Medical Ethics and Deontology

Practical Class Study Guide

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Seven case-based seminars for medical students

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Table of contents

How to use this study guide

This book is organised as seven practical classes in medical ethics and deontology. Each class introduces the concepts needed for seminar discussion, applies them to clinical practice, and ends with cases, an applied exercise, and a short reasoning task. It is a study guide rather than a comprehensive textbook.

Begin each case by clarifying the clinical facts and uncertainties. Identify the people affected, distinguish ethical arguments from legal and professional rules, compare reasonable options, and justify a recommendation that can be communicated to the patient or team. Legal statements are specific to a jurisdiction and should be checked against current official sources before they guide clinical action.

1 Ethics - definition and principles

A patient with a short history of cough, sore throat, and fever asks for an antibiotic because the same treatment seemed to help during a previous illness. The clinical findings suggest a self-limiting viral infection. Prescribing may reassure the patient and preserve the relationship, but it also exposes them to adverse effects and contributes to antimicrobial resistance. Refusing may be clinically justified, yet the way the refusal is explained could leave the patient feeling dismissed.

Clinical knowledge establishes what is likely to help and harm, but it does not settle every question raised by this encounter. The doctor must decide which interests matter, what duties apply, whether effects on other patients should influence the decision, and how to defend the chosen course of action. These are questions of ethical reasoning.

> **i** Class focus
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> This class prepares you to distinguish ethical problems from legal or professional questions, compare several approaches to moral reasoning, and use a structured method to justify a clinical decision when relevant values or duties conflict.

1.1 Essential concepts

1.1.1 Morality and ethics

Morality is the set of values, norms, and judgements through which people and communities distinguish right from wrong conduct. Moral beliefs are acquired through family life, education, culture, religion, professional formation, and personal experience. They influence clinical decisions, but the fact that a belief is familiar or widely shared does not by itself justify it.

Ethics is the disciplined examination of moral claims. It asks what a person ought to do, what reasons support that judgement, whether those reasons are consistent, and how the interests of affected people should be considered. In ordinary language, *ethics* may also refer to a recognised code of conduct. In this study guide, the term usually means reasoned reflection unless a professional code is specified.

Ethical reasoning begins with moral experience but goes beyond personal conviction. A statement such as “I would never accept that treatment” reports a preference. An ethical argument must explain why the preference should guide the decision, whether the same reasoning would apply to comparable cases, and how competing claims should be addressed. Emotions such as compassion, anger, fear, and moral unease may reveal that something ethically significant has been overlooked. They are sources of attention, not substitutes for justification.

Medical terminology varies across traditions, and the boundaries between the fields in Table 1.1 overlap. The distinctions are still useful because they show the range of questions that may be asked.

Table 1.1: Related fields in ethics and medicine.

Field	Practical meaning
Medical ethics	Ethical questions arising from the practice of medicine, with particular attention to the duties of physicians and decisions concerning patients.
Healthcare ethics	Ethical questions concerning all health professions, teams, organisations, and systems of care.
Bioethics	A multidisciplinary field concerned with ethical questions in medicine, healthcare, public health, research, biotechnology, and the life sciences.
Clinical ethics	The analysis of ethical problems arising in the care of particular patients.
Professional ethics	The values, duties, standards, and boundaries associated with a professional role.
Medical deontology	In medical education, the study of physicians' professional duties and standards. In moral philosophy, *deontology* has the narrower meaning of duty-based ethical theory.

1.1.2 Ethical problems and ethical dilemmas

An **ethical problem** arises when a decision affects morally relevant interests, rights, duties, relationships, or values and requires justification. Some ethical problems have a strongly supported solution once the facts and applicable duties are clear. Others remain difficult because evidence is uncertain, reasonable people assign different weight to competing considerations, or every available option carries a serious moral cost.

An **ethical dilemma** is a narrower type of problem in which two or more moral requirements conflict and none can be fully honoured. The word should not be used for every unpleasant choice. A shortage of time, an unclear protocol, or anxiety about criticism may complicate a decision without creating a genuine conflict of moral duties. Defining the problem accurately prevents practical difficulties from being mistaken for ethical disagreement.

Ethical uncertainty also differs from factual uncertainty. The team may disagree about what should be done even when the diagnosis and prognosis are known. Conversely, apparent ethical disagreement may disappear when missing facts are obtained. Before debating values, the clinician should therefore ask whether the parties are working with the same account of the patient's condition, options, preferences, and likely outcomes.

1.1.3 Ethics, law, professional standards, and policy

Ethics and law often address the same conduct, but they ask different questions. Ethics asks what ought to be done and why. Law determines what is required, permitted, or prohibited within a particular jurisdiction. Legal permission does not establish ethical acceptability, and an ethically defensible position does not establish legal permission. Any legal claim used in a case analysis must therefore identify the jurisdiction and be checked against a current authoritative source.

Professional standards translate some ethical commitments into expectations for members of a profession. Depending on the issuing body and jurisdiction, a standard may be advisory, contractually relevant, or connected to disciplinary consequences. Institutional policies organise local practice and may specify who decides, how a concern is escalated, or how scarce resources are allocated. A policy can support consistent decisions, but it cannot make an otherwise discriminatory or unlawful action acceptable. Personal beliefs also deserve careful attention, especially when they affect conscience or professional integrity, yet they must be distinguished from obligations attached to the clinical role.

The categories may point in the same direction, but they should still be recorded separately. This

prevents a familiar rule from being presented as a complete ethical argument and makes clear which questions require legal or professional verification.

1.2 Ethical framework

No single ethical approach captures every morally relevant feature of clinical practice. Comparing approaches can expose assumptions that remain hidden when a case is viewed through only one framework.

1.2.1 Consequences and utility

Consequentialism is a family of theories in which the moral assessment of an action depends on its consequences. Different consequentialist theories disagree about which consequences matter, whose welfare counts, and how benefits and harms should be compared. **Utilitarianism** is a prominent form of consequentialism that seeks to maximise aggregate well-being. The two terms are related but are not synonyms.

Consequentialist reasoning is useful when decisions affect many people, as in prevention, triage, and resource allocation. It directs attention to all foreseeable effects rather than only the clinician's intention. Those effects include delayed and indirect harms, unequal distribution of burdens, loss of trust, and the consequences of maintaining a rule over time. The slogan "the end justifies the means" is therefore a poor description: a serious consequentialist analysis must examine the full range and distribution of outcomes.

The approach also has limitations. Outcomes are rarely known with certainty, different benefits may be difficult to compare, and maximising aggregate welfare may leave an individual or minority exposed to a grave burden. A prediction of greater total benefit does not, by itself, answer an objection about rights or fairness.

1.2.2 Duties and respect for persons

Deontological ethics evaluates conduct through duties, rights, and constraints on how people may be treated. Kantian ethics, an influential form of deontology, asks whether a guiding rule could be willed consistently and requires that persons be treated as ends in themselves, not merely as instruments for another purpose. In clinical practice, duty-based reasoning supports commitments such as honesty, fidelity, respect for bodily integrity, and protection against exploitation.

Deontology is not simple obedience to a law, policy, or senior colleague. A rule must have a moral basis, and duties may require interpretation when they conflict. A duty to tell the truth, for example, does not determine when, where, and in what manner difficult information should be communicated. Duty-based approaches protect people against being sacrificed for aggregate advantage, but they may provide limited guidance when two justified duties cannot both be fulfilled.

1.2.3 Character and practical wisdom

Virtue ethics asks what a good practitioner would perceive, feel, and do. Its focus is moral character rather than a single rule or calculation. Honesty, compassion, courage, humility, fairness, and trustworthiness are relevant clinical virtues, but they must be guided by **practical wisdom**: the ability to recognise what a situation requires and to act for appropriate reasons.

Good intentions are not enough. A compassionate action may still be poorly judged, and courage can become recklessness when the practitioner ignores evidence or refuses advice. Virtue ethics helps explain why professional formation concerns habits and judgement as well as compliance.

It is less precise when people agree about the desirable virtues but disagree about which action expresses them in a particular case.

1.2.4 Relationships, care, and narrative

Care ethics draws attention to dependency, vulnerability, power, and the moral responsibilities created by relationships. It challenges the image of patients as isolated decision-makers and asks whether a response is attentive to the person who must live with its consequences. Care is not simply kindness. It requires accurate attention, competent action, responsiveness, and awareness of unequal power.

Narrative ethics examines how illness and treatment acquire meaning within a person's life story. A refusal may look irrational when reduced to clinical facts yet become understandable when the patient's past experiences, responsibilities, and fears are known. Narratives can also conflict: the patient's account, the family's account, and the clinical team's account may emphasise different facts and values. Listening to each story improves understanding but does not remove the need to decide between incompatible options.

Communitarian and public-health approaches place individual choices within shared practices, institutions, and common goods. They draw attention to solidarity, reciprocal responsibilities, and conditions that allow communities to flourish. This perspective is useful for vaccination, antimicrobial stewardship, and allocation. Its danger is that an asserted "community interest" may conceal the preferences of a dominant group or impose excessive burdens on a minority.

1.2.5 Principlism and the four principles

Principlism is a practical framework organised around four prima facie principles: respect for autonomy, beneficence, non-maleficence, and justice. A prima facie duty has moral force unless a competing duty is stronger in the circumstances. The principles therefore have no fixed hierarchy, and naming them does not decide the case.

Table 1.2: Questions raised by the four principles.

Principle	Question for the case	Limitation to remember
Respect for autonomy	Are the person's informed and voluntary choices being respected, and can they direct their own life according to their values?	Autonomy does not create an entitlement to every requested intervention and does not automatically override justified duties to others.
Beneficence	Which option is reasonably expected to promote the patient's welfare as the patient understands it?	Clinicians and patients may understand benefit differently; professional judgement and the patient's values both require examination.
Non-maleficence	What physical, psychological, social, or moral harms could each option cause or prevent?	Almost every effective intervention carries some risk, so avoiding all harm is impossible. The probability, severity, reversibility, and distribution of harm matter.

Principle	Question for the case	Limitation to remember
Justice	Are benefits, risks, opportunities, and resources distributed fairly, using relevant and consistent criteria?	Equal treatment is not always equitable treatment. Differences are justified only when they are relevant to the decision.

The framework seeks a shared moral vocabulary, but the meaning and application of each principle remain open to interpretation. Respect for autonomy may be understood in strongly individual terms or through the relationships that support a person's agency. Justice may concern equal opportunity, priority to those in greatest need, maximisation of health benefit, fair procedures, or protection from discrimination. These interpretations can point towards different decisions.

Two operations make the principles more useful. **Specification** gives an abstract principle a more precise meaning in context: "avoid harm" might become "do not expose this patient to a serious and irreversible risk when the expected clinical benefit is very small". **Balancing** compares the moral reasons supporting competing options. The comparison should address the importance of each interest, the probability and severity of harm, whether burdens can be reduced, and whether less restrictive alternatives are available. Plus and minus signs cannot perform this work. Ethical justification depends on reasons that other people can examine and challenge.

1.3 From principle to practice

Ethical analysis is most useful before the team has become committed to one interpretation. It creates a disciplined pause in which facts can be checked, assumptions exposed, and alternatives considered. The aim is not unanimous agreement at any cost. The aim is a decision that is clinically informed, ethically justified, lawful, and open to review.

