Northumbria Research Link

Chapter 3

Legal and ethical issues

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Aim

The aim of this chapter is to examine the legal and ethical considerations that are related to pharmacology and medicines management in contemporary healthcare settings.

Learning outcomes

By the end of this chapter, the reader will be able to:

1. Define commonly used legal and ethical concepts
2. Identify situations where legal and ethical considerations are required to make defensible decisions
3. Explain how legal and ethical considerations influence the decision-making process
4. Apply legal and ethical considerations to a variety of scenarios likely to be encountered in modern healthcare settings

Test your knowledge

1. According to UK law, what must be established in order to prove a case of negligence?
2. Can a wife consent to treatment on behalf of their husband who lacks capacity?
3. What is the meaning of beneficence in relation to ethics?
4. Can healthcare professionals provide treatment for children without the consent of their responsible parent in an emergency situation?
5. What is a professional body's primary function?

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Introduction

This section will introduce readers to fundamental ethical principles relating to nursing and healthcare, as well as some of the key legal concepts with which healthcare professionals should become familiar in order to ensure that decisions around pharmacology have a legal and ethical basis.

Any decisions made about pharmacology require consideration of various issues: what you are legally obliged to do, what you are professionally guided to do and what is in the best interests of the person within the situation. In practice, the three usually exist together; but before considering them as a whole, let's start with the fundamentals and look at them separately.

This chapter will consider the three components that underpin high-quality decision-making in pharmacology:

- the law
- ethical principles and theories
- regulatory bodies.

The law

Laws exist to protect patients and the public. Recent years have seen changes in the culture within healthcare in the United Kingdom (UK), with a notable rise in litigation. Unlike some countries, where there is a 'no-blame' process for medico-legal cases, the UK system operates a 'fault criterion' whereby fault has to be established for the complainant to prove a case. Clinical negligence claims quadrupled between 2007 and 2017 (National Health Service Improvement (NHSI), 2019) leading to an exponential growth in the number of cases involving healthcare professionals who are forced to defend their practice in a court setting. Failing to monitor a particular drug therapy, failure to recognise the prescription of a contraindicated drug, failure to warn patients of adverse effects and neglecting to protect a patient from harm are all examples of pharmacology cases whereby blame could be laid. As our professional remit grows, so does the legal expectation. Given the amount of resources and information health professionals have access to, the defence of lack of knowledge is wholly insufficient.

Laws originate from two sources: Common Law, sometimes referred to as 'Case' Law, and Statute Law known as 'Acts of Parliament'.

Common Law or Case Law refers to cases that are tried in courts of law, whereby a judge will give rule to a set of legal precedents. Common Law is constantly changing due to the ways in which judges interpret the law and use their knowledge of legal precedent and common sense as well as applying the facts of the case. Common Law safeguards that the law remains common throughout the land, and can be divided into either Criminal or Civil Law.

Statute Law or Acts of Parliament is law which is written down and codified into law. Acts begin as bills which then become Acts once the bills have been heard and possibly amended in the House of Commons and House of Lords before receiving 'Royal Assent'. The Acts can either be private or public. Private Acts may apply to detailed locations within the UK or they may grant specific powers to public bodies, such as local authorities. Public Acts are the laws that affect the whole of the UK or one or more of its constituent countries: England, Wales, Scotland and Northern Ireland.

Healthcare and the law in the UK are strongly entwined. The laws created to protect the health of an individual can be seen when under the care of the hospital and its medical team, through to public health and the legal requirements of health and safety. Across the UK, the laws and charters that exist have been created to ensure that the rights and health interests of the individual are protected throughout the duration of their medical care. Healthcare professionals therefore have a legal duty to act with reasonable care when providing services. This 'Duty of Care' is defined as a 'legal obligation imposed on individuals or organisations that they

take reasonable care in the conduct of acts that could foreseeably result in actionable harm to another' (Samanta and Samanta, 2011, p. 89). This includes prescribing drug therapy and drug administration, as well as consent, negligence and confidentiality – to name but a few. Failure to act with reasonable care could result in healthcare staff being held responsible in both criminal and civil courts.

Clinical considerations: The Bolam test

The majority of litigation in relation to medical malpractice comes under the category of negligence.

