report and/or intervene directly to ensure that patients are not harmed.

There are a range of potential interventions and the appropriate course of action will depend on the seriousness and frequency of the risk and contravention. We discuss some of the potential legal responses to patient harm in response to Q19. Less serious interventions include a professional dialogue with the offending physician to provide them with the opportunity to correct practice or reporting to senior clinicians with oversight responsibility. More serious interventions include reporting to hospital authorities and then to the GMC.

It has been claimed that the medical profession has a tendency to ‘protect its own’ or at the very least turn a blind eye to clinicians who fail to maintain appropriate standards of care: an observation made most recently in relation to surgeon Ian Paterson.³⁶¹ This is ethically unacceptable, particularly within a professional group which has been trusted with a high degree of self-regulation.

Nowadays, doctors are taught the importance of monitoring and responding appropriately and constructively to ‘bad practice’. They are also taught to reflect regularly on their own practice and to seek support and guidance where they feel it might be compromised.

Employing bodies are expected to put appropriate mechanisms in place to allow for both self-reporting and raising of concerns relating to others. The same processes should also be open and responsive to those who identify and report systemic failures which leave individual practitioners vulnerable to poor practice.

³⁶¹ James G. Rev'd (Chair). *Report of the Independent Inquiry into the Issues raised by Paterson*. 2020 HC 31.

Supplemental Q28. When answering question 31 in the initial letter of instruction:

a. Please consider what obligation or responsibility the clinician has from an ethical perspective to report such conduct to others.

We have set out a general duty to report the conduct to others in response to Q31. The obligation depends on the harm caused, potential for future harm, and the probability, correctability, persistence and inconsistency with standard practice. Public interest considerations may be operative. As previously stated (Q31), it is the responsibility of employers to put clear and safe reporting procedures in place which protect those who report perceived bad practice. As in any other setting there should also be consideration of due process and justice – allegations should be true and robust and the forum in which allegations are made should be appropriate to allow due process.

It is noteworthy that much progress has been made to protect ‘whistle-blowers’ from retaliation,³⁶² but historically workers who reported issues and suffered detriment (such as dismissal) as a result were comparatively poorly protected.

b. In the event that there is a duty to intervene, act or report to others, please set out in broad terms the steps that should be taken, who should be notified and whether there is an obligation or responsibility from an ethical perspective to inform the patient and/or the patient’s family of the steps taken.

Professional guidance and standards often describe a process – these differ according to the agency. Blood product safety is relevant to the Royal College of Pathologists, the pathology provider or other relevant body such as NHS Blood and Transplant, the Health and Safety Executive³⁶³ and the Medicines and Healthcare products Regulatory Agency. Clinical issues may be dealt with by clinicians, hospital departments, Trusts, standards committees of Royal Medical Colleges or the GMC.

The range of different organisations that can help in the event of a concern about practice (whether raised by a clinician or another) can be bewildering. The GMC has produced guides for patients³⁶⁴ and doctors. The latter makes clear that:

All doctors have a duty to raise concerns where they believe that patient safety or care is being compromised by the practice of colleagues or the systems, policies and procedures in the organisations in which they work. They must also encourage and support a culture in which staff can raise concerns openly and safely.³⁶⁵

The GMC guidance recognises obstacles to raising concerns and gives reasons why they should be overcome based on the ‘duty to put patients’ interests first and act to protect them, which overrides personal and professional loyalties’ as well as legal responsibilities and protections for whistle-blowers (para 9). In terms of procedure, the guidance recommends

³⁶² E.g. the Public Interest Disclosure Act 1998.

³⁶³ Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995. See HSE <https://www.hse.gov.uk/biosafety/blood-borne-viruses/incident-reporting.htm>.

³⁶⁴ GMC. *Who to Complain To*. <https://www.gmc-uk.org/concerns/information-for-patients/local-help-services>.

³⁶⁵ GMC. *Raising and Acting on Concerns about Patient Safety*. 2012, para 7. https://www.gmc-uk.org/-/media/documents/raising-and-acting-on-concerns-about-patient-safety---english-0617_pdf-48902813.pdf?la=en&hash=FB640A4DD572F0212BE069FE5EE46ECC4112D68A.

that near misses are reported to the local organisation (para 11) and safety concerns are relayed to a manager and relevant regulator (paras 11–16). The guidance recognises that a doctor might make the concern public if they have done all they can to deal with it through the organisation, patient safety is at risk and the disclosure will not breach patient confidentiality (para 17). It further states that: ‘You must also make sure that patients who suffer harm receive an explanation and, where appropriate, an apology’ (para 25).

Where wrongdoing is suspected and under investigation, or subsequently proven or dismissed, a clinician’s employing body needs to have processes in place to inform and support patients and families (see Q32 below on the duty of candour). Generally, a professional group should determine whether and how to inform patients and family, rather than individuals making this decision. This will take into account the degree of harm, existence of relationships with the person raising the concern, adequacy of responses, etc.