A method for ethical analysis

1. **Establish the facts and uncertainties.** Clarify the diagnosis, prognosis, available options, likely outcomes, time pressure, and missing information.
2. **Formulate the ethical question.** State who must decide what, for whom, and under which constraints.
3. **Identify the stakeholders.** Include the patient, people close to them, professionals, other patients, and institutions only where their interests are genuinely affected.
4. **Elicit values, preferences, rights, and duties.** Do not infer a person's values from age, diagnosis, religion, culture, or family membership.
5. **Distinguish the normative sources.** Record ethical arguments separately from legal requirements, professional standards, and institutional policy; identify matters that need current verification.
6. **Develop reasonable options.** Include compromise, delay, consultation, additional support, and non-intervention when they are clinically possible.
7. **Compare and justify.** Examine benefits, harms, fairness, relationships, professional integrity, and uncertainty through more than one ethical approach.
8. **Decide, communicate, and review.** Recommend an option, explain why competing options were rejected, plan how to communicate it, and identify what new information would prompt reconsideration.

The ethical question should be specific enough to guide action. "Is autonomy more important than beneficence?" is too abstract. "Should the surgeon offer an irreversible operation with little

expected clinical benefit to this patient, and how should the refusal or agreement be explained?" identifies the decision, the responsible professional, and the central conflict.

Stakeholders should not be counted as votes. A large group does not acquire greater moral weight merely because it contains more people, and not every emotional reaction creates a claim over the patient's care. The analysis should explain the nature of each interest and its connection to the decision. Particular attention is required when a person is dependent on the team, has difficulty being heard, or may carry a disproportionate burden.

Reasonable options are clinically possible actions that respect the main constraints of the case. Listing only "do everything" and "do nothing" often creates a false dilemma. Additional assessment, a time-limited plan, a second opinion, ethics consultation, transfer, or a change in communication may reduce the conflict. An option that is unlawful, clinically unavailable, or based on a false factual assumption should not be presented as equally viable, but the reason for excluding it should be stated.

A defensible recommendation acknowledges its moral cost. It explains why the supporting reasons are stronger in this case, how foreseeable harms will be reduced, and what remains uncertain. Ethical analysis does not guarantee a single answer. It does require more than intuition, authority, or a completed checklist.

1.4 Case workshop

1.4.1 Case 1: The requested antibiotic

Nadia, aged 36, attends a primary-care practice with four days of nasal congestion, sore throat, dry cough, and fatigue. She has no shortness of breath, her observations are normal, and the examination does not suggest a bacterial infection. The doctor expects the illness to resolve without antibiotics. Nadia says that she cannot afford to miss another shift at work and recalls recovering quickly after receiving an antibiotic for a similar illness. She has already been told by a colleague that another practice "always gives treatment". The waiting room is full, and the consultation is running late. The doctor must decide what to recommend and how to respond to Nadia's request.

1.4.1.1 Questions for discussion

1. Which facts support the clinical assessment, and what uncertainty remains?
2. Who is affected by the prescribing decision, and which interests are ethically relevant?
3. How would consequentialist, duty-based, care, and public-health reasoning approach the request?
4. How do beneficence, non-maleficence, autonomy, and justice apply without being treated as a numerical score?
5. What reasonable options are available besides immediate prescribing or a simple refusal?
6. What should the doctor recommend, and how could the recommendation acknowledge Nadia's concerns without misleading her?

1.4.2 Case 2: One intensive-care bed

During a severe respiratory-infection surge, two patients in the emergency department require invasive ventilation and there is one available intensive-care bed. Mr Petrov, aged 76, has severe chronic obstructive pulmonary disease and an estimated 40% chance of surviving to hospital discharge with intensive care. Ms Ilieva, aged 48, has acute bacterial pneumonia and an estimated 65% chance of surviving to discharge. Both estimates are uncertain, and both patients were living according to their own acceptable level of function before this illness. A bed may become available at another hospital, but transfer would take at least ninety minutes and either patient could deteriorate

during the journey. The hospital's policy requires allocation according to relevant clinical criteria but does not specify a tie-break procedure for this situation.

1.4.2.1 Questions for discussion

1. Which clinical facts require confirmation before the allocation decision is made?
2. Which possible criteria are relevant to justice, and which would amount to unjustified social judgement?
3. How would a utilitarian analysis differ from a rights-based or care-ethics analysis?
4. Should age influence the decision directly, indirectly through prognosis, or not at all? Justify the distinction.
5. What options could reduce the conflict, and what risks does each option create?
6. Which allocation process and decision are most defensible, and how should they be explained to the patient who does not receive the bed and to their family?

1.4.3 Case 3: The undocumented medication error

Dr Ivanov, a newly qualified doctor, notices that his patient received twice the intended dose of an intravenous antibiotic. The patient has no symptoms, their renal function remains stable, and serious injury appears unlikely, although further observation is appropriate. Dr Ivanov tells the supervising consultant, who replies that recording or disclosing a harmless error will only cause anxiety and invite a complaint. The consultant instructs him to correct the prescription quietly. Dr Ivanov has not yet checked the hospital's incident-reporting policy and is concerned that challenging the consultant may affect his assessment and future training opportunities.

1.4.3.1 Questions for discussion

1. What additional clinical, professional, and institutional information should Dr Ivanov obtain?
2. Which duties and virtues are engaged by the error, the instruction, and the power imbalance?
3. Does the absence of detected physical injury mean that no harm has occurred or could occur?
4. How would consequentialist, deontological, virtue, and care-ethics approaches assess silence and disclosure?
5. Which actions are open to Dr Ivanov, including routes for advice or escalation, and what are their foreseeable costs?
6. What should he do first, how should he communicate with the consultant and patient, and which parts of the decision require current professional or policy verification?

1.4.4 Case 4: Preventive surgery under uncertainty

Elena, aged 34, requests bilateral risk-reducing mastectomy after her mother and maternal aunt were treated for breast cancer. Genetic testing has found no recognised pathogenic variant. A specialist assessment places her risk above that of the general population but below the level at which the multidisciplinary team usually recommends preventive surgery. Enhanced surveillance is available. Elena understands that surgery cannot remove all cancer risk and may cause complications, altered sensation, and a need for further procedures. She has followed surveillance for two years but describes each appointment as intolerable and believes surgery would allow her to plan her life without constant fear. Her partner supports whichever decision she makes, while her sister believes grief and anxiety are driving the request. The surgeon must decide whether to offer the operation, seek further assessment, or decline.

1.4.4.1 Questions for discussion

1. Which facts about risk, alternatives, psychological distress, and expected outcomes are needed for a sound analysis?
2. How should Elena's own account of benefit and harm relate to the surgeon's clinical judgement?
3. Does respect for autonomy require the surgeon to provide the requested operation? Why or why not?
4. What would consequentialism, deontology, virtue ethics, care ethics, and principlism each add to the analysis?
5. Which interests of Elena's partner and sister are relevant, and which parts of the decision remain Elena's alone?
6. What course of action is most defensible, how could its burdens be reduced, and how should the surgeon explain it?

1.5 Applied class exercise

Work in small groups and select one case from the workshop. Complete the comparison in Table 1.3 using short, specific reasons rather than scores. Each group should prepare a three-minute recommendation that identifies the main uncertainty, defends one option, explains why the strongest alternative was rejected, and states what information could change the decision.

Table 1.3: Option comparison for the applied exercise.

Option	Reasons supporting it	Reasons against it	Uncertainty, safeguards, and verification needed
Option A			
Option B			
Additional or compromise option			

After each presentation, another group should offer the strongest reasoned objection. The presenting group may revise its recommendation, but it must explain which new reason changed the balance. Record any unresolved disagreement as precisely as possible: whether it concerns facts, interpretation of a principle, the weight of a moral claim, or the applicable legal or professional rule.

1.6 Self-check

1. Why is a sincerely held personal belief not yet a complete ethical argument?
2. Give an example of an ethical problem that is not a genuine ethical dilemma.
3. Explain why consequentialism and utilitarianism should not be used as interchangeable terms.
4. What is the difference between specifying a principle and balancing competing principles?
5. Why can neither a legal rule nor an institutional policy replace ethical justification?
6. Choose one workshop case and write a recommendation of no more than 150 words. State the decision, the two strongest reasons for it, its most serious moral cost, one safeguard, and the fact or rule that would most likely make you reconsider.

2 Autonomy implementation in clinical practice

Mrs Georgieva, aged 78, is advised to undergo a below-knee amputation for a gangrenous diabetic foot. She can explain that infection may lead to sepsis and death, yet she says that she would rather accept that risk than lose her leg. Her son insists that she is confused and tells the surgeon that he consents on her behalf.

The clinical recommendation may be clear, but consent cannot be inferred from the expected benefit of treatment. The team must establish whether Mrs Georgieva can make this particular decision, whether her choice is sufficiently informed and voluntary, what authority her son has, and how refusal should be managed without abandoning her care.

> **i** Class focus
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> This class prepares you to conduct a valid consent discussion, recognise and address threats to voluntariness, assess and support decision-making capacity, and distinguish ethical reasons from the legal rules governing adults, children, and treatment without consent.

2.1 Essential concepts

2.1.1 Autonomy and relational decision-making

Autonomy is a person's ability and opportunity to direct their life according to their values. Respect for autonomy requires more than accepting a stated preference. The person needs suitable information, freedom from controlling pressure, and a genuine opportunity to consider the available options. The professional must listen closely enough to understand what the decision means to that person.

Autonomy does not require patients to decide in isolation. Many people want help from a partner, relative, friend, faith adviser, or another trusted person. Some prefer to delegate parts of the discussion or ask the doctor to recommend an option. These choices can express autonomy when they reflect the patient's own wishes. Family participation becomes problematic when relatives filter information, answer in the patient's place, threaten withdrawal of care or support, or prevent the patient from speaking privately.

This relational understanding avoids two errors. The first is to assume that family involvement always weakens autonomy. The second is to treat a family-centred decision as voluntary merely because it is described as cultural tradition. The clinician should ask the patient whom they want involved, what role that person should have, and whether they would like an opportunity to speak alone.

2.1.2 Informed consent

Informed consent is a continuing process in which a person receives and understands relevant information, decides voluntarily, and authorises a particular intervention. A signature may document the process, but it cannot replace it. Consent obtained without adequate communication, decision-making capacity, or voluntariness is not repaired by a completed form.

Table 2.1: Elements of a valid consent process.

Element	Question for practice
Relevant information	Has the person received an understandable account of the condition, recommended option, reasonable alternatives, expected benefits, material risks and burdens, uncertainty, and the option of no intervention?
Decision-making capacity	Can the person make this decision at this time after receiving appropriate support?
Voluntariness	Is the choice free from coercion, manipulation, and pressure that overwhelms the person's own values?
Authorisation	Has the person clearly agreed to the specific intervention, and do they still agree when it is due to begin?

Assent is a person's affirmative agreement when they do not have independent legal authority to consent. It is often discussed in relation to children, but the underlying practice is wider: explain the proposed care in an accessible way, invite participation, attend to distress or resistance, and give the person's views appropriate weight. Assent does not automatically replace legally required consent, and passive compliance is not assent.