When considering cases of clinical negligence, courts will assess whether the health professional or organisation in question acted in line with the practice accepted as proper by a body of health professionals specialising in the specific field under scrutiny. This is known as the 'Bolam' test. The case (Bolam v Friern Hospital Management Committee, 1957), involved a patient who had suffered a fractured hip during electroconvulsive therapy (ECT). No relaxant or other restraint had been given to the patient in preparation for the treatment. The case explored this, along with the information the patient had been offered. The question was asked of a group of similar professionals and it was assessed that the practitioner had not been negligent as he had acted in accordance with accepted practice at that time. This set the standard and the Bolam test is now utilised in cases of negligence as a benchmark for whether the professional concerned acted in a reasonable manner. However, a judge can still make the assessment that the body of opinion is not reasonable.

There are several Acts or Laws that affect the provision of medicines which are illustrated on this timeline (see Figure 3.1).

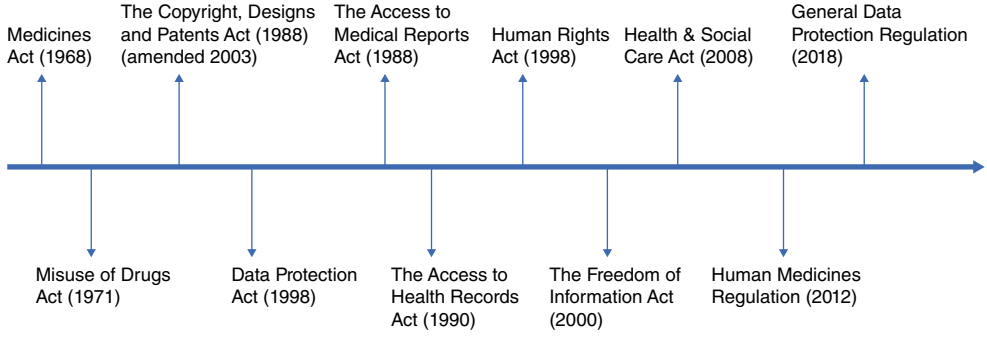

Figure 3.1 Acts or laws affecting the provision of medicines.

Ethical principles and theories

Making ethical decisions is about deciding on the right way to act in a given situation; this is underpinned by the moral values held by an individual or group. In 1979, Beauchamp and Childress (2009) developed a four-point theoretical framework to be used as a method of analysing ethical dilemmas in clinical medicine. The framework included beneficence, non-maleficence, autonomy and justice. These principles remain in healthcare along with the addition of a further two principles. Today the following ethical principles apply:

- beneficence
- non-maleficence

- autonomy
- justice
- veracity
- fidelity.

The principles outlined here are commonly felt to underpin judgments that health professionals believe to be right. First, *beneficence,* whereby we should endeavour to do good. This extends to protecting others and defending their rights, preventing harm and helping others. It is argued by some, such as Pellegrino (1988), that beneficence is the only fundamental principle within healthcare ethics and that the sole purpose of medicine should be to heal. By this assumption, medicines such as contraception, and treatments for conditions such as infertility, erectile dysfunction or aesthetics, could fall beyond its purpose. However, the notion of 'healing' is complex and dynamic, referring to more than just the rectifying of an immediate physical ailment or condition. Contraception, fertility treatment and plastic surgery support health and wellbeing in a myriad of direct and indirect ways, physically as well as psychologically, which is why the endeavour of beneficence is not as straight forward as it would first appear.

In practice, in order to do good, medical interventions and treatments can often carry a risk of harm and therefore require justification. *Non-maleficence* means that by our actions, we should do others no harm. The principle of non-maleficence therefore cannot be absolute and must be balanced against beneficence. For example, when treating patients with cytotoxic chemotherapy drugs for cancer, we balance beneficence (the potential to do good and eradicate the cancer) against non-maleficence and the risk of the chemotherapy itself to cause the patient's condition to deteriorate, possibly leading to death.