Question 32. The Inquiry’s Terms of Reference also require it to consider whether there has been a lack of openness or candour towards those who have been infected or affected. From an ethical perspective, what role does openness and candour have in clinical decision-making and practice? Are there different considerations depending on whether the errors identified are by individual clinicians, by organisations or as a result of defective systems?

Patients have a right to information relevant to their care and honest disclosure is an important virtue. Transparency is also an important ethical principle which maintains trust in hospitals, authorities, policies, etc. Honesty and candour both require not lying but also the positive provision of relevant information.

There are a number of ethical justifications for honesty and veracity; it enables valid consent; it is a professional virtue; it is a cornerstone of the doctor patient relationship; it is a marker of respect; and it maintains trust. Such is the importance of these values that the medical profession has moved towards being open about situations where a patient *could* have been harmed, even if the patient was oblivious at the time and would remain so, were they not informed.

Are there different considerations depending on whether the errors identified are by individual clinicians, by organisations or as a result of defective systems?

Ethical principles and considerations are similar in these cases, but the actions taken to respond to them may differ in terms of the individuals’ relationships, intimacy with the patient, professional responsibility, the capacity to effect change and other factors.

Today, organisations are monitored by the Care Quality Commission which establishes whether standards are met. NHS Improvement oversees NHS Trusts, Foundation Trusts and independent providers to enhance safety, and to investigate and learn from errors. A National Reporting and Learning System was set up in 2003 to record patient safety incident reports.

Looking back, the first NHS inspectorate – the NHS Hospital Advisory Service – was established in 1969 and the Office of the Health Service Ombudsman, which looks into complaints, followed in 1973. Shortcomings in this system were identified in the course of

the Bristol Inquiry, which reported in 2001.³⁶⁶ The Bristol Inquiry investigated the deaths of babies undergoing heart surgery at Bristol Royal Infirmary during the 1980s and 1990s. The inquiry found that there was no means of assessing the quality of care provided by clinicians or evaluating their performance. Failures regarding quality of care were in part a result of a period of rapid change in the NHS in the 1980s and 1990s – changes focussed on efficiency, competition and control in contrast to social justice, welfare and selflessness (4.4). The report acknowledged claims that the NHS was seriously underfunded during the 1980s and 90s (4.28–4.36) and that this was only properly acknowledged in 2000. Among the many recommendations there was focus on promoting openness and acknowledging and learning from mistakes.

Subsequently, Liam Donaldson's report, *An Organisation with a Memory* in 2000³⁶⁷ labelled the NHS reporting and information systems 'patchy' (para 3) and identified cultural and procedural barriers to learning from and preventing failures. The report called for a 'fundamental re-think'. Significant reform followed in relation to the clinician's duty of candour, organisational responsibilities and the systems of inspection.

Today, clinicians have a legal duty to tell patients of an error if the patient then suffers further harm as a result.³⁶⁸ Clinicians also have a wider ethical responsibility to act as advocates for their patients and the public. This means they should speak out about systemic factors which undermine patient care whether that be defective systems, inequity, lack of resource etc. GMC guidance on *Good Medical Practice* requires of clinicians:

You must be open and honest with patients if things go wrong. If a patient under your care has suffered harm or distress, you should: a put matters right (if that is possible); b offer an apology; c explain fully and promptly what has happened and the likely short-term and long-term effects.³⁶⁹

Looking back, from 1998 the GMC established an ethical duty of candour in its guidance: 'If a patient under your care has suffered serious harm ... you should explain fully to the patient what has happened, and the likely long and short-term effects.'³⁷⁰ Where the patient was under 16 and lacked competence, the parents should be told. Before that, the BMA advised that intra-professional disagreements should be 'resolved quickly and amicably within the profession itself' so as not to damage the reputation of the profession.³⁷¹

Many issues are not the fault of a single clinician, but rather flow from a series of factors, circumstances or events. Organisational responsibility has been significantly bolstered in recent years.³⁷² This flowed in part from the recommendations of the (then) Chief Medical

³⁶⁶ Kennedy I. *Learning from Bristol: the report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984 -1995 Command Paper: CM 5207*. 2001. <https://webarchive.nationalarchives.gov.uk/20090811143746/http://www.bristol-inquiry.org.uk/>.

³⁶⁷ Department of Health. *An Organisation with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS*. London, 2000. Also see Department of Health. *Supporting Doctors, Protecting Patients*. 1999.

³⁶⁸ *Gerber v Pines* (1934) 79 Sol Jo 13 (KB).

³⁶⁹ GMC. *Good Clinical Practice*. 2013, para 55; GMC. *Openness and Honesty When Things Go Wrong: The Professional Duty of Candour*. July 2015; NMC. *The Professional Duty of Candour*. 2019 at <https://www.nmc.org.uk/standards/guidance/the-professional-duty-of-candour/read-the-professional-duty-of-candour/>.

³⁷⁰ GMC. *Good Clinical Practice*. 1998, para 17.

³⁷¹ BMA. *The Handbook of Medical Ethics*. 1980, para 9.34; 1981, para 9.35.

