Chapter 1

Introduction to clinical consent: laying out the territory

Introducing consent

The process of seeking the consent of a patient to a medical procedure is, arguably, one of the most important skills a doctor, or indeed any clinician, should learn. In fact, the very idea that doctors may institute diagnostic or treatment processes of any sort without a patient's consent is utterly counter-intuitive to the modern practice of medicine.[1]

It was not always thus, and even now it can be reliably assumed that consent is still not sought and gained appropriately in every clinical encounter. To say that it should be sought and gained in this manner elevates the value of consent to a high level. It can be instructive to ask oneself why such a value might be held to be the case. The answer to this question lies in the philosophical underpinning of clinical consent, which sits within a notion of personal autonomy, and respect for autonomous decision-making. When we say that autonomous decision-making should be respected, we are endowing individuals with the ability to make their own decisions about their individual futures.[2] It is a philosophical axiom that this should be so, with a long history attached.[3]

Within that history, the best reference point is probably the Enlightenment: that flowering of science, arts and philosophy in the eighteenth century. Admittedly the Enlightenment was a primarily European phenomenon, but, notwithstanding that, it could be said that the dominant theme emerging from the Enlightenment was actually that of personal autonomy and the right of individuals to make decisions about their own futures.[4]

As such, it may have built on even older traditions from the Ancient World, and was certainly related to emerging political changes in the New World, but the notion that individuals (and indeed collections of individuals) could behave in this way and have rights so to do was indeed new. Previously, it should be noted, individuals in Europe lacked access to such rights, being confined within religious, monarchical or other structures. So medical consent as it is interpreted today stands not in clinical isolation but on a history of political change.

To this, we must add a more recent tendency in Western medical practice to be specific, personalized and clear about consent. Despite the Enlightenment ideals of centuries ago, it would be true to say that the practical application of

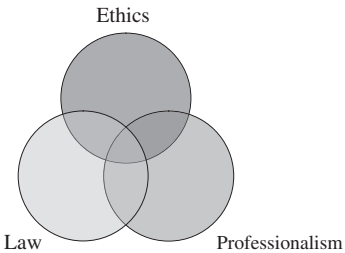

Fig. 1. A representation of doctors' duties.

autonomous reasoning by patients lacked a certain substance, at least until the later part of the twentieth century. Why might this be so?

To answer the question, it is necessary to consider medical decision-making more thoroughly. Consider the diagram in Fig. 1 as a representation of doctors' duties: they can be conceptualized in three ways as overlapping areas of interest.

Doctors will always need to practice within a framework of law, given by the country, or jurisdiction, within which they work. In the UK, this framework is determined by statute law, common law and a host of quasi-legal government orders. In a sense, the legal environment is a compulsory version of the ethical mores that pervade the same country. Ethics, of course, is more complex than that: any given country will generally contain a variety of peoples following differing ethical codes. These ethical codes spring from many sources: religious, secular and personal, all and each of which systematize the answers to the rather simple questions: 'What is the right thing to do?' or 'What is the right sort of person to be?' The impact of this kind of diversity on medical practice, including that pertaining to consent, is fairly clear: clinicians need to develop an understanding of the values important to all their patients, reaching accommodations with their own values, within the prevailing legal environment in order to practice ethically sound medicine. Whatever those values are, shared or personal, they drive individuals' decisions about their lives and are thus intimately linked to autonomous choice. Respect for autonomy is one of the four key medical ethical principles described and articulated by Thomas Beauchamp and James Childress, two American philosophers who have had enormous influence on clinicians' understanding of ethics.[5] There will be few health professionals currently working who have not heard of beneficence, non-maleficence, justice and respect for autonomy. Whilst the strength of this 'principlist' analysis is undoubted, although often contested, other moral perspectives will be considered in succeeding chapters.

The third element of Fig. 1 is professionalism. Doctors need also to remember the professional duties associated with their practice, and in the case of the

UK, these are determined by bodies including the General Medical Council (GMC). This regulatory authority interprets the law and sets standards to which doctors must adhere in order to practise in the UK. Other healthcare professionals have their own governance bodies setting similar standards of practice. For nurses in the UK, it is the Nursing and Midwifery Council who fulfil this function. Professional bodies do not necessarily share the same constitutional arrangements, intra-professional make-up or procedures, but the principles of professional guidance are common.