It is also generally believed that people should have the right to make decisions about what is right for them, provided they have sufficient capacity or understanding to do so. This principle is a respect for the *autonomy* of the individual and relates to enabling patients to make self-determined decisions regarding their care. Consent to treatment is a fundamental component of ethical patient care in addition to a legal requirement. It involves a genuine agreement (verbal or written) to receive treatment under circumstances where the patient has been assessed as competent, has been fully informed and where there is no undue pressure exerted (Herring, 2018). Beauchamp and Childress (2009) have argued that no decision can be truly autonomous, as patients rarely have the relevant knowledge to hold a full understanding of treatment options and, as such, are vulnerable to the coercion of health professionals who feel that they are best placed to make decisions in the interests of their patients (paternalism). However, increasingly patient groups have sought to increase autonomy for patients through changes in policies and practices which decrease the potential for coercion and increase patients' freedom to act (Williamson, 2010). An example of this has been seen in recent years, as a greater emphasis has been placed on models of shared decision-making between health professionals and patients. The shared decision-making approach seeks a balance between paternalistic care and the informed consent approach. Paternalistic care is where decisions about care are made by health professionals (predominantly doctors) and patients passively receive the care prescribed. This model does not factor in patients' own values and beliefs and can lead to patients feeling greater distress where there is a negative outcome (Stewart and Brown, 2001). The informed consent approach offers patients greater responsibility and will often involve health professionals offering patients all of the information required and then leaving them to make the decision unsupported. This can lead to patients feeling abandoned and unsure, creating anxiety and distrust (Corrigan, 2003; Deber et al., 2007). The shared decision-making approach involves health professionals and patients working together to devise a plan of care that is in line with the best available evidence as well as the values and beliefs of the individual patient, aligning to the principle of true autonomy.

Clinical considerations

A shared decision-making approach to care has been shown to benefit patients in terms of their active engagement in the treatment plan or taking the prescribed medications (Edwards and Elwyn, 2009). As such, it is an ethical approach to care which has also been shown to reduce the incidences of medico-legal claims where there is a negative outcome (Studdert et al., 2005). As health professionals, we should always aim to fully involve patients in decisions about drug treatments to maximise engagement and increase the potential for success.

Health professionals also abide by the principle of *justice,* which is the belief that people should be treated fairly, equally and reasonably. At its heart, justice is about equality; but how equality is determined can be ambiguous and problematic in healthcare. An example of the difficulties posed within this principle is often seen in relation to the fair and equal distribution of resources: 'distributive justice'. A drug for a specific condition may be available within one healthcare trust but the same drug is not available to patients with the same or similar condition in another trust. Sometimes colloquially labelled the 'postcode lottery', this occurs as a result of differing priorities for resources among those who make difficult commissioning decisions about resources on a local level.

Health professionals should also be honest and tell the truth to enable someone to have the full information relevant to them in order to make full rational choices about their care. This is known as *veracity* and involves conveying accurate and objective information to the patient. Giving patients full information regarding treatment options is the most common application of the veracity principle. Disclosures of medication errors are also an obvious example of veracity, and the recent introduction of the 'Duty of Candour' guidance for health professionals (NMC and GMC, 2015) highlights the importance of the veracity principle. Informing patients when something has gone wrong, apologising, and offering a remedy are measures that are advised by Sir Robert Francis in his report on the failings of the Mid-Staffordshire Health Trust (2013). Francis (2013) stated that candour and transparency are key components of a safe and effective culture for patient care. However, in reality, true veracity is a complex notion. Returning to the example of the drug that is available in one health trust and not another, health professionals engage in such rationing 'inconspicuously' (Williamson, 2010, p. 201) without necessarily informing patients that they are being denied something that could benefit them. Aside from the greater ethical issues concerned with who makes the decisions and how they are implemented, there is the more immediate concern relating to veracity and the decision on whether to inform patients.

Finally, the principle of *fidelity* requires the act of loyalty and trustworthiness; it involves keeping our promises, performing our duties and doing what is expected of us within our relationships with patients. This principle can be conflicted where the health professional's loyalty or obligation may be torn between their patients and colleagues or the organisation for which they work. Conflict may also arise as a result of the patient lacking capacity to make an informed choice and the health professional being compelled to override the wishes of their patient in their best interests.

Clinical considerations: Consent to treatment (adults)

Adults with capacity: The authority to treat comes solely from the patient. According to UK law, consent by proxy is not permitted for the care or treatment of adults who have the capacity to make an informed decision.

Adults lacking capacity: Where a patient does not have the mental capacity to make an informed decision regarding their care due to an impairment or disturbance to the functioning of the mind – e.g. acute confusional state, dementia, brain injury, being unconscious – then under the Mental Capacity Act (MCA, 2005) the health professional can decide upon the treatment that is deemed in the best interests of the patient without the consent of the next of kin.

Section 3(1) of the MCA (2005) sets out the following benchmarks by which to assess an adult's capacity:

a. If they are unable to understand the information given to them relating to the decision.
b. They are unable to retain the information.
c. They are unable to weigh the information as part of the decision-making process.
d. They are unable to communicate their decision.