³⁷² E.g. in England through the NHS Standard Contract 2013; Care Act 2014, s 81 and Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, Regulation 20. In Scotland through the Apologies (Scotland) Act 2016; Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016, The Duty of Candour Procedure (Scotland) Regulations 2018 and the Scottish Government. Organisational duty of candour: guidance. 2018, <https://www.gov.scot/publications/organisational-duty-candour-guidance/>. In Wales see Health and Social Care (Quality and Engagement) (Wales) Bill 2019-20.

Officer Sir Liam Donaldson in his reports, *An Organisation with a Memory* in 2000 and *Making Amends* in 2003.³⁷³ Institutions should tell patients about incidents that have caused significant harm or have potential to do so. The information should include what is known about the incident, an apology, what will happen next and what support is available.³⁷⁴ The organisational duty is not universal. It does not, for example, apply in the same way to GPs or in private healthcare, but individual clinicians in those settings are still bound by the ethical duty to be open and honest.

Supplemental Q29. When answering question 32 in the initial letter of instruction, please consider what obligation or responsibility a clinician has from an ethical perspective to notify patients of any errors, adverse events and/or wrongdoing that have occurred during the course of the patient's care.

Clinicians continue to have an ongoing obligation even after testing or treatment to promote the best interests of the patient and facilitate autonomous decision-making by the patient. When an adverse event occurs, or an error, or wrongdoing, it would almost invariably promote both of these goals to inform the patient. As we discussed in response to Q32 there are also organisational duties of candour which extend to apologies, redress and learning from mistakes to mitigate against potential repetition.

Question 33. The above questions focus on the decisions and actions of clinicians in relation to their individual patients. More broadly:

Q33a. If a clinician is involved in commissioning care, purchasing treatments, authoring guidelines or issuing advice to other clinicians, what do you see as the ethical principles that should guide such actions? What factors should a clinician consider, from an ethical perspective, and how should a clinician weigh those factors?

As discussed in response to Q19 above, the relevant principles for a clinician are:

- Best interests of the patient
- Distributive justice (including the interests of patients more generally)
- Enabling autonomous decision-making

Where a clinician is involved in commissioning care, purchasing treatments, authoring guidelines or issuing advice to other clinicians, their focus will shift from the best interests of individual patients to the goal of maximising the benefits for groups of patients, local populations, or in some cases society more generally. So, for example, in a commissioning role, the clinician may believe that shifting a generation of patients to a cheaper form of treatment might be justified even though individual patients would not necessarily see this as in their best interest. If the money saved could be redistributed to support other elements of care for the same patients the clinician could claim that their interests were being indirectly

³⁷³ Department of Health. *Making Amends: A consultation paper setting out proposals for reforming the approach to clinical negligence in the NHS*. 2003. https://webarchive.nationalarchives.gov.uk/20120809195448/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4060945.pdf.

³⁷⁴ Care Quality Commission. *The Duty of Candour*. 2016. <https://www.cqc.org.uk/sites/default/files/Duty-of-Candour-2016-CQC-joint-branded.pdf>.

supported. Even where this is not possible one could argue that rational funding decisions are essential in order to support the health care system, and are therefore in the interest of all patients.

A clinician also has an obligation to be informed and to use best evidence.

Action should be guided by rational systems which are evidence based, involve patients and stakeholders. These systems should be revisable, transparent and based on defensible values, enforceable and fair, unbiased (real and perceived conflicts of interest must be managed).

Weighing of relevant factors should not be done by an individual but by an appropriately constituted group, responsible to the population. Weighing should be conducted by a representative group, publicly and with appropriate consultation

Q33b. There is evidence (yet to be fully explored) that a number of clinicians also played a role in relation to a cohort of patients (for example, those attending a particular haemophilia centre), by selecting the particular product or products of a particular genus (such as commercial Factor VIII, or NHS product) for use in treating clotting disorders, and purchasing that product rather than other products; or by administering tests for the presence of virus in local supplies of blood for transfusion although such tests were not in general national use at the time, and that others were critical of this as “jumping the gun” or “breaking ranks”. What do you see as the ethical principles that should guide such behaviours?

The basic principle is that doctors should act in best interests of the patient. It is generally desirable to have a coherent national approach. However, clinicians have a duty to offer what they believe is in the best interest of their patients, consistent with distributive justice.

Innovation is important. At times, institutions and national bodies are, or are perceived to be, ill informed, ponderous or failing to keep up with evidence that is rapidly emergent. Individual clinicians may take a professional decision to change practice. Where they do so, they must do this explicitly, rationally, with justification, and explain this to the patient or those affected. Such action is most defensible where the steps taken can be defended as precautionary or protective of patients' welfare. They should also audit their practice and share the data with others to build an evidence base which could possibly challenge prevailing approaches.

Question 34. What principles should guide the introduction of new interventions into clinical practice?

The introduction of new interventions should be guided by the best interests of the patient and distributive justice. Generally, this means they should be safe, effective, cost effective, and provide arguable net benefit over existing alternatives. New interventions should also be tested through rigorous methods to establish evidence of efficacy. Clinicians using new interventions should be trained and informed. Where new interventions emerge as a result of incremental changes to common practice as opposed to formal research it is just as important to share the findings and invite review and critique.