So, in broad terms, clinicians considering the area of consent will need to remember the law pertaining to consent, the professional rules surrounding consent, and the ethical basis of consent and autonomous reasoning. These will be amplified in succeeding chapters, and we will focus on the general issues surrounding consent with particular reference to its relevance in day-to-day clinical practice. For this reason, the text is liberally sprinkled with case examples and their analysis. Professional and ethical approaches tend to dominate, and where legal frameworks are discussed, they will have a UK bias, although comparative reference is occasionally made to other jurisdictions. Clinical problems are still manifestations of patient suffering, wherever they may occur around the world, and this is the starting point for this book. Simple guidance as to 'what to do' or 'what to say' in seeking and gaining a person's consent to a medical intervention is dealt with in many procedural guides,[6] signposted throughout the text, but we also hope to open out the theoretical substructure of consent and its clinical application for the reader to reflect upon.

Challenges for the clinician

Ethical dilemmas are often cast in terms of possible actions and outcomes. Consider the following:

> Andy Milton presents to the accident and emergency department of a rural hospital, with superficial injuries, sustained in a fight in the street outside a public house. He is intoxicated, and therefore a full account of the episode is difficult to determine. While treatment for his injuries is being given by Dr Berry, the emergency medicine registrar, a police unit arrives in the department and the officers make enquiries as to whether anyone has arrived after a fight at the local pub. Andy is made aware of the presence of the police by the clinical staff, but he requests – and indeed requires – them not to tell the police of his presence or medical state. Dr Berry considers what she should do.

This clinical encounter is easy to conceptualize as one of consent: Andy Milton is not consenting to the release of any information about his state to law enforcement officers, so the dilemma for the duty registrar appears

clear: should she cooperate with Andy's instruction? There are legal issues that are relevant, for example the various statutes on police enquiries[7] and the common law on medical confidentiality.[8] The registrar will also be aware of GMC guidance on sharing clinical information with agencies such as the police.[9] Dr Berry will also consider what would be the morally right thing to do, and there are various perspectives available to her. It could be argued that she should decide which approach is liable to generate the best consequences, and this may include how she might foster the prevention of further street disturbances, or treatment of any possible alcohol misuse by the patient. She may regard Andy's view as absolutely determinative, as a rule she cannot ignore and to which he has an inviolable right. All of these ethical perspectives focus on the action: whether Dr Berry should be guided by Andy's refusal or not.

Perhaps less familiar, but no less rigorous, is consideration of the scenario from the point of view of Dr Berry herself. What moral qualities might it be relevant for her to show in dealing with this case? Analysing cases from this point of view illustrates the *virtues* necessary for the practice of medicine. We could say that she should display courage (if she has to refuse the police request or even Andy's), integrity (in holding to the moral decisions she might make) and wisdom (in fully considering her position and discussing it with colleagues). This sort of ethical analysis is both ancient and modern – it forms the basis of the Hippocratic Oath – and consideration of what it means to be a virtuous practitioner is a re-emerging feature of medical ethics discourse today.[10] These three separate ways of considering the ethical aspects of the situation reflect the three most important strands of moral theory described. To give them their more usual descriptors: theories concerned with the moral value of outcomes and consequences are *consequentialist* or *utilitarian*, those concerned with duties and rights are *deontological*, and those concerned with the moral agency of the people involved are *virtue* theories.

Clinical consent: its composition

Most authorities recognize four components to valid medical consent, as follows:

- Adequate information.
- A capacitous (competent) patient.
- Freedom from coercive influence.
- Dynamism: the continuing nature of consent and the ability to withdraw permission.

These components form the chapter headings for this book, dealing with each in sequence. Thus, any consent sought and gained by a clinician of a patient should have all of these elements fully addressed to be professionally, lawfully and ethically sound. It is a high standard to reach, and thus could be held to merit the attention it is given in this text and elsewhere. A term often heard in

daily clinical practice, and seen in the literature, is the shorthand 'informed consent'. This form of words has a particular legal meaning in the US, which will be described in Chapter 3. In the UK, the use of 'informed consent' does not imply primacy of the information component over the remaining three listed above. Valid consent requires consideration of all four components.