When ethical dilemmas in practice are met, consideration needs to be given to which principles are in conflict to then consider which is more important. In helping to resolve ethical dilemmas, ethical theories are called upon. Several exist, including:

- utilitarian/consequentialism
- deontological ethics
- virtue ethics
- nursing ethics.

Utilitarian or consequentialism theory considers the rightness of an act as that which, when considering the costs and benefits, creates the greatest good for the greatest number. For example, the issue of immunisation is currently a controversial one with a minority of parents deciding to opt out of immunisation programs for their children. This puts children and other vulnerable members of society at risk of developing some diseases that were previously eradicated in the UK, e.g. measles (Public Health England, 2019), with the associated implications to the individuals, wider society and to the health service. The utilitarian perspective would be that all eligible children should be immunised irrespective of the views/wishes of their parents. Utilitarianism would not be concerned with the autonomy of the individual (the right to not give consent to the vaccine) as this is arguably in conflict with the greater good.

Clinical considerations: Consent to treatment – children

Sixteen to seventeen-year-olds with capacity: According to Section 8(1) of the Family Law Reform Act (1969), consent can be sought from the child for medical and dental treatment. However, those with parental responsibility may still consent on the child's behalf.

Sixteen to seventeen-year-olds lacking capacity: Anyone with parental responsibility can consent on behalf of a child who lacks capacity. In situations where those with parental responsibility do not consent to treatment, but where treatment is felt to be in the best interests of the child, a court order may be obtained. In an emergency situation, treatment may still be provided without parental consent where it is deemed a necessity (Glass v UK, 2004).

Under sixteen years of age: An assessment of the child relating to 'Gillick' competence (Gillick v West Norfolk and Wisbech Area Health Authority, 1985) would determine whether the child has sufficient maturity and understanding of what is involved to enable them to make a decision to consent to treatment or not.

Deontological ethics, or deontology, is an approach to ethics that determines goodness or rightness from examining acts rather than the consequences of the act as in utilitarianism. Deontologists look at rules and duties. For example, the act may be considered the right thing to do even if it produces a bad consequence, if it follows the *rule* that 'one should do unto others as they would have done unto them'. According to deontology, we have a *duty* to act in a way that does those things that are inherently good as acts. In this approach, the duty of care to the individual takes priority over any other considerations. Going back to our example of immunisations, children are, in reality, not forced to have immunisations where parents have opted out. Health professionals have a duty to ensure that any care given is consented to (within the parameters of the MCA 2005 as outlined above). Without this consent we cannot inject a live vaccine into a child no matter what the potential implications might be for wider society. So the act itself is good (abiding by rules of consent), but the consequence may be a negative one (the child contracting measles and passing this on to others). For deontologists, the ends or consequences of our actions are not important, nor are our intentions. Duty is the key consideration. However, it is not always clear what one's duty is. While we may agree that our duty is to 'do no harm', there will be instances where health professionals will have to override this with their duty of care.

Virtue ethics focuses on how we ought to behave, and how we should think about relationships, rather than providing rules or formulas for ethical decision-making. It considers the virtues a 'good' person would have: honesty, compassion, generosity and courage, for example (Velasquez et al., 1988). With the common good in mind, these virtues will be applied to actions and decisions. A group of virtues can be accredited to particular roles or professions, and it could be argued that nurses are attracted to the profession because they already function according to these virtues.

This leads us to nurse ethics. The focus of nursing ethics is on developing a caring relationship and seeking a collaborative relationship with the person. Recently, care, compassion, courage, communication, commitment and competence (the 6 Cs Department of Health, 2012) have been highlighted as the required virtues of nurses. Common themes of nursing ethics emphasise respect for the autonomy of the individual and maintaining the dignity of the client by promoting choice and control over their environment.

What is deemed to be right is not therefore bound by absolute rules or duty, or purely the greatest good, but also considers the virtues that individuals and society value. The ethical views held by society affect healthcare laws and how they are implemented. As society's moral values alter, legislation follows. An example of this was in 1967 when UK society's beliefs changed regarding abortions. It became largely accepted that in some cases they were necessary for saving women's lives as well as reducing the potential for suffering (psychologically as well as physically) of the woman and her pre-existing family, and so the Act was introduced (Abortion Act, 1967).