Supplemental Q30. What ethical principles should inform the approach to the recording of information on a person's medical record? In particular:

a. In broad terms what kind of information should be recorded?

The patient notes should record information necessary to promote the patient's interests – this will pertain to what has been done, its rationale, follow up etc. to enable continuity of care and ensure the patient's ongoing needs can be determined.

The following should be recorded: history, symptoms, signs, investigations, diagnoses, interventions/management including options and recommendations, information provided to patient, patient's values and desires, likely disease trajectory and prognosis. There should also be a clear account of how much of this information has been shared with the patient. Entries should be dated, timed, contemporaneous, accurate, legible, and signed. Any consent obtained should always be documented, with information about the information provided and the decision made. Measures should also be in place to protect the patient's confidentiality.

The GMC requires that a clear accurate and legible record is maintained as part of good medical practice. In particular, it advises that records include:

- (a) relevant clinical findings
- (b) the decisions made and actions agreed, and who is making the decisions and agreeing the actions
- (c) the information given to patients
- (d) any drugs prescribed or other investigation or treatment
- (e) who is making the record and when' (para 21).³⁷⁵

As we discussed above (Q26), a patient's right of access to medical records was introduced in the Access to Medical Reports Act 1988 (for medical reports supplied by clinicians for employment or insurance purposes), and the Access to Health Records Act 1990 and then the Data Protection Act 1998. Before this time, the terminology and abbreviations used by clinicians in notes may have reflected the fact that only healthcare professionals were likely to view them. In some cases, personal, 'humorous' and even offensive comments were noted. This would not reflect well on the clinician because medical records should be clear, accurate and objective. Today, the Medical Defence Union says:

Avoid jokey comments: Offensive, personal or humorous comments could undermine your relationship with the patient if they decide to access their records and damage your professional credibility if the records are used in evidence.³⁷⁶

Alongside the issue of offence that could be caused to patients were they to see these sorts of comments, it is also important to accept that the way in which a patient is described or referred to might cause other clinicians to see or treat them in particular ways (consciously or subconsciously). This is very problematic particularly when there are cultural codes at work which would not be obvious to non-clinical readers. On the one hand a doctor might be warning a colleague to be careful in their dealings with an articulate and engaged patient described as 'this intelligent woman', or inviting them to be receptive to someone they describe

³⁷⁵ GMC. *Good Medical Practice*. 2013, paras 19-21.

³⁷⁶ MDU. *Effective Record Keeping*. 2017. <https://www.themdu.com/guidance-and-advice/guides/good-record-keeping>.

as ‘pleasant’. On the other hand, careless use of words such as ‘neurotic’ or ‘un-cooperative’ will potentially undermine the patient’s ability to forge a good relationship with anyone reading that description.

b. Are there any circumstances (and if so, what) in which it is ethical to record information about a person’s infective status, diagnosis, or exposure to testing, research or treatment, that has not been shared with the patient?

If the information is available, it should be recorded to promote care. In general, the patient should be informed of what is recorded, including the fact it is recorded in notes. Where this is not immediately possible, perhaps because the patient is too unwell, all effort should be made to inform them at the earliest possible opportunity and before any relative or significant other.

Over the last 30 years, it has become normal for patients to have access to all that was recorded in their notes. This was not the norm in the past.

The patient record is a plan of management and record of communication. In general, they should match.

c. Is it appropriate that visible signs/labels/stickers (e.g. stating “Biohazard”) are placed on an infected person’s medical record signposting their infective status? How should a clinician balance the need to maintain patient confidentiality with the need to ensure proper safety precautions are taken?

There are some circumstances in which hospitals use signs to signal health risks of a patient’s care – these are to protect patients and staff. At times these might be interpreted inappropriately and lead to stigmatisation and discrimination. These risks can be managed by disclosure to the patient and by education of professionals and others within institutions. Confidentiality should be maximised relative to the management of risk. Labelling or signage should be done consistently across infectious risks and in a manner that discloses as little information as possible about the patient. Infection precaution notices can be used effectively without disclosing specific diagnoses. The use of universal precautions also reduces necessity for warnings. Warnings should be of a general kind whenever possible.

d. Is it ever permissible (and if so, in what circumstances) for a medical professional to keep notes or records in respect of a patient which are not included in the patient’s health record?

Ethically and clinically, if a medical professional has notes or records that are relevant to the care and interests of the patient, they should be in the patient records. Withholding this information may limit the capacity of others to care for the patient.

Supplemental Q31. What ethical principles should inform the approach to the disclosure by clinicians of any commercial relationship with, or any remuneration, support or assistance received from, suppliers of products or treatments used by the clinician? In particular, is there an obligation to disclose this information, if so, to whom, when does this obligation arise, and what information in broad terms should be disclosed?

In all situations, where there is a real or perceived conflict of interest, financial or non-financial, this should be disclosed and managed as appropriate. Management will depend on the conflict and may vary from declaration to divestment to transfer of care.