It should also be noted that, whereas there is an enormous amount of literature that describes and analyses the components of consent to do with information provision and capacity, there is relatively little published material about the exercise of free and dynamic consent. Among other aims, this book attempts to correct that imbalance and to give due consideration to these two underdescribed areas.

Forms of consent

For now, we shall first consider forms of consent, in which all of these components are considered, in various degrees, to be involved. A US case from 1914 offered what is still a fine statement of law summarizing medical consent. Justice Cardozo said: '*Every human being of adult years and sound mind has a right to determine what shall be done with his own body* …'[11] He was making an ethical statement about capacity and status, and founding it on a rights analysis (more common in the USA than the UK in 1914). Judge Cardozo then put a sting in the legal tail by going on to say '… *and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages*.'

Even allowing for the intervening hundred years or so, this short summary of law is still relevant. Doctors who operate or initiate any medical intervention without consent can face legal consequences and may have to pay damages or endure other consequences such as disciplinary action. So, to update to the early twenty-first century, consider the following judicial quotation:

> Recognizing an individual right of autonomy makes self-creation possible. It allows each of us to be responsible for shaping our lives according to our own coherent or incoherent – but, in any case, distinctive – personality. It allows us to lead our lives rather than be led along them …

This is actually a secondary quotation by Lord Steyn, a judge in a UK medical negligence case.[12] The original quote is from one of the finest pieces of medical ethics writing ever seen.[13] His Lordship too conjoins ethics and law in his judgment, and uses this form of words to amplify his opinion that '*due respect is given to the autonomy and dignity of each patient*', and in doing so, is agreeing with Judge Cardozo, from earlier times, the primacy of the patient's consent to medical intervention. Both these examples are deliberately chosen both to illustrate the close relationship between law and ethics and also the enduring nature of the principles that lie behind the law. Consent and autonomy

mattered as much at the start of the twentieth century as at the start of the twenty-first.

However not all medical interventions are surgical operations and the question should be asked as to how patients and doctors should define and implement the seeking and obtaining of consent. Various forms are in use and will be summarized below.

Express consent is sought from patients when it is thought to be necessary. This rather vague form of words captures its vague application. All surgical procedures, minor or major, need an express form of consent, where at the conclusion of discussion between doctor and patient, written forms are signed to evidence the acceptance of the procedure. In recent years, these forms have become more detailed and complex.[14] Some authors have even suggested pre-printing consent forms with all complications listed by procedure.[15] The value of standardized forms is in the prompts to professionals to discuss the relevant material with patients. However, it should be remembered that these forms are merely types of evidence that a discussion has taken place between doctor and patient, not that full understanding has been achieved, or legal immunity acquired, or indeed anything else.

Implied consent is just that: the assumption by a healthcare professional that the patient permits the intervention without the full legal panoply of a consent form, or even necessarily a discussion about the process. This is probably much more common in the day-to-day practice of clinical medicine, where the formal seeking of consent is not done, abbreviated or recorded. Consider the scenario below.

> Bhupinder Singh attends his primary care clinic to discuss some foot stiffness he has been having over the previous few months. Dr Whinny examines the relevant joints and then writes out some forms for blood tests, asking him to go to another part of the clinic to have the tests done. He does suggest some differential diagnoses to Bhupinder and asks him to return. He also offers to check Bhupinder's blood pressure, as it has not been taken for a couple of years. He happily rolls up his sleeve to accommodate the sphygmomanometer cuff.

Implied consent was probably operating in at least three ways in this consultation. When the patient unlaced his shoe, took off his sock and presented the offending foot to the doctor, we could say that he was, in effect, consenting to the visual, and probably tactile, examination. Indeed, his presence in the clinic that day with those symptoms could be taken to be indicative of some measure of consensual engagement.

Considerably more invasive than a foot examination is a blood test and the phlebotomist may have checked that Bhupinder was happy to proceed as he sat in the relevant chair. The story does not record whether he knew what blood

tests he was destined for, or the ramifications thereof. Finally, Bhupinder seemed cheerful about having a blood pressure check, where the doctor proceeded again on the presentation of the arm. There are issues in each of these encounters to do with how much information he might have had, or whether he was coerced into these actions, and these will be dealt with in later chapters. The point to note here is that consent was not written, expressly given or acknowledged as such – given the limitations of the scenario. It may be perfectly legal, though arguably less moral, and certainly not adequately professional.[16]

There are various other categories of medical consent described in texts and guides: tacit consent, verbal and written consent, explicit and implicit consent, and others. It is our suggestion that none contains as clear a distinction as that between express and implied, and should preferably be set aside.