The terms **capacity** and **competence** are used differently across jurisdictions. In this class, *decision-making capacity* means the functional ability to make a particular healthcare decision at a particular time. *Legal competence* should be used only when a relevant legal system gives it a defined meaning. The common claim that clinicians assess capacity while courts alone determine competence is not a universal rule and should not be transferred uncritically into Bulgarian practice.

Confidentiality and privacy support autonomous decision-making, but their detailed rules belong in Practical Class 3. The phrase "right to confidence" is misleading in English. *Confidence* describes trust or assurance; **confidentiality** is the duty to protect information, while **privacy** concerns access to a person's body, space, and personal life.

2.2 Ethical framework

Respect for autonomy protects people from unwanted interference and from being used merely as a means to professional, institutional, or family goals. It also supports truthful communication because a person cannot direct their care when relevant options or consequences are concealed. Deontological reasoning emphasises duties of respect and honesty, while virtue ethics asks whether the clinician shows integrity, patience, and practical wisdom during the discussion.

Beneficence and non-maleficence remain relevant. The clinician should recommend care that is reasonably expected to help and should warn against avoidable harm. These duties do not normally justify taking control of a decision from a person who can make it. Respecting refusal is compatible with continued efforts to correct misunderstandings, relieve fear, offer alternatives, and preserve the therapeutic relationship.

Autonomy is strongest as a protection against unwanted intervention. It does not give a patient an unrestricted claim to a treatment that the clinician considers harmful or clinically inappropriate. A doctor who declines such a request should explain the clinical reasoning, consider a second opinion where appropriate, and continue to provide other suitable care. Professional integrity and fair use of resources remain part of the decision.

Voluntariness can be impaired without an explicit threat. A clinician may exaggerate benefits, minimise alternatives, choose a frightening description, or present only one option as morally acceptable. Relatives may make continued housing or financial support conditional on the patient's agreement. The ethical question is whether the influence prevents the person from deciding ac-

cording to their own values. Advice, persuasion through reasons, and emotional support are not necessarily coercive, but their effect must be considered in the context of dependency and unequal power.

An apparently unwise choice does not establish incapacity. Capacity concerns how the decision is made, not whether the outcome agrees with medical advice. Serious risk does justify a careful assessment and a more detailed conversation because the person must understand what is at stake. It does not justify changing the test until the desired answer is obtained.

2.3 From principle to practice

2.3.1 Conducting the consent discussion

Consent discussions should begin early enough for questions, reflection, and consultation with trusted people where the clinical situation allows. The treating professional should explain the recommendation in plain language and adapt the pace, format, and amount of information to the person. A professional interpreter is preferable when language differences could affect the decision; a relative may have interests of their own, omit sensitive information, or lack the vocabulary required for accurate interpretation.

The information required is shaped by both the intervention and the patient. A risk may matter because it is frequent or severe, but a less common risk may also be material when it threatens an activity or outcome that this patient values. The clinician should therefore ask what matters to the person rather than rely only on a standard list. Clinical uncertainty should be stated openly. Overconfidence can be as misleading as omission.

A consent conversation

1. **Invite participation.** Ask what the person already understands, how much detail they want, and whom they want involved.
2. **Explain the decision.** Describe the condition, purpose of the proposed intervention, reasonable alternatives, and the option of no intervention.
3. **Compare outcomes.** Discuss expected benefits, material risks, burdens, uncertainty, and what may happen with each option.
4. **Explore values and pressure.** Ask what matters most, what worries the person, and whether anyone is making it difficult for them to choose freely.
5. **Check understanding.** Invite the person to explain the options and consequences in their own words; correct misunderstandings without turning the exchange into an examination.
6. **Confirm and record.** Establish the specific decision, document the discussion proportionately, and check again before the intervention if time or circumstances have changed.

A patient may decline some information or ask for another person to receive it. This preference should be explored: the clinician needs to know whether it is voluntary, whether the person understands the general nature of the decision, and whom they authorise to receive information. Under the Bulgarian Health Act, a patient may decline specified information and may authorise another person in writing to receive information instead. The statutory exception concerning danger to other people's health must be kept separate from a general claim that clinicians may override a wish not to know.

2.3.2 Form, scope, and duration of consent

Consent may be expressed orally, in writing, or through a clear action. Non-verbal or "implied" consent is limited to the immediate, evident act: extending an arm after an explanation may authorise a blood-pressure measurement, but it does not authorise unrelated tests. Silence, lack of resistance, admission to a teaching hospital, or a relative's agreement does not establish consent.

Bulgarian law requires written information and written consent for surgery, general anaesthesia, invasive procedures, and other diagnostic or therapeutic methods that create increased risk or temporarily alter consciousness. In other situations, the form of consent should match the intervention, current professional standards, and local documentation requirements. A signed form records agreement; the health record should also preserve the information discussed, significant questions, the patient's expressed priorities, and any interpreter or decision support used.

Consent is specific. Authorisation for one procedure does not normally cover an additional intervention discovered after anaesthesia, unless the prior discussion addressed that possibility or a valid emergency exception applies. Consent is also continuing. A delay, change in diagnosis, new treatment option, altered risk, or change in the patient's wishes may require a renewed discussion.

The person may withdraw consent or refuse continuation. If withdrawal occurs during a procedure, the clinician should stop as soon as this can be done safely and explain any immediate danger created by stopping. The Bulgarian Health Act sets rules for documenting refusal and permits its withdrawal. Treatment against a person's will requires a specific legal basis.

> Ethics and current Bulgarian law
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> The statutory summary in this class was checked against the Bulgarian Ministry of Health's current presentation of Health Act Articles 87–92 on 17 August 2026. Article 90(4) states that when refusal places the patient's life at risk, the head of the medical establishment may decide that life-saving treatment should be provided. This legal provision does not settle the ethical question and should not be generalised to another jurisdiction. A real contested refusal requires current legal, senior clinical, and ethics advice.

2.3.3 Assessing and supporting decision-making capacity

Capacity should be assessed when there is a specific reason for concern, such as delirium, altered consciousness, marked inconsistency, inability to engage with relevant information, or evidence that a disorder is affecting the decision. Age, disability, psychiatric diagnosis, intoxication, unusual beliefs, and disagreement with the team do not by themselves establish incapacity.

Support comes before a conclusion of incapacity whenever time permits. Treat pain, hypoxia, fever, intoxication, or other reversible causes. Choose a time when attention is best, reduce distractions, use hearing or communication aids, provide a professional interpreter, divide information into manageable parts, and allow a trusted supporter if the patient wants one. Communication difficulty is not evidence that the person cannot decide.

The functional questions in Table 2.2 provide a clinical reasoning aid. They do not constitute a complete Bulgarian statutory test and must be used with current local law and professional guidance.

Table 2.2: Functional guide to supported capacity assessment.

Ability	Functional question	Possible support
Understand	Can the person grasp the nature and purpose of the decision, the main options, and the reasonably foreseeable consequences?	Plain language, visual material, repetition, interpreter, correction of sensory barriers.
Retain	Can the person hold the relevant information long enough to make the decision?	Written or recorded information, shorter discussions, prompts, repeated sessions.
Use or weigh	Can the person apply the information to their own situation and compare reasons for the available options?	Explore values, correct false factual beliefs, treat reversible distress, allow time.
Communicate	Can the person express a stable choice by speech, writing, gesture, assistive technology, or another reliable method?	Communication aid, specialist support, agreed yes/no method, accessible environment.

A person does not need to repeat medical terminology. The assessment should establish whether they understand the information that matters to the decision. A false belief may be relevant when it prevents the person from applying the information to themselves, but a value that the clinician finds unusual is not a cognitive failure. The reasoning and support provided should be documented, together with the decision, timing, participants, and factors that may cause capacity to fluctuate.

2.3.4 When an adult cannot decide

If the decision can safely wait, reversible impairment should be treated and the discussion repeated. When delay is not possible, the team should identify the legally authorised decision-maker or other applicable statutory route. Relatives can provide evidence about the person's wishes, values, usual functioning, and relationships, but kinship alone should not be assumed to confer authority to consent for an adult.

Ethical substitute decision-making should remain centred on the patient. Previously expressed wishes and values should guide the decision where they are known. If they do not determine the answer, the team should compare all foreseeable benefits and burdens for that person, consider the least restrictive reasonable option, and avoid substituting the family's preferences for the patient's interests.

For higher-risk procedures when life is immediately threatened, Article 89 of the Bulgarian Health Act specifies conditions under which care may proceed without written informed consent when consent cannot be expressed or obtained in time. This is not "implied consent" from an unconscious person. It is a statutory exception that must be documented and limited to what the emergency requires.

2.3.5 Children and adolescents

Children should receive honest, age-appropriate information and take part in decisions to the extent they can. Their assent or dissent may reveal fear, misunderstanding, pain, or a settled view about the burdens of treatment. Parental authority exists to protect the child and is constrained by the child's interests; it is not ownership.

The current Bulgarian statutory structure is summarised in Table 2.3. The terms *minor* and *child* are used differently in English sources, so the age range should always be stated.

Table 2.3: Bulgarian consent structure for children and adolescents.

Age or situation	Bulgarian consent structure	Ethical task
Under 14	A parent or guardian expresses informed consent, subject to statutory exceptions.	Inform the child appropriately, seek assent where possible, and investigate resistance or distress.
Age 14–17	The young person's informed consent and the consent of a parent or custodian are both required for medical activities.	Support the young person's developing autonomy and address disagreement without reducing their role to a formality.
Age 16–17: specified preventive care	Parental or custodian consent is not required for the health consultations, preventive examinations, and tests specified by ministerial regulation.	Verify that the activity falls within the current regulation; do not extend the exception to unrelated treatment.
Parent or young person refuses necessary care	The applicable statutory, emergency, safeguarding, and escalation procedures must be identified.	Clarify urgency, seek a less restrictive agreement, protect the child, and distinguish ethical reasoning from legal authority.

Rules such as the UK doctrine of *Gillick* competence or North American categories of emancipated minors may be useful comparisons, but they are not Bulgarian law. Detailed questions about advance decisions and treatment near the end of life are addressed in Practical Class 5. Their legal effect must be checked in the relevant jurisdiction rather than inferred from consent rules for a present decision.

2.4 Case workshop

2.4.1 Case 1: Refusal of amputation

Mrs Georgieva, aged 78, has a gangrenous diabetic foot. The vascular team recommends a below-knee amputation because infection may progress to fatal sepsis. She has mild short-term memory impairment but can describe the proposed operation, the likelihood of death without it, and the expected effect on her mobility. She says that bodily integrity and remaining at home matter more to her than survival after amputation. Her son insists that memory impairment makes her incapable and says that he consents to surgery. The operation is urgent but there is time for further assessment and discussion.

2.4.1.1 Questions for discussion

1. What facts and uncertainties must be clarified before assessing Mrs Georgieva's decision?
2. How should the team support her understanding, memory, and ability to compare the options?
3. Does the content of her refusal show incapacity, or does it express a value the team finds difficult to accept?
4. What role should her son have, and what authority should not be assumed from kinship alone?
5. How do respect for autonomy, beneficence, non-maleficence, relational care, and current Bulgarian law bear on the decision?
6. What should the team do next, and how should it communicate with Mrs Georgieva and her son?