Regulatory bodies

In order to practice, healthcare professionals are aligned to a regulatory body such as the Nursing and Midwifery Council (NMC) or the Health and Care Professions Council (HCPC). The purpose of a regulatory body is primarily to protect the public, and as such they are established and based upon a legal mandate. Their function is regulatory and to impose requirements, restrictions and conditions – as well as offering a means of support and guidance to professionals. They also set standards in relation to practice activities, securing compliance and enforcement of their practitioners. Regulatory bodies have traditionally provided their practitioners with ethical guidance in the form of a 'code' or an 'oath', such as the NMC Code of Conduct (2018) or the Hippocratic Oath for doctors. A word of caution though; codes such as the NMC Code of Conduct (2018) could be viewed as merely being concerned with specifying rules of responsibility and conduct rather than focusing specifically on ethics.

Within healthcare, regulatory bodies have a duty to protect, promote and maintain the health and safety of the public. They do this by ensuring proper standards are in place in order to practice. Such standards define the overarching goals and the expected role and duties of their practitioners through listing the obligations associated with their individual

responsibilities and skill set. The overarching goals are aspirational and represent an optimal position ethically, thus encouraging the individual to strive towards the optimal position. Healthcare professionals, like the public and their patients, possess their own values and beliefs which in turn influence their practice.

Imagine yourself working in a very busy gynaecological outpatients and you are required to administer mifepristone (medically induced abortion) to a young intravenous drug user (IVDU), currently sofa surfing among friends. Your service user is advised to return in between 24 and 48 hours for the second medication – misoprostol, to complete the treatment. She does not return. You notice certain client groups tend not to return to the clinic and you begin to think about why this is the case, using the principles of ethical professional practice, beneficence (do good) and non-maleficence (do no harm).

Within this scenario, there is a possibility the service user's care has been affected by the healthcare professionals implicit bias (IB) towards certain social groups. Several authors have emphasised that a well-meaning, egalitarian (fair) minded individual can have implicit biases which demonstrate the imbalance between their unconscious ways of thinking and how they explicitly perceive themselves treating people (Fitzgerald and Hurst, 2018; Lang et al., 2016). The elements of IB are one's perceived stereotypes (a mental picture of what one thinks, knows and expects) and prejudices (feelings) associated with certain categories of people, learnt through a shared culture, which over time slips into one's unconsciousness, which means it is hidden (Lang et al., 2016). As Stone and Moskowitz (2011) explained, this means the healthcare professionals are unaware of their biases, which impacts on the quality of care delivered, seen in how they may judge and behave towards particular groups (Kelly and Roedderts, 2008). Merino et al. (2018) highlighted over 60% of healthcare professionals harbour variants of IB towards marginalised/vulnerable groups. Examples of vulnerable or marginalised groupings can be based on: gender, age weight, homelessness, ethnicity, immigration status, socio-economic status, educational achievement, mental ill-health, sexual orientation, IVDUs, disabilities and social circumstances – or anyone rendered vulnerable in certain situations (Fitzgerald and Hurst, 2018).

There is a consensus that stereotyping saves cognitive resources in stressful environments, a situation healthcare professionals often find themselves in (Hall, 2017). Drawing on these stereotypes enables the healthcare professional to make timely decisions based on the minimal information available in times of fatigue, tiredness, heavy workload, uncertainty and inadequate support (Stone and Moskowitz, 2011). Nonetheless, it remains that there is a clear link between IB and the quality of care delivered and how it potentially influences the healthcare professionals ability to engage in person-centred care (Merino et al., 2018). Fitzgerald and Hurst (2018) stated that a healthcare professionals IB behaviour towards marginalised groups can impact on the service user's access to healthcare service by producing false diagnoses, non-referral to appropriate services, limiting treatment options or withholding of treatment. Goyal et al. (2015) detailed how IB may have contributed to the creation of health disparities, as African-American children were less likely to receive adequate pain management post-appendectomy than their white counterparts. IB influences within clinical interactions can leave the service user feeling uncomfortable as they pay attention to the healthcare professionals non-verbal mannerisms, such as eye contact, physical closeness and speech errors which can demonstrate the healthcare professionals dislike or unease of dealing with particular clientele (Stone and Moskowitz, 2011). This in turn may not only impede patient–healthcare professional communication, but may also affect patient concordance and willingness to seek future care.