The context of medical consent

It is a truism that conversations between clinicians and patients about consent, choice and decision-making do not take place 'in a box' insulated from the ward, clinic or the wider milieu.[17] A traditional view would be that a relationship of trust exists between doctor and patient, where the former has only the latter's best interests at heart; and therefore the seeking and gaining of consent to medical intervention is merely a formality. This approach clearly does not capture the subtlety of the interaction. Other factors that mediate the nature of the discussion include the clinical judgement of the clinician,[18] the skills and the seniority of the clinician and some practical considerations such as time available for discussion.[19]

Of particular interest in the developed world currently is the issue of availability. A perfect notion of autonomous choice that a patient might exercise could include all possible types of available intervention. Consider the case below.

> Gregorius Pawlicki, aged 50, is discussing options for control of his morbid obesity with his physician, Dr Wellington. He has a body mass index of 45 and several co-morbidities. Both doctor and patient agree that weight reduction is going to be an important part of his care. They review options, which include dietary intervention, exercise regimes, appetite-modifying drugs and bariatric surgery. On balance, and after much thought, Gregorius prefers a surgical approach. His clinician agrees but then has to pass on to the patient the news that recent budget cuts will prevent him accessing this intervention. Gregorius is not pleased and threatens to involve local politicians.

On the face of it, a well-conducted evaluation of options has led to a dissatisfied patient. Although full formalized consent to bariatric surgery has not yet occurred, Gregorius has made an autonomous choice, supported by a full

discussion with his advisor. The rehearsal of management options is now held to be a vital part of patient decision-making, and one way in which the trust relationship is realized.[20] To have concealed the surgical option may have led to a less difficult conversation but is hardly consistent with the manifestation of trust. In any event, information about alternatives in treatment is more generally available than it was, for various practical and social reasons. This can be conceived as social progression, the sharing of professional power or even as part of a consumerist change.[21]

Thus, resource constraints can also affect the potential for decision-making, choice and, ultimately, clinical consent. The larger issue that needs confronting in this sort of case is beyond clinical consent, in its barest form, and touches on the duty of the doctor to reveal all the possible interventions that might be available: essentially a duty of truth-telling or of candour. As such, this area reflects the scope of information transfer and will be dealt with in Chapter 4.

Conclusion

We have seen thus far the ways in which consent can be described as a formalization of respect for the ethical principle of patient autonomy. Successive chapters will explore the components of that principle, as described in the first box in this chapter. In essence, the aim of these theoretical approaches is to maximize the choices available to persons under clinical care, maximizing respect for autonomy in the process. Although such choice can be limited by factors outside clinical control[22] (e.g. economic, organizational and social factors), the duty nonetheless remains with the clinician not to indulge in a paternalist constraint of choice

This theme, as hinted at the top of this chapter, that medical practice has moved to a less paternalist mode in recent years is consistent with other approaches to modern ethical practice described in the relevant literature. Under this heading would be found the issues of patient-centredness,[23] narrative-based care, shared decision-making (between doctor and patient)[24] and the notion of therapeutic alliance.

A greater attention to the theory and practice of good clinical consent therefore does not stand on its own but reflects more general trends in the humanization of medical practice in recent years.

As stated, this book now opens up into detailed consideration of the four components of valid clinical consent: its implicit aim is to provoke reflection, as well as to inform. One way of doing that is simply to read and think. We suggest that the reflective process may be better stimulated by putting the book aside after each clinical case scenario and conjuring up thoughts and ideas, before moving on to the next section. We suspect that the overall aim of rendering assistance to the healthcare practitioner may be better made in this way.

Resources for further reading and amplification of points made are to be found in the notes. They are for enthusiasts only, and should not necessarily be seen as 'compulsory'.