2.4.2 Case 2: Consent through a family interpreter

Ms Marinova, aged 60, has early-stage breast cancer. The surgeon recommends breast-conserving surgery followed by radiotherapy, while mastectomy is also clinically possible. Ms Marinova speaks limited Bulgarian and attends with her adult daughter, who interprets. The daughter frequently answers before her mother can speak and says that the family has chosen mastectomy because a family friend had a recurrence after breast-conserving surgery. Ms Marinova nods but appears uncertain when the surgeon discusses the different burdens of the options. A professional interpreter is available the following morning, and waiting will not affect the clinical outcome. The daughter objects to another appointment and asks the surgeon to obtain written consent now.

2.4.2.1 Questions for discussion

1. Which barriers prevent the surgeon from knowing whether Ms Marinova is informed and deciding voluntarily?
2. What are the benefits and risks of using a relative as interpreter in this discussion?
3. How can the surgeon respect family involvement while creating space for Ms Marinova's own questions and preferences?
4. What information about alternatives, recurrence, treatment burden, and uncertainty must be checked or explained?
5. Is postponing the consent discussion justified, and what moral cost might delay create for the family?
6. How should the next discussion be organised and documented?

2.4.3 Case 3: An adolescent refusing cancer treatment

Denis, aged 15, has a newly diagnosed osteosarcoma for which chemotherapy and limb-sparing surgery offer a high probability of cure. Without treatment, progressive disease is expected. Denis understands that the treatment may save his life but fears long-term adverse effects and loss of sporting ability. He says he would prefer a shorter life without chemotherapy. His parents want treatment and ask the team to begin despite his active refusal. The situation is serious, but treatment does not need to start during this consultation.

2.4.3.1 Questions for discussion

1. What should Denis be told, and how should his understanding and reasons be explored?
2. What is the difference between his capacity to participate, his assent or dissent, and legal authority to consent under Bulgarian law?
3. How should the parents' authority, distress, and duty to protect Denis be understood?
4. Which features might change the ethical weight given to Denis's refusal without stereotyping adolescents as incapable?
5. What supportive, psychological, clinical, safeguarding, or legal steps could reduce the conflict?
6. If disagreement persists, what course should the team recommend, and how should it justify and communicate that recommendation?

2.4.4 Case 4: Capacity that changes during the day

Mrs Stoyanova, aged 72, has bipolar disorder and is admitted with acute cholecystitis. In the morning she is calm, understands the proposed laparoscopic operation and alternatives, and gives written consent. Later, after opioid analgesia and a rising fever, she becomes disorientated, accuses the team of intending to harm her, tears up the form, and refuses to go to theatre. Surgery can be delayed for several hours while reversible causes are treated, but a longer delay may increase the risk of

complications. Her daughter holds a general financial power of attorney and demands that the morning consent be followed.

2.4.4.1 Questions for discussion

1. Which factors may be affecting Mrs Stoyanova's ability to decide, and which should not be treated as proof of incapacity?
2. What practical support and treatment should precede a renewed capacity assessment?
3. How should the team interpret the conflict between her morning agreement and later refusal?
4. Does the daughter's financial power of attorney establish healthcare decision-making authority?
5. Which options balance the risks of delay, unwanted surgery, and preventable deterioration?
6. What should be documented, who should be consulted, and what event would trigger reassessment of the plan?

2.4.5 Case 5: An unexpected finding during surgery

Mr Kolev consents to removal of a nasal polyp. The discussion covers removal of the polyp and the possibility of taking tissue for examination, but not wider resection. During the operation, the surgeon finds a suspicious lesion on a nearby structure. A rapid pathological assessment suggests malignancy. Wider surgery now could remove the lesion but may alter appearance and function. Stopping after biopsy would require a second anaesthetic and operation, yet a short delay is unlikely to change the prognosis. Mr Kolev is under general anaesthesia, and no authorised representative is available.

2.4.5.1 Questions for discussion

1. What exactly did Mr Kolev authorise, and which facts about the new finding remain uncertain?
2. Does the benefit of avoiding a second operation justify exceeding the scope of consent?
3. How would a genuine immediate threat to life alter the ethical and legal analysis?
4. What do respect for autonomy, beneficence, non-maleficence, professional integrity, and law each contribute?
5. What could the pre-operative team have discussed to prepare for a foreseeable unexpected finding?
6. What should the surgeon do, and how should the decision and later conversation with Mr Kolev be handled?

2.5 Applied class exercise

Work in groups of three using Case 2 or Case 5. One student is the patient, one is the doctor, and one observes. The doctor has five minutes to conduct the central part of the consent discussion without reading from a form. The patient should introduce one concern that changes which risk or benefit matters most to them.

The observer should record whether the doctor established the decision to be made, explained reasonable options and no intervention, explored the patient's values, checked voluntariness, tested understanding without interrogation, and confirmed the scope of authorisation. Repeat the discussion after feedback, changing roles. The group should finish by writing one sentence that would belong in the health record and one sentence that would be inadequate because it records only a signature or a conclusion.

2.6 Self-check

1. Why is a signed form evidence of consent rather than consent itself?
2. Give two examples of influence that may support a decision and two that may undermine voluntariness.
3. Why does an apparently unwise refusal not establish incapacity?
4. What support should be attempted before concluding that a person cannot make a decision?
5. Distinguish the role of assent from the legal authority to consent for treatment of a child.
6. Choose one workshop case and write a recommendation of no more than 180 words. State who should decide, what further information or support is required, the strongest reason for your recommendation, its main ethical cost, and the current legal or professional rule that must be verified.

3 Confidentiality

A competent patient is admitted with a new diagnosis of cancer. His wife asks the ward doctor for the result before she visits him, explaining that she needs time to prepare the family. The doctor knows that the couple are close, but the patient has not authorised disclosure. Refusing to answer may appear cold; answering may disclose information that the patient wanted to communicate himself.

The problem is not solved by asking whether the wife has good intentions. The doctor must establish what the patient wants, which information is necessary for care, whether another person's safety is at stake, and which ethical, professional, and legal rules apply. Confidentiality protects the patient's control over personal information, but it is neither secrecy at any cost nor permission to share whenever disclosure seems helpful.

> **Class focus**
>
> This class prepares you to identify confidential information, decide when sharing is justified, and defend the extent and method of a disclosure. The cases require you to separate an ethical reason to disclose from a legal power or duty to do so.

3.1 Essential concepts

3.1.1 Confidentiality and privacy

Privacy concerns a person's control over access to their body, personal space, relationships, communications, and information. **Confidentiality** is the duty placed on a person or institution that receives private information in a relationship of trust. A clinician may invade bodily privacy during an examination without disclosing information, or breach confidentiality without entering the patient's physical space. The two concepts overlap, but they are not interchangeable.

The traditional expression **medical secrecy** emphasises the physician's promise not to reveal what is learned in practice. Modern care requires a broader account because information is handled by teams, laboratories, administrative staff, digital systems, insurers, and public authorities. The practical duty is therefore to protect information from unjustified access, use, loss, and disclosure while allowing necessary information to support safe care.

Confidentiality applies to more than a diagnosis. It includes the fact that a person sought care, appointment details, test results, images, recordings, prescriptions, genetic findings, family and social information, professional opinions, and data that identify a person indirectly. A rare condition, location, occupation, and date may identify someone even when their name has been removed. Information learned from a relative during the patient's care may also require protection.

Personal data identify or can reasonably be linked to a person. **Pseudonymised data** use a code in place of direct identifiers, but a key or other information can restore the link; they remain personal data. **Anonymised data** cannot reasonably be linked back to an individual by the means likely to be used. Removing a name does not necessarily anonymise a record, especially when the clinical details are unusual.

Data protection is the legal and organisational framework governing how information is collected, used, stored, shared, corrected, and destroyed. Confidentiality is one ethical and professional

component of that framework. A disclosure may breach confidence even when it causes no obvious injury, while a data-protection failure may occur without a clinician deliberately telling anyone.

3.1.2 Why confidentiality matters

Confidentiality protects autonomy because patients have a strong claim to influence who knows intimate facts about them. It also limits avoidable harm. Disclosure of a psychiatric diagnosis, reproductive history, infectious condition, or genetic result may expose a person to stigma, discrimination, family conflict, or financial loss.

Trust gives the duty a wider clinical and public value. Patients who expect casual disclosure may conceal symptoms, avoid testing, or delay care. This can harm the patient and, in some circumstances, other people. The public interest therefore supports a confidential health service as well as carefully limited disclosure to prevent serious harm.

Confidentiality is also an expression of fidelity. The patient becomes vulnerable by sharing information needed for care; the professional accepts a corresponding responsibility not to use that information for curiosity, entertainment, personal advantage, or an unrelated purpose. The duty continues when a case is memorable, when the clinician is off duty, and after the clinical relationship ends.

3.2 Ethical framework

3.2.1 Sharing for care

Modern treatment depends on appropriate information sharing. A laboratory must receive enough information to process a specimen, a consultant needs the relevant history, and a nurse needs the current plan. Sharing within a team is justified by the purpose of direct care, the patient's reasonable expectations, and the responsibilities of each recipient. It is not justified merely because the recipient works in the same hospital.

The practical tests are purpose, relevance, and access. The person receiving the information should have a legitimate role in the patient's care; the information should be relevant to that role; and the method should be reasonably secure. Curiosity about a colleague, neighbour, public figure, or unusual case does not create a clinical need to know.

Consent for information sharing is not identical to consent for treatment. Some necessary clinical processing has a legal basis other than consent under data-protection law. Even so, patients should ordinarily be told how information is used, their objections should be taken seriously, and express authorisation should be obtained before disclosure to relatives, employers, insurers, or other third parties unless another lawful basis applies.

3.2.2 The minimum necessary disclosure

When sharing is justified, the recipient does not automatically need the full record. The clinician should disclose only the information required for the stated purpose. An employer asking whether a person can safely perform a task may need a functional opinion, not the diagnosis and complete history. A school may need an emergency plan, not unrestricted access to a child's record.

Minimum disclosure concerns content, recipient, timing, and method. Correct information sent to the wrong address remains a breach. A justified warning given in a crowded corridor may expose more information than necessary. The professional must therefore verify identity and authority, choose a secure channel, and record the reason and extent of a non-routine disclosure.

3.2.3 Disclosure without consent

Confidentiality is a strong presumption, not an absolute rule. Disclosure without consent may be required or permitted by a specific law, necessary for safeguarding, or ethically justified to prevent a serious threat to another person. The categories must not be collapsed. An ethical argument that warning is desirable does not itself provide legal authority; a legal duty to report does not remove the need to minimise harm and communicate respectfully.

The seriousness, probability, proximity, and preventability of harm matter. A vague possibility of embarrassment is different from a credible threat of grave injury. The potential victim's identifiability may matter because a targeted warning can sometimes prevent harm more effectively than broad disclosure. Less intrusive alternatives should be explored, including persuading the patient to disclose, arranging urgent treatment, limiting a dangerous activity, or obtaining senior and legal advice.