While there is an ethical obligation to declare, the way in which declarations are made has changed over 30 years. Previously declarations were not made to patients but to institutional bodies, committees, journals, colleges, grant awarding bodies, etc. In recent years there has been professional debate about the necessity of public declaration of interests, however, there is not yet consensus on this.

Material and relevant interests should be disclosed as these will be relevant to the clinician's role, e.g. researcher, clinician, teacher, or policymaker.

Supplemental Q32. What ethical principles should inform or guide medical professionals involved in the collection of blood?

The ethical principles that guide blood collection (whether in the context of research or donation to a public blood service) are the same as those that inform any medical intervention: the best interests of the patient, justice, and autonomy.

The collection of blood should be undertaken by competent and trained medical professionals, in a safe and effective manner, and with the consent of the patient.

Any conflict of interests between donor and recipient should be identified, balanced and decisions should be evidence based and explicitly articulated.

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 Directive 92/27/EEC of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets

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National Health Service Act 1946

Offences Against the Person Act 1861

Organ Donation (Deemed Consent) Act 2019

Patient Rights (Scotland) Act 2011

Public Health (Control of Disease) Act 1984

Public Interest Disclosure Act 1998

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The Duty of Candour Procedure (Scotland) Regulations 2018

Vaccine Damage Payments Act 1979

Verifying Statements

Each contributing group member confirms that he or she understands his or her duty to provide independent evidence and has complied with that duty.

All contributing group members confirm that in respect of those parts of the report to which they have contributed:

- (i) They have made clear which facts and matters referred to in this report are within their knowledge and which are not.
- (ii) Those that are within their knowledge they confirm to be true.
- (iii) The opinions they have expressed represent their true and complete professional opinions on the matters to which they refer.

CO-CONVENORS

Professor Emma Cave

Emma Cave is Professor of Healthcare Law at Durham University. She publishes widely in the field of Medical Law and is an editorial board member of *Medical Law Review* and the *Journal of Medical Law and Ethics*. Her principal areas of research include compulsion, capacity and consent and she has published recently on public health, NHS redress and medical research. Professor Cave has worked on a number of multidisciplinary research projects. One developed professional training for research ethics committees, another analysed the role of empirical methods in bioethics, while another looked at adolescent consent to and refusal of medical treatment. Her latest project considers the implications of the Supreme Court judgment *Montgomery v Lanarkshire Health Board* [2015] on informed consent. She was awarded a Scottish Parliament Academic Fellowship in 2018 to produce a Scottish Parliament Information Centre Briefing on information disclosure. Professor Cave currently serves as a member of the Human Fertilisation and Embryology Authority.

Professor Bobbie Farsides

Bobbie Farsides is Professor of Clinical and Biomedical Ethics at Brighton and Sussex Medical School, prior to which, she was Senior Lecturer in Medical Ethics at the Centre of Medical Law and Ethics at King's College London. Professor Farsides has served on a wide range of national bodies as an ethics expert, and has twice acted as a Specialist Adviser to House of Lords Committees. She currently sits on the Genomics England Ethics Advisory Board and is a member of the British Medical Association Ethics Committee. She chaired the Nuffield Council of Bioethics working group on Children and Clinical Research and was a member of the NICE guidance writing group on Children's End of Life Care. Her research has focussed on staff and patient experience of operating in ethically challenging areas of biomedical science and healthcare, including stem cell science, antenatal screening and testing, organ donation and most recently genomics. Her work has been supported by the Wellcome Trust, ESRC, NIHR, Multiple Sclerosis Society and European Commission.

TEAM MEMBERS

Dr Melinee Kazarian

Dr Kazarian is a lecturer in law within Southampton Law School at the University of Southampton. She researches healthcare law and criminal law issues, as well as comparative and French law. Her PhD thesis was on 'The role of the criminal law and the criminal process in healthcare malpractice in France and England', which she has been working on expanding to form the basis of an upcoming book. She has been involved in different research projects, including an AHRC-funded project entitled 'The Impact of the Criminal Process on Health Care Ethics and Practice', which aimed to offer a comprehensive analysis of the role of the criminal justice system in regulating healthcare practice and ethics in the UK. Dr Kazarian's research interests are in medico-legal, criminal and comparative law issues, in particular the

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Professor Ian Kerridge

Ian Kerridge is Professor of Bioethics and Medicine at the University of Sydney. His research focuses on the philosophical, moral and socio-cultural concepts, frameworks and issues that underpin health, health policy and biomedicine including in public health, research and clinical care. His research explores topics which include public health ethics, the experience of illness and survival, organ transplantation, cord blood and tissue donation, and the pharmaceutical industry. He is a haematologist and bone marrow transplant physician at Royal North Shore Hospital in Sydney and a Founding Director of PRAXIS Australia, a not-for-profit organisation promoting education and ethics in research. Professor Kerridge is currently Chair of the Royal Australasian College of Physicians Ethics Committee, Chair of the South Eastern Sydney LHD Clinical Ethics Committee and Board member of the Bone Marrow Transplant Society of Australia and New Zealand (BMTSANZ) and the NSW Stem Cell Network. He was previously Chair of the Australasian Bone Marrow Donor Registry (ABMDR) Ethics Committee and Director of Sydney Health Ethics at the University of Sydney.