Endnotes

1. See Manson, N. C. (2010). Consent and informed consent. In R. Ashcroft, A. Dawson, H. Draper and J. McMillan, eds., *Principles of Health Care Ethics*, 2nd edn, pp. 297–304. Chichester: Wiley; O'Neill, O. (2003). Some limits on informed consent. *J Med Ethics* **29**, 4–7; Meisel A. and Kuczewski, M. (1996). Legal and ethical myths about informed consent. *Arch Intern Med* **156**, 2521–6.
2. Delany, C. (2008). Making a difference: incorporating theories of autonomy into models of informed consent. *J Med Ethics* **34**, e3.
3. See O'Neill, O. (2002). Autonomy, individuality and consent. In *Autonomy and Trust in Bioethics*, pp. 28–48. Cambridge: Cambridge University Press.
4. Isaiah Berlin's famous essay, *Two Concepts of Liberty*, in *The Proper Study of Mankind: an Anthology of Essays* (1997), H. Hardy and R. Hausher, eds., London: Chatto and Windus, is a key analysis of the political and social aspects of Enlightenment thinking.
5. Beauchamp, T. and Childress, J. (2001). *Principles of Biomedical Ethics*, 5th edn. Oxford: Oxford University Press.
6. Not least of which is the *Reference Guide to Consent for Medical Examination or Treatment*, 2nd edn (2009). London: Department of Health. Available at http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_103653.pdf.
7. In England and Wales, police enquiries are governed for the most part by the Police and Criminal Evidence Act 1984, as amended.
8. *W v. Egdell* [1990] 1 All ER 835 is the leading case on medical confidentiality. There are a variety of UK statutes relevant to specific areas of clinical practice.
9. General Medical Council (2009). *Confidentiality*. London: General Medical Council (paragraphs 53–55).
10. For a brief overview of virtue theory, see Rachels, J. (1995). Feminism and the ethics of care. In *The Elements of Moral Philosophy*, pp. 160–172. Singapore: McGraw-Hill. See also Toon, P. (2002). The sovereignty of virtue. *Br J Gen Pract* **52**, 694–5; and Toon, P. (2002). Defining and cultivating the virtues. *Br J Gen Pract* **52**, 782–3.
11. *Schloendorff v. Society of New York Hospital* [1914] 211 NY 125.
12. *Chester v. Afshar* [2002] EWCA Civ 724; [2003] QB 356.
13. Dworkin, R. (1995). *Life's Dominion: an Argument about Abortion, Euthanasia and Individual Freedom*. London: Harper Collins.

14. See http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4074657.rtf for a standardized UK written consent form.
15. Rahman, L., Clamp, J. and Hutchinson, J. (2011). Is consent for hip fracture surgery for older people adequate? The case for pre-printed consent forms. *J Med Ethics* **37**, 187–9.
16. Getz, L., Sigurdsson, J. A. and Hetlevik, H. (2003). Is opportunistic disease prevention in the consultation ethically justifiable? *BMJ* **327**, 498–500.
17. Corrigan, O. (2003). Empty ethics: the problem with informed consent. *Sociol Health Illn* **25**, 768–92.
18. Judgement can be argued to be similar to the ancient attribute of *phronesis*, or practical wisdom. See Downie, R. S. and Macnaughton, J. (2000). *Clinical Judgement: Evidence in Practice*. Oxford: Oxford University Press.
19. Powerfully argued in Tallis, R. (2009). *Hippocratic Oaths*. London: Grove Atlantic.
20. Elwyn, G. (2008). Patient consent: decision or assumption. *BMJ* **336**, 1259–60; Parks, J. A. (1998). A contextualised approach to patient autonomy within the therapeutic relationship. *J Med Humanities* **19**, 299–310.
21. Slowther, A., Ford, S. and Schofield, T. (2004) Ethics of evidence based medicine in the primary care setting. *J Med Ethics* **30**, 151–5.
22. Agledahl, K. M., Forde, R. and Wifstad, A. (2011). Choice is not the issue: the misrepresentation of health care in bioethical discourse. *J Med Ethics* **37**, 212–15.
23. See Launer, J. (2002). *Narrative-Based Primary Care: a Practical Guide*. Oxford: Radcliffe Press.
24. Marshall, M. and Bibby, J. (2011). Supporting patients to make the best decisions. *BMJ* 342, 775–6; Gulland, A. (2011). Welcome to the century of the patient. *BMJ* **342**, 792–5.