The clinician should not promise absolute secrecy before hearing what a patient wishes to say. They can explain that information is kept confidential within defined limits and that any proposed disclosure will, where safe and possible, be discussed with the patient first.

A disclosure decision

1. **Clarify the information and purpose.** What is known, who is requesting it, and what decision would disclosure support?
2. **Check consent and authority.** What has the patient authorised, and does a current legal rule require or permit sharing?
3. **Assess the threatened harm.** Consider severity, probability, urgency, the people at risk, and the uncertainty in the evidence.
4. **Explore less intrusive options.** Seek voluntary disclosure, practical risk reduction, or anonymised advice where possible.
5. **Limit and direct the disclosure.** Choose the authorised recipient, minimum information, secure method, and appropriate timing.
6. **Consult, communicate, and record.** Obtain senior, safeguarding, data-protection, ethics, or legal advice when time allows; tell the patient unless doing so would increase the danger; document the reasoning and review the result.

3.2.4 Children, adolescents, and adults who cannot decide

Children and adolescents have privacy interests and should be given age-appropriate explanations about confidentiality. Parental responsibility does not make every disclosure automatically beneficial. The clinician should consider the young person's developing autonomy, the nature of the information, the risk of harm, and the current Bulgarian consent and safeguarding rules described in Practical Class 2.

An adolescent's request for confidentiality may enable them to seek advice about substance use, sexuality, mental health, or violence. Automatic disclosure can drive risk underground. A serious safeguarding concern may nevertheless justify sharing. The clinician should explain the limits of confidentiality, involve the young person in planning any disclosure, and disclose no more than protection requires.

When an adult lacks decision-making capacity, incapacity does not erase confidentiality. Information may be shared to support a lawful decision about that person's care, but relatives do not gain unrestricted access merely because they are concerned. The team should identify who has authority, what information is necessary, and how the person's prior wishes and present dignity can be respected.

3.2.5 Genetic information and relatives

Genetic information concerns one patient but may reveal a risk shared by biological relatives. This creates tension between an individual account, in which the result belongs to the patient, and a familial account, in which the information describes a biological relationship. Neither account supplies an automatic answer.

The clinician should first help the patient understand the implications, explore reasons for refusing disclosure, and offer assistance with communication. Non-consensual disclosure requires a careful assessment of the seriousness and preventability of harm, the reliability of the result, the relative's ability to act, and the applicable law and professional guidance. A warning framed around the relative's possible risk may sometimes reveal less about the patient, but it can still allow identification and must not be treated as anonymous by assumption.

3.2.6 Confidentiality after death

Ethical reasons for confidentiality continue after death. Respect for the deceased, promises made during life, effects on relatives, and public confidence all support continued restraint. Other considerations may justify access, including investigation of care, administration of an estate, or prevention of serious familial harm.

Current Bulgarian law gives specified heirs and relatives access to a deceased patient's health information and medical documents. This differs from rules in some foreign textbooks. Access under law does not make insensitive or unrestricted discussion ethically neutral. Staff should verify the requester's status, follow the medical establishment's procedure, and disclose through an authorised channel.

3.2.7 Digital communication and clinical images

Telephone calls, email, messaging, video consultations, photographs, and electronic records change the route of communication but not the duty. Before a telephone disclosure, staff should verify the caller, confirm the patient's authorisation, and consider calling back through a known number. Personal devices and consumer messaging services should not be used for identifiable clinical material unless an authorised system and policy permit it.

Clinical photographs require a defined care or educational purpose, proportionate consent or another valid basis, secure storage, and controlled access. A closed social-media group is not equivalent to a clinical consultation system. Removing a name may be insufficient when a face, tattoo, rare diagnosis, location, or date permits recognition.

Accidental breaches require action. The professional should contain the disclosure where possible, report it through the medical establishment's information-governance process, preserve relevant facts, and cooperate with assessment of risk and notification duties. Concealing an error can enlarge both the harm and the loss of trust.

Current Bulgarian and EU rules

The Bulgarian Health Act and EU data-protection law provide several lawful grounds for handling health information; explicit consent is not the only ground. The Health Act also regulates disclosure, access to records, access after death, and professional secrecy. These rules were checked against official sources on 17 August 2026. A real disclosure decision still requires the current consolidated law, the medical establishment's procedure, and specialist advice where the consequences are serious.

3.3 From principle to practice

Requests from relatives should begin with the patient. The clinician can acknowledge the relative's concern, receive information from them, and explain the confidentiality boundary without confirming the patient's condition. Listening does not require reciprocal disclosure. If the patient wants the relative involved, the team should clarify what may be shared and whether that authorisation continues as circumstances change.

Conversations should be planned with the same care as written records. Ward rounds, lifts, cafeterias, teaching rooms, and online meetings can expose information to unintended listeners. Educational discussion should use no more detail than needed and should follow institutional rules for consent and de-identification. A vivid case does not become public property because it is educationally useful.

The health record should show the decision rather than a defensive formula. For an unusual disclosure, record the request, relevant facts, patient discussion, legal or professional basis considered, advice obtained, alternatives rejected, recipient, content, method, and plan for review. This makes the reasoning open to later scrutiny and supports continuity if another clinician must manage the risk.

3.4 Case workshop

3.4.1 Case 1: The waiting spouse

Mr Petrov, aged 58, is admitted with abdominal pain. Imaging suggests pancreatic cancer, but tissue confirmation is pending. He is alert and has asked the consultant not to discuss the possible diagnosis with anyone until he has spoken to his adult children. His wife arrives while he is having another test and asks the ward doctor whether the scan showed cancer. She explains that they have been married for thirty years and that she needs to prepare the family before he returns. She becomes distressed when the doctor hesitates.

3.4.1.1 Questions for discussion

1. What has Mr Petrov authorised, and which information can the doctor receive from his wife without disclosing information in return?
2. Do marriage, good intentions, or emotional distress create authority to receive the result?
3. How can the doctor respond honestly without confirming or indirectly revealing the diagnosis?
4. What should be discussed with Mr Petrov when he returns, and how should any later authorisation be recorded?
5. Which ethical considerations support confidentiality, and what is the moral cost of the recommended response?

3.4.2 Case 2: The bus driver with seizures

Ms Angelova, aged 32, drives an intercity bus and has continued seizures despite treatment. Her neurologist explains that driving passengers presents a serious risk and tells her to stop immediately while the licensing and occupational procedures are clarified. She refuses, saying that she will lose the household's only income and has never had a seizure at work. At review two weeks later, she admits that she is still driving full routes and asks the neurologist to keep the conversation confidential.

3.4.2.1 Questions for discussion

1. Which facts about seizure control, occupational duties, alternatives, and current law must be established?
2. How serious, probable, and preventable is the threatened harm, and who is at risk?
3. What steps could reduce the danger without disclosure?
4. If disclosure becomes justified or required, who should receive what minimum information?
5. What should the neurologist say to Ms Angelova and record before and after the decision?

3.4.3 Case 3: The adolescent's request

Paula, aged 17, has an inherited metabolic disorder and attends an annual specialist review with her father. She asks to speak to the doctor alone and discloses occasional use of stimulants at parties. The combination with dehydration could precipitate a metabolic crisis. She understands the warning and wants help reducing the risk, but insists that her father must not be told because he has threatened to make her leave home if she uses drugs. There is no evidence of an immediate overdose or current crisis.

3.4.3.1 Questions for discussion

1. What should Paula understand about confidentiality and its limits before the discussion continues?
2. How do her age, understanding, health risk, and dependence on her father affect the ethical analysis?
3. What further questions are needed about safeguarding, coercion, frequency of use, and available support?
4. Would disclosure to her father reduce the risk, increase it, or do both in different ways?
5. Recommend a plan that addresses safety, communication, documentation, and the Bulgarian rules that must be verified.

3.4.4 Case 4: The photograph in the group chat

A junior doctor treats a child with a rare rash. Wanting a rapid second opinion, she photographs the affected areas on her personal telephone and posts the images with the child's age, admission date, and hospital in a private messaging group of eighty clinicians. She omits the name. A participant recognises the child from the combination of details and forwards the post to a dermatologist outside the group. The parents had agreed to clinical photography for the health record but were not asked about online consultation.

3.4.4.1 Questions for discussion

1. Which separate decisions concern taking, storing, posting, and forwarding the images?
2. Why does omission of the name fail to establish anonymity?
3. Could the clinical purpose have been achieved through a less intrusive and more secure route?
4. What should the junior doctor and medical establishment do once the breach is discovered?
5. How should the incident be explained to the family without speculation or concealment?

3.4.5 Case 5: A result shared by a family

Mrs Hristova, aged 41, receives a confirmed result showing a hereditary cancer predisposition. Her adult sister may carry the same variant and could consider surveillance if informed and tested. Mrs Hristova refuses any contact with her sister after a longstanding family dispute. She understands

the possible implications but says that the result is hers alone. The genetics team has no clinical relationship with the sister and is uncertain whether non-consensual contact would be lawful.

3.4.5.1 Questions for discussion

1. Which parts of the result concern Mrs Hristova alone, and which describe a familial risk?
2. What information is needed about penetrance, preventability, urgency, and the sister's ability to act?
3. How should the team explore Mrs Hristova's reasons and support voluntary disclosure?
4. Compare continued confidentiality, anonymised advice, indirect contact, and direct warning as possible options.
5. Which ethical reasons support the preferred option, and which legal and professional rules require current verification?

3.5 Applied class exercise

In groups of four, use Case 2 or Case 5. One student represents the patient, one the clinician, one the person potentially at risk, and one an ethics adviser. The group must produce a disclosure plan stating the purpose, lawful or professional basis requiring verification, alternatives attempted, recipient, minimum content, communication method, and documentation.

The clinician then explains the plan to the patient in no more than two minutes. The observer should note whether the explanation avoids threats, false promises of secrecy, and claims that the law settles the ethical question. Reverse the decision and identify which single factual change would make the alternative more defensible.

3.6 Self-check

1. Distinguish privacy, confidentiality, medical secrecy, and data protection.
2. Why is pseudonymised information still personal data?
3. What makes sharing within a healthcare team justified, and what limits it?
4. Give four dimensions of the minimum necessary disclosure.
5. Why does a relative's concern permit the clinician to listen but not necessarily to disclose?
6. Choose one workshop case and write a recommendation of no more than 180 words. State the facts still needed, the strongest reason for and against disclosure, the minimum action proposed, and the current rule that must be verified.

4 Patient-Physician relationship

A woman attends an oncology consultation with her adult son. Before the doctor enters, the son asks that the diagnosis not be disclosed because his mother will "lose hope". During the consultation, the patient asks directly whether the biopsy shows cancer. The doctor must respond to the patient while preserving a workable relationship with a frightened family member who believes concealment is protective.

Clinical relationships are shaped by unequal knowledge, vulnerability, time pressure, and the power to examine, prescribe, certify, admit, discharge, and disclose. Respectful communication can reduce these asymmetries but cannot remove them. The physician-patient relationship therefore requires more than courtesy: it requires disciplined use of professional authority and clear boundaries around the role.