Professor Julian Savulescu

Professor Savulescu has held the Uehiro Chair in Practical Ethics at the University of Oxford since 2002. He has degrees in medicine, neuroscience and bioethics. He directs the Oxford Uehiro Centre for Practical Ethics within the Faculty of Philosophy, and leads a Wellcome Trust Senior Investigator award on Responsibility and Health Care. He also directs the Oxford Martin Programme for Collective Responsibility for Infectious Disease at the University of Oxford, and co-directs the interdisciplinary Wellcome Centre for Ethics and Humanities in collaboration with Public Health, Psychiatry and History. In 2018, he concluded an extended tenure as Editor of the *Journal of Medical Ethics*, the highest impact journal in the field, and is the founding editor of *Journal of Practical Ethics*, an open access journal in Practical Ethics.

Letters of instruction

This report answers the following questions, extracted from the two the letters of instruction to the medical ethics expert group.

Initial Letter of Instruction

General

19. What are the ethical principles and approaches that apply, broadly, to clinical decision-making and practice? Please include a consideration of the ethical principles and approaches that apply when patients are wronged or harmed.
20. What are the principles of informed consent? In particular:
 - a. What information about risks and benefits ought to be disclosed?
 - b. What are the principles which ought to govern gathering more information prior to disclosure to the patient?
21. Should consent always be expressly obtained (assuming that the patient has capacity)?
22. What do you understand by the concept of implied consent?
23. Is it ever acceptable, from an ethical perspective, to treat a person with capacity without their express and informed consent?

Treatment

24. What ethical principles should inform decision-making about the treatments to offer a patient? In particular, and from a medical ethics perspective:
 - a. What factors should a clinician consider when determining whether a treatment is clinically indicated and so can be offered to a patient?
 - b. How should a clinician weigh those factors?
 - c. What obligation or responsibility does the clinician have to identify and offer the best treatment for a patient?
 - d. What obligation or responsibility does the clinician have to identify and offer alternative treatments for a patient?
 - e. In broad terms what kind of information should a clinician provide to a patient about possible treatments?
 - f. What obligation or responsibility does the clinician have to inform the patient of the risks of a particular treatment that is being recommended or considered?
 - g. Where there is a risk (even a small one) of exposure to a serious infection, is it always incumbent upon the clinician to inform the patient of that risk so that the patient can take an informed decision for themselves?

- h. What obligation or responsibility does the clinician have to inform the patient of the possible side-effects, or possible health complications, of a particular treatment that is being recommended or considered?
- i. Does it make a difference if the patient is a child? If so, how and why?

Testing for infection

25. What ethical principles should inform the approach to testing a patient to determine whether they have been infected with a disease? In particular and from a medical ethics perspective:

- a. When should a clinician or health body inform a person they may have been exposed to an infectious risk?
- b. What factors should a clinician consider when deciding whether or not to offer a patient a test?
- c. How should a clinician weigh those factors?
- d. In broad terms what information should a clinician provide to a patient prior to the patient deciding whether or not to be tested?
- e. Are there any circumstances in which it would be ethical for a clinician to test a person with capacity without their knowledge or consent? If so, what are they?
- f. What obligation or responsibility does the clinician have to inform the patient of the result of the test?
- g. Are there any circumstances in which it would be ethical for a clinician to withhold a test result from a person with capacity? If so, what are they?
- h. Is it ethical for a clinician or hospital to store samples (e.g. of a patient's blood), for later testing and/or for research, without their knowledge or consent?
- i. Does it make a difference if the patient is a child? If so, how and why?
- j. To what extent if at all is it legitimate to test the likelihood that a particular therapy may give rise to infection by administering it to a patient?

Informing people of infections

26. What ethical principles should inform the approach to telling a patient that they have been infected with a serious disease? In particular and from a medical ethics perspective:

- a. What obligation or responsibility does the clinician have to inform the patient of their diagnosis?
- b. Are there any circumstances in which it would be ethical for a clinician to withhold a diagnosis from a person with capacity? If so, what are they?
- c. Are there any circumstances in which a clinician should inform a patient of their diagnosis (for example, on public health grounds) contrary to the patient's expressed wish? If so, what are they?
- d. What factors should a clinician consider when deciding when, how and in what setting to inform a patient that they have contracted a serious disease?

- e. What are your views on clinicians providing information to patients about the possibility (or fact) of infection with a serious disease in a group setting, with other patients present?
 - f. What obligation or responsibility does the clinician have to inform the patient that they may have contracted, or did, contract the disease as a result of their medical treatment?
 - g. In broad terms, what categories of information should a clinician provide to a patient when informing them that they have been infected with a serious disease?
 - h. What kind of counselling or support should be offered to a patient by a clinician who is informing them that they have contracted a serious disease?
 - i. Does it make a difference if the patient is a child? If so, how and why?
 - j. Does it make any difference to the decision as to whether, when, and if so, how, to inform the patient, if the disease is one for which there is no available and/or effective treatment? If so, how and why?
27. What ethical principles should inform the approach to telling a patient that they may have been, or have as a matter of fact been, exposed to the risk of a serious disease for which there is no diagnostic test?
- 28.
- a. What ethical principles should inform decision-making about whether, and if so, in what circumstances, a clinician could or should disclose confidential information about a patient's health to a third party (e.g. a partner who might themselves be at risk of being infected or a public health authority)?
 - b. What obligations does a clinician have in the public interest to protect others when a patient has been informed they may have contracted an infectious disease?
 - c. How should a clinician weigh those factors when making a decision?