Puddifoot (2017) highlighted that IB can cause an ethical dilemma, demonstrated earlier, as there is potential to do harm within these client groups through the healthcare professionals judgment and behaviour based on their IB. Positive beneficence requires the healthcare professional to consider benefits for others alongside balancing the risks (Baillie and Black, 2015), which is compromised through the harbouring of IB. Such behaviours are in direct contradiction of the professional regulatory bodies' codes of professional performance; therefore, the healthcare professional should reflect upon how they interact with certain client groups to develop awareness of any implicit biases they may have (Lang et al., 2016). Additionally, Stone and Moskowitz (2011) recommend learning courses to expand the healthcare professionals cultural competence by learning about IB.

There are a number of guidelines set out by various professional bodies in relation to pharmacology. The General Medical Council (GMC) have outlined expectations of doctors' ethical prescribing practices which aim to provide more detailed advice on how to apply ethical principles when prescribing and managing medicines (2013). Additionally, largely in response to the withdrawal of the Medicines Management standards by the NMC (2015), the Royal Pharmaceutical Society and the Royal College of Nursing collaborated in developing the 'Professional Guidance on the Administration of Medicines in Healthcare Settings' (2019). These standards seek to promote patient safety in relation to the administration of medicines by acknowledging the importance of guidance for health professionals that is enabling and supportive while being clear and concise. The document recognises the importance of a commitment to ethics, values and principles which put patients first. It is incumbent upon the individual healthcare professional to ensure that they are familiar with the most current guidance related to their own sphere of practice to ensure that ethical and legal considerations are applied.

Clinical considerations

All healthcare professionals have a responsibility to ensure that they are familiar with legislation related to the prescribing, storage and administration of medicines within their sphere of practice. A list of key documents that will support you in the development of knowledge in this area is offered in the Further Reading section.

Research

The legal and ethical standards which govern research into pharmacological treatments are very specific to the context of clinical drug trials. During the Second World War, Jewish prisoners in Nazi concentration camps were used as subjects in medical experiments against their will, leading to permanent disfigurement, disability, trauma and in many cases death. In response to these atrocities, the Nuremberg Code (1947) was developed as international guiding ethical principles for the conduct of research involving human participants. They include principles of informed consent, non-coercion and the right to withdraw, as well as the importance of robust protocols underpinned by beneficence. These principles were later encapsulated within the Declaration of Helsinki (World Medical Association, 2008) and further legislation has evolved to ensure the safety of human participants in clinical trials including: Data Protection Act (2018), Human Tissue Act (2004) and the Medicines for Human Use (Clinical Trials) Regulations (2004) as well as the Human Rights Act (1998).

Research is an important mechanism for healthcare professionals to ensure that the drug treatments we offer patients are thoroughly tested for safety and efficacy. Additionally, there is strong evidence emerging that research-active hospitals have better patient outcomes, highlighting the importance and the responsibility healthcare providers have to offer their service users the opportunity to be involved in clinical trials (Ozdemir et al., 2015). It is essential that legislation enables clinical researchers to conduct clinical trials in the endeavour of medical advancement, while ensuring that participants are fully informed of the potential risks and benefits, are not coerced into consenting to participate, and are aware of their right to withdraw from participating at any time. The guiding principle is that the wellbeing and safety of the participants is paramount and takes priority over any other consideration.

Research Ethics Committees (RECs) have the remit to review any proposed research that involves human participants. Made up of a number of lay-people and professionals experienced in their own field, it is the responsibility of the REC to interrogate the research protocol and to identify any aspects of the research consent and treatment processes which may pose an unacceptable risk to participants or the public. Approval from a REC is essential before a trial can go ahead. As the trial progresses, researchers will also need to seek ethical approval to make any amendments to the protocol, which may be something as minor as a change of wording within a participant information sheet, to something more substantial such as a

change in the dose of medication to be administered. These changes will be implemented in line with Good Clinical Practice (GCP) principles (MHRA, 2012).

Despite these safeguards, there are notable incidences that have occurred in recent years related to the conduct of some clinical trials. For example, in 2006, volunteers in an early phase drug trial at the Northwick Park Hospital became seriously ill. The story became headline news after six participants reacted badly to the medication, suffering a severe immune response leading to organ failure and one participant requiring the amputation of his fingers. This led to a full investigation and the resulting report changed a number of practices in the running of drugs trials which sought to prevent this from happening again (Expert Scientific Group on Phase One Clinical Trials, 2006).

Fortunately, however, the ethical and legal frameworks which surround clinical research, limit these incidents and provide principles and guidance for the safe conduct of research and researchers.