> **Class focus**
>
> This class prepares you to recognise how relationship models, communication choices, and professional boundaries affect an ethical decision. The workshop asks you to respond without abandoning either the patient's agency or the physician's responsibility for safe, honest care.

4.1 Essential concepts

4.1.1 A relationship of trust and unequal power

The **physician-patient relationship** is a professional relationship directed towards the patient's health needs. The patient contributes knowledge of their experience, values, circumstances, and acceptable burdens. The physician contributes clinical knowledge, technical skill, judgement, and access to health services. These contributions are different but both are necessary.

Trust is the patient's willingness to become vulnerable in the expectation that the physician will use their role competently and for proper purposes. Trust should not be confused with obedience. A trusting patient may disagree, request another opinion, or refuse a recommendation. A physician who invites questions does not surrender professional judgement.

Fidelity is faithfulness to the commitments created by the role. It includes honesty, confidentiality, continuity where possible, attention to the patient's welfare, and avoidance of exploitation. **Respect** requires recognition of the patient as a person whose rights and values do not disappear because they are ill. **Empathy** is the effort to understand the patient's perspective and communicate that understanding. Empathy does not require the physician to share the patient's belief or offer an intervention that is clinically inappropriate.

Power arises from more than medical knowledge. The physician controls time, setting, access to records, physical examination, and institutional pathways. Illness, pain, undressing, dependency, stigma, and fear may increase the patient's vulnerability. Professional boundaries channel this power towards care and prevent its use for emotional, sexual, financial, or social advantage.

4.1.2 Relationship models

Models of the relationship are analytical tools rather than fixed personalities. A consultation may move between them as the patient's condition and wishes change.

Table 4.1: Models of the physician-patient relationship.

Model	Physician's role	Patient's role	Main ethical risk
Paternalistic	Selects and recommends the option judged to promote the patient's welfare, with limited patient direction.	Receives protection and may have little influence over the decision.	Values may be imposed and information withheld in the name of benefit.
Informative	Supplies clinical facts and implements the patient's selected option.	Chooses according to established preferences.	The patient may be left without guidance, and medicine may be reduced to a menu of services.
Interpretive	Helps the patient clarify values and recommends the option that fits them.	Examines what matters and chooses with support.	The physician may mistake their interpretation for the patient's own account.
Deliberative	Discusses health-related values and argues for a clinically and ethically defensible option.	Considers reasons and retains authority over voluntary choices.	Persuasion may become manipulation when power or dependency is ignored.

Paternalism is not established merely because the physician makes a firm recommendation. **Paternalism** occurs when the professional overrides or restricts a person's choice for that person's supposed benefit. It may be defensible in a narrow emergency when the patient cannot decide and delay would cause grave harm, but it is not a general model for competent adults.

Shared decision-making combines professional advice with the patient's values. It does not require equal technical knowledge or agreement on every point. The physician should define the clinically reasonable options, explain uncertainty, and make a recommendation when one is warranted. The patient may accept, refuse, or seek another opinion. Autonomy permits refusal of an offered treatment; it does not create an entitlement to an intervention that lacks a reasonable clinical indication.

4.2 Ethical framework

4.2.1 Truth-telling and clinical uncertainty

Honesty supports autonomy, trust, and preparation for the future. Deliberate deception may make consent invalid and prevent the patient from arranging work, relationships, care, or personal affairs. A family request for concealment should therefore be explored but should not silently displace the patient's right to information.

Truth-telling is more than stating facts without regard to effect. The physician should establish what the patient already understands, how much detail they want, and whom they wish to involve. Information can be staged when the clinical picture is evolving, but uncertainty must not be presented as certainty. "The scan raises a serious concern, and we need the biopsy to know more" is honest in a way that either premature reassurance or unsupported finality is not.

A patient may prefer limited information or ask another person to receive detail. This can be an autonomous choice if it is voluntary and the patient understands the general nature of the decision. The physician must still provide enough information to support any consent or refusal and must revisit the arrangement when circumstances change.

Families sometimes ask for concealment because they fear despair, stigma, or cultural disrespect. The clinician can ask what harm they expect, how similar news has been handled in the family, and whether the patient has expressed a preference. This conversation respects the family without treating culture as a rule that overrides the individual.

4.2.2 Breaking bad news

Bad news is information that significantly changes a person's understanding of their health or future. Its effect depends on what the person expected, values, and fears. A recurrence that is clinically treatable may be devastating to one patient; permanent loss of a valued function may matter more than prognosis to another.

Structured protocols such as SPIKES and ABCDE are memory aids, not scripts. They share several practical tasks: prepare the setting and relevant facts, assess the patient's understanding and preferences, give information in manageable parts, acknowledge emotion, and agree the next step. A protocol cannot determine how much a particular patient wants to know or remove the need for clinical judgement.

A difficult conversation

1. **Prepare.** Check the facts, choose a private setting, arrange an interpreter, and allow enough time.
2. **Establish perspective.** Ask what the patient understands, expects, and wants from the conversation.
3. **Invite information preferences.** Clarify the desired level of detail and who should be present.
4. **Give a warning and explain.** Use plain language, short sections, and explicit uncertainty; avoid euphemisms that obscure the message.
5. **Respond to emotion.** Pause, name or acknowledge the response, and check what the patient has heard.
6. **Plan.** Summarise the decision or next investigation, identify support, check safety, and arrange follow-up.

Silence after bad news is not a failure of communication. It gives the patient time to absorb the message. Reassurance should be specific: the physician can promise continued care, symptom control, or another meeting, but should not promise cure or certainty that the evidence does not support.

4.2.3 Communication barriers

Language, hearing, cognition, health literacy, pain, fatigue, fear, and hierarchy can obstruct communication. A professional interpreter should be used when a language difference could affect a significant decision. Relatives may support the patient, but they may filter information, answer in the patient's place, or face their own conflict of interest.

The physician should speak to the patient, not to the interpreter, and use short segments that can be translated accurately. Sensitive questions may require part of the consultation without relatives. The interpreter's identity and role should be documented where material to the decision.

Communication also fails when the patient is technically informed but not heard. Interruptions,

unexplained jargon, standing at the door, or typing without acknowledgement may convey that questions are unwelcome. Active listening requires attention to the content and the concern beneath it. It should lead to a checkable clinical response, not merely an empathic phrase.

4.3 From principle to practice

4.3.1 Professional boundaries

Professional boundaries mark the limits within which the relationship remains directed towards the patient's care. A boundary crossing is not automatically harmful: accepting a modest culturally customary gift or attending a patient's funeral may be appropriate in context. A **boundary violation** exploits the relationship, creates a serious conflict, or places the professional's needs above the patient's interests.

The ethical assessment should consider purpose, patient vulnerability, value or intimacy, secrecy, frequency, reciprocity, effect on judgement, and how the conduct would appear in the health record or to a professional peer. Repeated exceptions are particularly concerning because small changes may gradually transform the relationship.

4.3.2 Gifts and conflicts of interest

A small gift may express gratitude and refusing it abruptly may cause distress. High-value, repeated, secret, or conditional gifts can create obligation, influence access, and change expectations. The physician should consider the patient's means, the timing, local policy, and whether acceptance could affect or appear to affect certification, prescribing, waiting-list priority, or other decisions.

Alternatives include accepting a card, sharing a modest consumable gift with the team, directing a donation through an authorised route, or declining with an explanation that protects the relationship. The gift and response should be recorded when value or circumstances make the boundary significant.

Conflicts also arise from industry sponsorship, referral arrangements, private financial interests, and requests for certificates. Disclosure of a conflict is necessary but may not be sufficient. The conflict may require recusal, independent review, or refusal of the transaction.

4.3.3 Sexual and romantic boundaries

A sexual or romantic relationship with a current patient is incompatible with the clinical role. The power imbalance, access to intimate information, and patient's dependence can compromise apparent consent and expose the patient to harm. The physician should recognise feelings without acting on them, maintain clear limits, seek confidential professional advice, and arrange transfer of care if this can be done safely and without abandonment.

Ending the formal relationship does not instantly remove vulnerability or knowledge acquired through care. The seriousness and duration of the former illness, type of care, emotional dependence, time elapsed, and likelihood that contact uses the previous professional position all matter. Current professional rules must be checked; personal confidence that the relationship is "equal now" is not an adequate safeguard.

4.3.4 Digital boundaries and social media

Online contact can blur personal and professional roles. Accepting a patient's friendship request may expose private information about both parties, create expectations of access, and make later

boundary-setting feel like rejection. Clinical questions sent through personal accounts may be missed, insecure, or absent from the record.

Clinicians should use authorised communication routes, avoid searching for patient information online without a defensible care or safety reason, and keep educational discussion free of identifiable details. Privacy settings do not guarantee privacy. The confidentiality principles in Practical Class 3 apply to photographs, posts, group chats, and online teaching.

4.3.5 Treating relatives, friends, and colleagues

Minor advice may seem harmless, but an informal relationship can impair history-taking, examination, documentation, and willingness to discuss sensitive matters. Prescribing for oneself or someone close also creates risks of convenience, secrecy, and missed follow-up. Emergency assistance may be necessary, but continuing care should usually be transferred to an independent clinician when one is available.

The same concern applies when a colleague becomes a patient. Professional courtesy should not reduce the standard of assessment or create informal access to records. The person should be treated as a patient, with ordinary consent, confidentiality, documentation, and follow-up.

4.3.6 Raising concerns about a colleague

Collegial loyalty does not justify exposing patients to preventable harm. When a colleague appears impaired, the observer should distinguish evidence from rumour, protect any immediate patient, and use an appropriate senior or institutional route. Direct conversation may be suitable when risk is not urgent, but it should not delay action when a procedure is about to begin.

The aim is protection and fair assessment, not punishment by accusation. The report should state observations, timing, and risk rather than speculate about diagnosis. The colleague may need confidential health support, but patient safety remains the first operational concern.

Ethics, professional standards, and law

Bulgarian law protects patients' rights to respectful, non-discriminatory care, accessible information, safety, another medical opinion, and access to records. The Bulgarian Medical Association publishes the professional ethics code and maintains ethics committees. The relevant official sources were checked on 17 August 2026. Detailed rules on gifts, digital conduct, intimate examinations, and personal relationships should be verified before a real disciplinary or legal conclusion is made.

4.4 Case workshop

4.4.1 Case 1: The diagnosis the family wants hidden

Mrs Dimitrova, aged 67, attends with her son to receive a biopsy result. Before the consultation, the son asks the oncologist to say only that an "inflammation" was found because the word cancer will destroy his mother's hope. Mrs Dimitrova has previously asked for her son to attend but has not asked him to receive information instead of her. During the meeting she looks at the doctor and asks, "Is this cancer, and can it be treated?" The son interrupts and answers that more tests are needed.

4.4.1.1 Questions for discussion

1. What is known about Mrs Dimitrova's information preferences, and what should not be inferred from her son's request?
2. How can the oncologist acknowledge the son's fear without colluding in deception?
3. What information should be given now, and how should uncertainty be expressed?
4. Which relationship model best describes a defensible response, and why?
5. Formulate the next three sentences the oncologist should say.