Research

29. What is the difference between audit of practice and research? What different ethical principles apply to each?
30. What ethical principles should inform decisions about participation in research? In particular and from a medical ethics perspective:
- a. What factors should a clinician take into account when considering whether a patient might take part in a research project or otherwise be the subject of research or study?
 - b. What obligation or responsibility does the clinician have to inform the patient that they are participating in a research project or are the subject of research or study?
 - c. In broad terms, what kinds of information should a clinician provide to a patient to enable the patient to give informed consent to participating in a research project or being the subject of research or study?
 - d. What obligation or responsibility does the clinician have to tell the patient that information about them is being provided to others for research or monitoring or public health purposes?
 - e. Are there any circumstances in which it would be ethical for a clinician to enrol a patient in a research project, or make them an object of research or study, without the patient's knowledge or informed consent?

- f. Are there any circumstances in which it would be ethical for a clinician to provide information about a patient (on a named, de-identified or on an anonymous basis) to others for research or monitoring or public health purposes, without the patient's knowledge or informed consent?
- g. Does it make a difference if the patient is a child? If so, how and why?

Other

31. If a clinician becomes aware of (for example) conduct such as that summarised in paragraph 10 above [in the Letter of Instruction], what obligation or responsibility does the clinician have, from an ethical perspective, to intervene or take action?

32. The Inquiry's Terms of Reference also require it to consider whether there has been a lack of openness or candour towards those who have been infected or affected. From an ethical perspective, what role does openness and candour have in clinical decision-making and practice? Are there different considerations depending on whether the errors identified are by individual clinicians, by organisations or as a result of defective systems?

33. The above questions focus on the decisions and actions of clinicians in relation to their individual patients. More broadly:

a. If a clinician is involved in commissioning care, purchasing treatments, authoring guidelines or issuing advice to other clinicians, what do you see as the ethical principles that should guide such actions? What factors should a clinician consider, from an ethical perspective, and how should a clinician weigh those factors?

b. There is evidence (yet to be fully explored) that a number of clinicians also played a role in relation to a cohort of patients (for example, those attending a particular haemophilia centre), by selecting the particular product or products of a particular genus (such as commercial Factor VIII, or NHS product) for use in treating clotting disorders, and purchasing that product rather than other products; or by administering tests for the presence of virus in local supplies of blood for transfusion although such tests were not in general national use at the time, and that others were critical of this as "jumping the gun" or "breaking ranks". What do you see as the ethical principles that should guide such behaviours?

34. What principles should guide the introduction of new interventions into clinical practice?

Supplemental Letter of Instruction

General

6. When answering questions in this letter of instruction and the initial letter of instruction please refer, to the extent that you consider appropriate, to any sources of international ethical principles set out in international codes and declarations that you consider relevant.

7. When answering question 19 of the initial letter of instruction (which asks you to identify the ethical principles and approaches that apply broadly to clinical decision-making and practice), please address what the ambit of medical ethics is and how medical ethics interact with the legal obligations of a clinician.

8. When answering question 20 of the initial letter of instruction (which asks about the principles of informed consent) please:

a. Consider in particular what information ought to be disclosed about the risks and benefits of existing, proposed and/or alternative treatments.

- b. Set out the categories of information that a person would need to know and understand in order to give consent to treatment.
 - c. Consider whether a clinician is required to determine if a person has understood the information and is in a position to give informed consent.
9. When answering question 21 of the initial letter of instruction (which asks whether consent should always be expressly obtained) please consider how the patient's consent should be obtained and recorded.
10. When answering question 22 of the initial letter of instruction (which asks about the concept of implied consent) please also consider when, if ever, it is permissible for a clinician to rely on the concept of implied consent.
11. When answering question 23 of the initial letter of instruction (which asks whether it is acceptable to treat a person with capacity without their express and informed consent), please also consider whether it is ever acceptable to treat a child without their or their parent's express and informed consent.
12. When a patient is given treatment (such as a blood transfusion or the administration of blood products) in emergency circumstances, what ethical principles and obligations should guide the clinician's actions at the time of, and following, such treatment? Would this be different, and if so, how, if a patient is unconscious or under general anaesthetic?