Skills in practice: How to use medical ethics

Not all decisions are made easily, and, in some cases, there are multiple factors that influence decision-making, such as personal experience, religion, regulatory codes, legal issues and so on. In practice, a practitioner will use a combination of all such factors to reach a decision; this is sometimes described as a systematic study of moral choices. In the first instance, the code of behaviour or conduct presented by a regulatory body is considered correct. Within healthcare, there are many examples of ethical decision-making process which include varying numbers of steps to follow. Overall, there is the general adoption of principle-based ethics to guide decision-making practice within healthcare, which is evident in this example.

Step 1 – Ability to recognise an ethical issue. Ask yourself: could this scenario or decision cause harm or damage to someone or some group? Are there choices between different alternatives; for example, a good and bad alternative or, maybe, two bads or two goods? Is this situation bigger than what is efficient? Or what is legal? What are your initial gut reactions? By considering the scenario on an emotive level you can recognise your own assumptions, values and biases so that you can set them aside before analysing the situation critically.

Step 2 – Gathering the facts. What facts are already known? What other relevant facts need to be gathered? Who are the relevant stakeholders within this scenario and its outcome? Has everyone involved been consulted? Are some concerns more important than others?

Step 3. Evaluation of alternative options or actions. Includes questions from a range of approaches. From a utilitarian approach ask: which actions/option do the least harm and produce the most good? Considering the deontological approach – which actions/option best respects all stakeholder rights? From a nursing approach, which actions/option treat people proportionately or equally? Which actions/option best serve the whole community and not just some if its members? From a virtue approach, also consider which actions/option lead me based on the type of person I want to be?

Step 4. Make the decision. When all approaches have been considered, which actions/option best addresses the scenario? Which action/option is best based on all the stakeholder core values? Consider what others might say when you have shared your chosen actions/option, can you justify your choice?

Step 5. Carry out the actions/option chosen and reflect on the outcome. Plan how your decision can be implemented with the upmost care, pay attention to any concerns raised by all of the stakeholders. Implement your plan and evaluate. Reflect on the results of your choice of decision and what have you learned from this specific scenario. Consider how the ethical problem could be prevented in the future.

Episode of care

Paul is a 65-year-old man who has attended the walk-in centre with a suspected oral infection. He is allergic to penicillin so is prescribed metronidazole 200 mg twice daily for seven days. However, he smells strongly of alcohol and it states in his previous notes that he has had multiple admissions with alcohol-related injuries and has a chronic alcohol addiction. You as the nurse query this with the doctor who has prescribed the antibiotics, knowing that the British National Formulary (Joint Formulary Committee, 2019) indicates that alcohol and metronidazole are contraindicated and can cause a severe reaction. The doctor states that she has discussed this with Paul and he is aware that he must refrain from drinking alcohol for the course of the treatment. Consider this from an ethical perspective. While the treatment may be doing 'good' (beneficence), it has the potential to do harm (maleficence). It is imperative that health professionals discuss medication plans prior to treatment to ensure that patients are aware of the impact this will have on their daily activities. In Paul's case, it is highly unlikely that he will refrain from alcohol and could either take the metronidazole regardless, risking an adverse reaction, or he may decide to not take the antibiotics and risk further infection and possible sepsis. Key message? Ensure every decision made fully involves the patient and aligns with their own values and lifestyle.

Episode of care

Maya is an 85-year-old woman who lives alone. She is usually independent with all of her activities of living and, although she does not like to leave the house, she is usually in good physical and mental health. Her daughter visits her three times a week and has noticed some increased confusion over the past few days. Today she has visited and felt it necessary to call the GP as Maya is extremely confused and smells strongly of malodorous urine. The GP refers her to the acute admissions unit with a suspected Urinary Tract Infection (UTI). Further tests are undertaken in hospital, but the admissions team decide to prescribe intravenous (IV), broad-spectrum antibiotics to treat the UTI as per the guidance from the National Institute for Health and Care Excellence (NICE NG109, 2018), which they hope will also alleviate the acute confusional state. However, Maya becomes very distressed when the nurse attempts to cannulate and Maya's daughter states that she does not consent to her mother receiving IV antibiotics. Maya has been assessed as an adult lacking capacity by health professionals. In accordance with the Mental Capacity Act (2005), she is cannulated and receives the IV antibiotics. Over the course of the next 24 hours her condition improves and her acute confusional state dissipates. The health professionals have acted in accordance with legal standards. They have also balanced their duty to respect Maya's autonomy with their duty of care in ensuring beneficence (doing good by giving the required treatment in Maya's best interests) and non-maleficence (doing no harm by omitting care that was in her best interests).