4.4.2 Case 2: The operation the patient demands

Mr Iliev has chronic back pain without neurological deficit. Two specialists recommend rehabilitation and explain that surgery is unlikely to help and carries substantial risk. He insists that the neurosurgeon operate, saying that autonomy means the choice is his. He threatens a complaint if refused and reports that a private clinic abroad advertised the procedure. The surgeon is concerned that a blunt refusal will end the relationship and drive him towards unsafe care.

4.4.2.1 Questions for discussion

1. What does respect for autonomy require, and what does it not require?
2. How should the surgeon distinguish a firm recommendation from paternalism?
3. Which uncertainties, goals, and alternative treatments need further discussion?
4. Is referral for another opinion supportive, defensive, or both?
5. Recommend a plan that preserves professional integrity and continued care.

4.4.3 Case 3: The expensive watch

Dr Nikolova has cared for Mr Vasilev, a wealthy patient with chronic lung disease, for twelve years. At the end of an appointment he offers her a watch worth several thousand euros. He says refusal would insult him and that the gift is insignificant compared with what her care has meant. Dr Nikolova accepts it privately. A week later he asks her to write a medical certificate stating that delay in a commercial permit would place his life at immediate risk, although the clinical evidence does not support that claim.

4.4.3.1 Questions for discussion

1. Which features make the gift ethically different from a card or modest shared gift?
2. How might acceptance affect judgement, reciprocity, and public confidence even if Dr Nikolova feels impartial?
3. What should she do about the certificate and the watch now?
4. Which institutional or professional rules should be checked?
5. How can she explain the decision without humiliating Mr Vasilev?

4.4.4 Case 4: Contact outside the clinic

Dr K is the only GP in a small town who regularly manages Elena's severe migraines and depression. Elena is separating from her partner and tells Dr K that he is the only person she trusts. She begins sending messages to his personal account late at night. He responds at length, meets her for coffee after clinic, and develops romantic feelings. Elena attempts to kiss him and says that their relationship is voluntary. Dr K believes transferring her care would leave her without adequate treatment.

4.4.4.1 Questions for discussion

1. Which boundary crossings have already occurred, and when does the risk become a violation?
2. How do clinical dependency, depression, local access, and personal messaging affect apparent consent?
3. What immediate boundaries should Dr K establish?
4. How can continuity of care be protected without maintaining a dual relationship?
5. What consultation, documentation, and professional guidance are required?

4.4.5 Case 5: The senior surgeon

A resident preparing for an elective operation notices that the supervising surgeon smells strongly of alcohol, has slurred speech, and struggles to sign the theatre checklist. The surgeon denies impairment and says that the resident's assessment will suffer if the case is delayed. The patient is anaesthetised, another consultant is in the hospital, and local policy provides an urgent route for raising safety concerns.

4.4.5.1 Questions for discussion

1. Which observations are facts, and which conclusions remain uncertain?
2. What duties are owed to the patient, the colleague, the team, and future patients?
3. Should the resident speak to the surgeon again before escalating, or would this create avoidable risk?
4. What should be communicated through the urgent route, and what should be omitted?
5. How should the institution respond after immediate safety is secured?

4.5 Applied class exercise

Work in groups of three using Case 1. One student is Mrs Dimitrova, one is the oncologist, and one is her son. Conduct the first four minutes of the consultation. The oncologist must establish the patient's information preference, respond to the son's concern, state the result clearly, acknowledge emotion, and agree one next step.

Repeat the exercise with a different relationship model. The observers should identify the precise sentence in which guidance became coercion, information became abandonment, or family support became substitution. Finish by writing a version that uses professional authority without taking the decision away from the patient.

4.6 Self-check

1. Why does trust not require obedience?
2. Distinguish a strong clinical recommendation from paternalism.
3. What can a bad-news protocol contribute, and what can it not decide?
4. Name five features that make a gift or personal contact ethically concerning.
5. Why is ending the formal clinical relationship not always enough to remove a sexual-boundary concern?
6. Choose one workshop case and justify a response in no more than 180 words. Include the patient's perspective, the physician's proper authority, the boundary at risk, and the next sentence that should be communicated.

5 End of life issues. Euthanasia and assisted suicide

A patient with advanced lung disease is admitted for the third time in two months. Non-invasive ventilation may reverse the present deterioration, but each admission leaves him weaker. He says that he wants comfort and time with his family; his daughter insists that every available treatment must continue. The team is uncertain whether he is dying during this admission or could recover for several months.

End-of-life decisions rarely arrive with complete prognostic certainty. The ethical task is to identify the patient's goals, distinguish treatment from the underlying disease, compare likely benefits and burdens, and communicate what medicine can and cannot achieve. Decisions about cardiopulmonary resuscitation, artificial nutrition, sedation, euthanasia, and assisted suicide use different concepts and must not be merged into a single question about "letting someone die".

> **Class focus**
>
> This class prepares you to analyse decisions near the end of life without confusing refusal, treatment limitation, symptom relief, euthanasia, and assisted suicide. The cases require a recommendation that addresses uncertainty, family disagreement, and the distinction between ethical argument and Bulgarian law.

5.1 Essential concepts

5.1.1 End of life and prognostic uncertainty

The **end of life** is a period in which a person is living with an advanced, progressive, or life-limiting condition and death has become a foreseeable clinical concern. The period cannot be defined by a single time threshold for every purpose. Some patients deteriorate over hours; others experience repeated crises over months or years. Palliative needs may arise long before the last days of life.

Prognosis is an estimate, not a date. Cancer, organ failure, frailty, dementia, and neurological disease follow different trajectories. Clinicians should explain the range of plausible outcomes, the evidence supporting the estimate, and the events that would prompt review. Statements such as "there is nothing more to do" are usually inaccurate. Disease-modifying treatment may no longer offer benefit while symptom relief, nursing care, psychological support, rehabilitation, family support, and planning remain active forms of care.

Palliative care is an approach that prevents and relieves suffering associated with life-threatening illness through attention to physical, psychological, social, and spiritual needs. It may accompany treatment intended to prolong life. Palliative care is therefore not synonymous with imminent death, abandonment, or sedation.

5.1.2 Goals of care and advance care planning

A **goals-of-care discussion** connects the clinical situation with what the patient values. The clinician should ask which abilities, relationships, and outcomes matter; which burdens would be unacceptable; and what the patient hopes to avoid. A goal such as "live as long as possible" still requires interpretation because an intervention may prolong biological function without restoring an outcome

the patient would value.

Advance care planning is a continuing conversation about values, preferences, possible future decisions, and the people who should be involved if the patient cannot decide. It may produce a written record, but the conversation is not reducible to a form. Preferences should be revisited when the diagnosis, prognosis, care setting, or patient's views change.

An advance statement of values is ethically relevant even when it is not a legally binding refusal. Foreign concepts such as a UK advance decision or a North American living will must not be assumed to have the same legal effect in Bulgaria. The team should establish what document exists, whether it applies to the present circumstances, and which current national procedure governs it.

5.1.3 Decision-making when capacity is impaired

Capacity remains decision-specific and time-specific near the end of life. Opioids, delirium, hypoxia, infection, metabolic disturbance, fatigue, and severe distress may affect the person's ability to decide, but diagnosis or proximity to death does not prove incapacity. Support and treatment of reversible factors should precede a conclusion when time allows.

If the patient cannot decide, relatives can provide evidence about prior wishes, values, and relationships. They should not be treated automatically as owners of the decision. The clinical team must identify any legally authorised representative and the applicable Bulgarian process. Ethically, the decision should follow the patient's known wishes where these are reliable and applicable; otherwise it should compare benefits and burdens for that patient rather than the preferences of the loudest participant.

5.2 Ethical framework

5.2.1 Withholding and withdrawing treatment

Withholding treatment means not starting an intervention. **Withdrawing treatment** means stopping one that has begun. When the reason, intention, and expected outcome are the same, the ethical justification may be the same. Clinicians often experience withdrawal as more difficult because an action is visible and a relationship with the technology has developed. That psychological difference deserves support but does not by itself justify continuing a burdensome intervention.

Stopping an intervention does not mean that the clinician causes the underlying disease. Causal responsibility is more complex than the distinction between action and omission: removing ventilation may be followed closely by death, while not starting it may have the same result. Ethical analysis should examine the patient's wishes, indication, proportionality, alternatives, intention, and manner of withdrawal rather than rely on grammar alone.

A treatment may be refused by a patient with capacity. A treatment may also be judged clinically inappropriate because it cannot achieve its physiological aim or because any possible benefit is grossly disproportionate to its burdens. The term **futility** is often used too broadly. "CPR will not restart circulation" is a physiological judgement; "survival with severe disability is not worthwhile" is a value judgement and requires the patient's perspective. **Potentially inappropriate treatment** is a more accurate term when disagreement concerns the value of an achievable outcome.

Patients may refuse an intervention, but they cannot require a professional to provide treatment outside reasonable clinical practice. The team should explain the judgement, offer appropriate alternatives, obtain another opinion when disagreement persists, and follow institutional escalation and current law. Unilateral action under avoidable uncertainty can damage trust even when the clinical conclusion is sound.

5.2.2 Cardiopulmonary resuscitation decisions

A decision not to attempt cardiopulmonary resuscitation concerns CPR after cardiac or respiratory arrest. It does not mean "do not treat", exclude intensive symptom control, or decide every other intervention. Each treatment needs its own indication and discussion.

The patient should be involved when discussion is possible and appropriate. The aim is not to ask them to choose a medically impossible outcome, but to explain the clinical assessment, hear their values, and correct misunderstandings. If CPR is unlikely to work or would leave an outcome the patient would reject, the reasoning should be specific. Family members should be informed and heard when the patient wants them involved or cannot decide, but their distress does not make a non-beneficial intervention effective.

5.2.3 Artificial nutrition and hydration

Clinically assisted nutrition and hydration use tubes or intravenous routes and should be assessed as medical interventions. Food, drink, mouth care, and assistance with eating also express care and relationship, which explains why families may experience withdrawal as starvation or abandonment.

The relevant questions are whether the patient experiences hunger or thirst, whether swallowing is safe, what the intervention can achieve, and what burdens it creates. In the last days of life, artificial hydration may not improve comfort and can sometimes increase oedema, secretions, or procedures; the assessment is individual. Good mouth care, symptom treatment, and supported oral intake when safe remain essential. A decision not to insert a feeding tube should be explained as a treatment judgement, not as removal of basic respect.

5.2.4 Opioids, symptom relief, and double effect

Appropriately titrated opioids are used to relieve pain and breathlessness. Fear that any opioid will hasten death can leave symptoms undertreated. Dose, route, clinical indication, previous exposure, monitoring, and proportionality matter. Reckless dosing cannot be justified by claiming a good intention.

The **doctrine of double effect** is one way of analysing an action with a beneficial intended effect and a foreseeable harmful effect. It asks whether the act is otherwise permissible, the harmful effect is not intended or used as the means, the benefit is proportionate, and less harmful effective options are unavailable. Intention matters, but it is not the only evidence. The chosen dose, titration, documentation, expertise, and response to the patient's condition help show what the clinician was doing.

5.2.5 Palliative sedation

Palliative sedation is monitored use of medication to reduce consciousness for relief of otherwise refractory suffering. It can be light or deep, intermittent or continuous. Continuous deep sedation until death is an exceptional form, not the definition of all palliative sedation.