Treatment

13. When answering questions 24(a) and (b) of the initial letter of instruction (which ask about the factors that a clinician should consider when considering whether to offer treatment and how those factors should be weighed), please consider whether there is an ethical obligation or responsibility on the clinician to explain to the patient the factors that he/she has weighed and/or an obligation or responsibility to explain to the patient how he/she has weighed those factors.
14. When answering question 24(f) of the initial letter of instruction (which asks about the provision of information about the risks of a particular treatment):
- a. Please consider not only well-known and widely-accepted risks, but also risks that are beginning to be suspected or known as a result of developing medical and scientific understanding.
 - b. Please consider whether, in circumstances where there is no reliable data to indicate that a product or treatment is safe, there is an ethical obligation to inform the patient of this.
15. When answering question 24(h) of the initial letter of instruction (which asks about the clinician's obligation to inform a patient of possible side-effects or complications of treatment), please also consider what obligation or responsibility a clinician has to offer other treatment or medication to mitigate such side-effects or complications.
16. Is there an ethical obligation or responsibility on clinicians to share information they have about the risks and benefits of products or treatments, with professional colleagues?
17. Is there an ethical obligation or responsibility on clinicians to keep themselves informed and up-to-date with current knowledge relating to the risks and benefits of products or treatments they are prescribing?

Testing for infection

18. When answering question 25 of the initial letter of instruction (which asks about the ethical principles informing the approach to testing a patient for infection), please also consider the following:

- a. In what circumstances should the clinician give advice about the testing of spouses, partners and others?
- b. Are there any circumstances in which it is ethical for a clinician to take blood from a patient (with capacity) without the patient (or, in the case of a child, the parent) being informed about what it is being taken for?
- c. Are there any circumstances in which it is ethical for a patient's test results to be shared with any third party without the consent of the patient (or, in the case of a child, the parent)?
- d. Is there an ethical obligation on clinicians to offer pre-test counselling to patients and if so in what broad circumstances?

19. When answering question 25(j) of the initial letter of instruction, please also consider whether (and if so why) it makes a difference if the patient is an adult or a child, and whether (and if so why) the patient's existing state of health makes a difference.

Informing people of infections

20. When answering questions 26 and 27 of the initial letter of instruction (which ask about ethical principles informing the approach to telling patients that they have been infected with a serious disease), please read 'serious disease' as incorporating potentially serious diseases or infections.

21. Does it make a difference, and if so what, to your answers to question 26 if the disease or infection is understood by the clinician to be less serious or relatively minor?

22. When answering question 26(a) of the initial letter of instruction (which asks what obligation or responsibility the clinician has to inform the patient of their diagnosis) please also address with what speed or urgency the clinician should inform the patient of the diagnosis.

23. When answering question 27 of the initial letter of instruction please consider whether it makes a difference if the disease is an infectious one.

24. If a patient is told that they have been or may have been exposed to the risk of a serious disease for which there is no diagnostic test, what categories of information, in broad terms, should be provided to them?

25. Is there an ethical obligation or responsibility on a clinician to advise a person who has contracted an infectious disease, of the risks of infecting others such as family and friends?

26. What ethical principles should inform the approach a clinician should take to answering reasonable questions from a patient about how they became infected and about their previous treatment? Please set out in broad terms the kind of information a clinician should provide to a patient in such circumstances.

Research

27. When answering question 30(d) in the initial letter of instruction (which asks whether there is an obligation to tell a patient that information is being provided to others for research or other purposes), please also consider whether there is a duty to seek the person's consent for information about them to be shared for research, monitoring or public health purposes.

Other

28. When answering question 31 in the initial letter of instruction (which asks about the obligation or responsibility to intervene or take action when a clinician becomes aware of conduct such as that described in paragraph 10 of the initial letter):

a. Please consider what obligation or responsibility the clinician has from an ethical perspective to report such conduct to others.

b. In the event that there is a duty to intervene, act or report to others, please set out in broad terms the steps that should be taken, who should be notified and whether there is an obligation or responsibility from an ethical perspective to inform the patient and/or the patient's family of the steps taken.

29. When answering question 32 in the initial letter of instruction (which asks about the role of openness and candour in clinical decision-making and practice), please consider what obligation or responsibility a clinician has from an ethical perspective to notify patients of any errors, adverse events and/or wrongdoing that have occurred during the course of the patient's care.

30. What ethical principles should inform the approach to the recording of information on a person's medical record? In particular:

a. In broad terms what kind of information should be recorded?

b. Are there any circumstances (and if so, what) in which it is ethical to record information about a person's infective status, diagnosis, or exposure to testing, research or treatment, that has not been shared with the patient?

c. Is it appropriate that visible signs/labels/stickers (e.g. stating "Biohazard") are placed on an infected person's medical record signposting their infective status? How should a clinician balance the need to maintain patient confidentiality with the need to ensure proper safety precautions are taken?

d. Is it ever permissible (and if so in what circumstances) for a medical professional to keep notes or records in respect of a patient which are not included in the patient's health record?

31. What ethical principles should inform the approach to the disclosure by clinicians of any commercial relationship with, or any remuneration, support or assistance received from, suppliers of products or treatments used by the clinician? In particular, is there an obligation to disclose this information, if so, to whom, when does this obligation arise, and what information in broad terms should be disclosed?

32. What ethical principles should inform or guide medical professionals involved in the collection of blood?