Conclusion

This chapter has sought to outline the fundamental legal and ethical principles relating to pharmacology in healthcare. The three key components that underpin high-quality decision-making with and for patients in our care are related to the law, ethical principles and regulatory bodies. A variety of legislation has been discussed to offer an understanding and insight into how healthcare professionals manage and administer medicines within the confines of the law. The interplay of legislation, ethical principles and professional regulation is a fine balance that health professionals seek to strike in order to optimise the safety and efficacy of treatment.

Working in healthcare requires an acknowledgement of the areas of ambiguity and conflict that may be encountered; and while we seek to always 'do good', there are countless situations where this endeavour may be obstructed by other considerations such as patients' capacity or the wider public interest.

Acknowledgement of the issues that have been outlined within this chapter and a deeper understanding of how to apply the knowledge of ethical principles will ultimately improve practice and provide safer and higher quality patient care. It is incumbent upon all health professionals (and students) to act with integrity within these frameworks and to make individualised decisions which are in the patients' best interest and, wherever possible, fully informed.

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Further reading

Useful reads: Medical Protection www.medicalprotection.org/uk/hub/ethics.
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Multiple choice questions

1. Common Law is also known as:
   (a) Criminal Law
   (b) Case Law
   (c) Statute Law
   (d) All of the above
2. Failure to act with reasonable care could result in healthcare staff being held responsible in which courts:
   (a) Criminal Court
   (b) Civil Court
   (c) Civil and Criminal Court
   (d) Family Court
3. What year did the Medicines Act become statute?
   (a) 1966
   (b) 1967
   (c) 1968
   (d) None of the above
4. Utilitarian theory considers:
   (a) The greatest good for the greatest number
   (b) Your duty of care takes priority over any other considerations
   (c) How we ought to behave and seek relationships
   (d) All of the above
5. When adopting principle-based ethics to guide your decision-making, where do you need to gather the facts from?
   (a) From all the stakeholders involved within the scenario
   (b) From what is already known
   (c) From other facts that are relevant from other scenarios
   (d) All of the above
6. Sensitive topics such as abortion can lead to the practitioner having _____ dilemma:
   (a) an Ethical
   (b) a Clinical
   (c) a Legal
   (d) All of the above
7. Implicit means:
   (a) Hidden
   (b) Obvious
   (c) Available
   (d) Explicit
8. Elements of Implicit Bias include:
   (a) Stereotypes
   (b) Prejudices
   (c) Stereotypes and prejudices
   (d) Impartialities
9. Healthcare professionals harbour a _____ level of implicit bias as the general population:
   (a) Lower
   (b) Higher

(c) Equal
(d) None of the above

10. The influences of implicit bias on the practitioner's professional behaviour include:
    (a) Making the client feel uncomfortable
    (b) Helping them access services
    (c) Correct diagnoses and treatment
    (d) Patient concordance
11. What is the Bolam test?
    (a) A test to assess patients' capacity
    (b) The opinion of a professional body as to whether the action was accepted practice
    (c) An assessment of competency of a patient under 16
    (d) All of the above
12. Shared decision-making:
    (a) Is an approach to care that increases patient engagement in treatment
    (b) Improves patient engagement with care and treatment
    (c) Reduces medico-legal claims
    (d) All of the above
13. What is distributive justice in relation to healthcare?
    (a) The fair and equal distribution of health resources
    (b) The 'postcode lottery'
    (c) An assessment of patient need
    (d) All of the above
14. Why is research in healthcare so important?
    (a) To test drugs for safety and efficacy
    (b) To develop better treatments for patients
    (c) To improve outcomes for patients
    (d) All of the above
15. What must professionals do in order to abide by the 'Duty of Candour'?
    (a) Tell the patient when a serious incident has occurred
    (b) Inform patients and their families of everything related to the patient's care at all costs
    (c) Apologise to patients
    (d) All of the above

Find out more

The following is a list of considerations, guiding legislation and ethical frameworks for safe and effective practice. Find out more about each of these and make notes in the section provided about what each of these involve and how it impacts upon the care of patients.

The consideration	Your notes
Mental Capacity Act (2005)	
Burden of proof for negligence	

The consideration	Your notes
Human Medicines Regulation (1971)	
Research Ethics Committee	
Northwick Park drug trials controversy	