Before sedation, the team should confirm that the symptom is severe and refractory, seek specialist input where available, assess capacity and consent, consider the proportional depth and duration, discuss nutrition and hydration separately, and establish monitoring and review. Sedation differs from euthanasia in its immediate aim, method, dose selection, clinical endpoint, and expected mechanism of death. Merely naming the intention is insufficient; practice must be consistent with relief of symptoms rather than production of death.

A treatment-limitation decision

1. **Define the intervention.** Specify what may be started, continued, withheld, or withdrawn; avoid global labels such as "full treatment".
2. **Clarify the clinical aim.** State what the intervention can realistically achieve and the uncertainty around that estimate.
3. **Establish the patient's position.** Assess and support capacity, identify current preferences, and examine applicable prior statements.
4. **Compare benefits and burdens.** Include symptoms, function, invasiveness, time, relationships, and the patient's account of an acceptable outcome.
5. **Consider alternatives and review.** Include time-limited trials, second opinions, palliative measures, and triggers for reassessment.
6. **Communicate and document.** Record the decision for each intervention, the participants, reasons, disagreement, escalation route, and care that will continue.

5.2.6 Euthanasia and assisted suicide

Euthanasia is an intentional act by one person, commonly a clinician, that causes another person's death at that person's voluntary request, with relief of suffering as the stated reason. **Physician-assisted suicide** occurs when a physician provides the means or prescription and the person performs the final act themselves. The broader phrase **assisted dying** is used differently across jurisdictions and arguments; it should be defined whenever used.

Non-voluntary killing, in which a person cannot request death, and involuntary killing, against a person's wishes, are not extensions of voluntary choice. The expression **passive euthanasia** should be avoided because it confuses euthanasia with withholding or withdrawing treatment that is refused or no longer indicated.

Arguments supporting voluntary assisted dying appeal to autonomy, relief of suffering, compassion, equality for people physically unable to end their own lives, and transparent regulation of practices that might otherwise occur secretly. These arguments differ on eligibility: terminal illness, unbearable suffering, decision-making capacity, prognosis, and the role of physicians.

Arguments opposing it appeal to protection of life, professional commitments, diagnostic and prognostic uncertainty, the possibility of treatable depression or coercion, effects on palliative care and trust, and the risk that social neglect or fear of being a burden will shape requests. Slippery-slope claims require evidence about institutions and safeguards; they should not substitute for analysis of a particular proposal.

A request to die is first a clinical communication, not proof of a settled wish or incapacity. The clinician should explore pain, breathlessness, depression, delirium, family pressure, financial fear, loss of control, spiritual distress, and what the patient means by the request. Responding seriously does not commit the clinician to providing an unlawful intervention.

Bulgarian legal context

The Bulgarian Health Act prohibits euthanasia and regulates consent, refusal, and palliative care. Bulgarian law does not acquire the rules of another country because a textbook describes them. The official national sources were checked on 17 August 2026, but a contested decision requires the current consolidated law and appropriate senior, ethics, palliative, and legal advice.

5.3 From principle to practice

Communication should begin before crisis when possible. The physician can ask whether the patient wants broad information or numerical detail, who should be present, and which decisions they most want to influence. Hope need not be tied only to cure. It may concern relief of breathlessness, attending an event, returning home, speaking with family, or avoiding a burdensome intervention.

When relatives demand continued treatment, the team should identify the fear beneath the demand. They may believe that stopping ventilation is killing, that morphine is euthanasia, or that agreeing to comfort care betrays the patient. A clear account of what will continue is often more useful than repeating that treatment is futile. A time-limited trial can sometimes test uncertainty, but it requires agreed outcomes and a plan for what happens if they are not achieved.

Documentation should avoid ambiguous phrases such as “for comfort only”. It should specify decisions about CPR, ventilation, antibiotics, dialysis, fluids, nutrition, hospital transfer, monitoring, and symptom treatment as relevant. The record should state the patient’s capacity and wishes, information given, family contributions, professional assessment, unresolved disagreement, and review triggers.

The Liverpool Care Pathway was withdrawn in the United Kingdom after concerns about implementation and communication. It should be studied as a warning against turning individual care into an uncritical checklist, not used as a current protocol. Good end-of-life care is based on repeated assessment, clear communication, and an individual plan.

5.4 Case workshop

5.4.1 Case 1: Stopping dialysis

Mr Stoyanov, aged 60, has received haemodialysis for six months. He has capacity, is not clinically depressed, and understands that stopping dialysis will probably lead to death within a limited period. He says that treatment leaves him exhausted, prevents him from living at home, and no longer serves a goal he values. His wife believes that accepting withdrawal would be suicide and asks the nephrologist to continue dialysis against his wishes.

5.4.1.1 Questions for discussion

1. What should be confirmed about capacity, symptoms, alternatives, and voluntariness?
2. Is stopping dialysis ethically different from refusing to start it six months earlier?
3. What role should Mr Stoyanov’s wife have, and what authority should not be assumed?
4. Which care must be planned if dialysis is stopped?
5. How should the decision be explained and documented under current Bulgarian rules?

5.4.2 Case 2: The intensive-care impasse

Mrs Borisova, aged 81, has advanced dementia, metastatic cancer, septic shock, and multi-organ failure. She is ventilated and requires increasing vasopressor support. The intensive-care team believes continued organ support cannot produce recovery outside intensive care and recommends withdrawal with active symptom treatment. Her daughter demands that every machine continue until the heart stops, saying that withdrawal would make the doctors responsible for death. Mrs Borisova left no written plan, but previously told her GP that she feared prolonged dependence on machines.

5.4.2.1 Questions for discussion

1. Which prognostic claims are clinical facts, and which contain value judgements?
2. How much weight should be given to the previous conversation with the GP?
3. What benefits and burdens does continued organ support create for Mrs Borisova?
4. How should the team respond to the daughter's moral and religious concerns?
5. Which second-opinion, ethics, legal, and review steps are appropriate if disagreement persists?

5.4.3 Case 3: The unexplained resuscitation decision

Mr Todorov, aged 82, has severe heart failure but remains able to discuss his care. A registrar records a decision not to attempt CPR because cardiac arrest would probably be irreversible and attempted resuscitation would be traumatic. The registrar does not speak to Mr Todorov, fearing that discussion will destroy hope. His son sees the entry and accuses the ward of abandoning treatment. Antibiotics, diuretics, oxygen, and rehabilitation are still planned.

5.4.3.1 Questions for discussion

1. What does the resuscitation decision cover, and what does it leave unchanged?
2. Was there a defensible reason not to involve Mr Todorov?
3. How should prognosis and the limits of CPR be communicated without asking him to demand a clinically ineffective procedure?
4. What role should his son have if Mr Todorov retains capacity?
5. What should the team do now to repair the communication failure?

5.4.4 Case 4: Refractory breathlessness

Ms Simeonova, aged 54, has advanced motor neurone disease and severe breathlessness despite specialist treatment. She remains able to communicate with an eye-tracking device and requests sedation because the episodes are terrifying. The palliative team considers proportionate sedation, with possible progression to continuous deep sedation if lighter measures fail. Her husband agrees but fears that medication will cause her death. The team has not yet discussed how sedation would affect communication or decisions about hydration.

5.4.4.1 Questions for discussion

1. What makes a symptom refractory, and who should contribute to that judgement?
2. What should Ms Simeonova understand about depth, duration, review, and loss of communication?
3. How do intention, method, dose, and endpoint distinguish sedation from euthanasia?
4. Which decisions must remain separate from the decision to sedate?
5. Design a communication and monitoring plan that addresses her husband's concern.

5.4.5 Case 5: A request for assisted dying abroad

Ms Petrova, aged 64, has a progressive neurological disease and an estimated life expectancy of several years. She fears loss of speech and dependence more than pain. She asks her neurologist for a summary of her records to approach an organisation in a country where assisted suicide may be lawful. Her family opposes the plan but says they would travel with her rather than leave her alone. Recent assessment shows mild cognitive changes, and the neurologist is uncertain whether depression or family burden is influencing the request.

5.4.5.1 Questions for discussion

1. What does Ms Petrova mean by her request, and which clinical factors require assessment?
2. How should respect for autonomy be balanced with uncertainty, vulnerability, and the possibility of coercion?
3. Distinguish access to one's medical information from professional participation in an assisted death.
4. Which actions may be ethical but unlawful, lawful but professionally contested, or both?
5. What should the neurologist say and do at the next consultation?

5.5 Applied class exercise

Use Case 2 in groups representing the patient, daughter, intensive-care team, palliative-care team, and ethics adviser. Prepare a time-limited treatment plan with two clinical goals, a review time, criteria for success, a plan if the goals are not met, and care that will continue in either outcome.

One student should explain the plan to the daughter without using "futile", "nothing more", or "withdrawal of care". The group then identifies the strongest objection to its own plan and states what new fact would change the recommendation.

5.6 Self-check

1. Why may withholding and withdrawing treatment have the same ethical justification?
2. Distinguish physiological futility from disagreement about the value of an achievable outcome.
3. What does a decision not to attempt CPR leave undecided?
4. Which safeguards distinguish proportionate palliative sedation from euthanasia?
5. Why should the phrase "passive euthanasia" be avoided?
6. Choose one workshop case and write a recommendation of no more than 180 words. State the patient's goal, the intervention being decided, the main benefit and burden, the strongest opposing argument, and the current legal rule that must be verified.

6 Organ transplantation and ethical issues in human reproduction

A transplant team has one compatible liver and two candidates with comparable urgency. In another department, a patient receiving fertility treatment disagrees with her former partner about the use of embryos created while they were together. The clinical details differ, but both decisions concern control over the body, the status of biological material, vulnerability, and the fair use of limited medical resources.

Transplantation depends on donation, public trust, and defensible allocation. Reproductive medicine concerns intimate choices but also affects partners, donors, children, and institutions. Neither field can be governed by autonomy alone. Consent must be voluntary, harms must be proportionate, and the interests of people with less power must be made visible.

> **Class focus**
>
> This class prepares you to analyse donation, allocation, reproductive choice, and assisted reproduction without treating biological possibility as ethical permission. The workshop asks you to identify whose consent is required, which interests are morally relevant, and which parts of the decision depend on current Bulgarian law.

6.1 Essential concepts

6.1.1 Transplantation and the determination of death

Transplantation transfers an organ, tissue, or cells to restore a function in a recipient. **Allotransplantation** occurs between genetically different members of the same species. **Autotransplantation** returns material to the same person, while **xenotransplantation** uses material from another species and remains ethically connected to research risk, animal welfare, and possible population-level infection.

Organs may be donated by living or deceased people. Deceased donation requires a valid determination of death made independently of the need for organs. Death may be established through circulatory or neurological criteria under defined clinical and legal procedures. **Death by neurological criteria** is not a coma or a persistent disorder of consciousness: it concerns irreversible loss of the functions specified by the applicable standard.

The **dead donor rule** states that vital organs should be removed only after the donor has been declared dead and that procurement must not cause the donor's death. The rule protects donors and public trust. Its application requires clear separation between the team determining death and the transplantation interests of recipients. A family should not be approached as though death were uncertain merely because circulation is being supported mechanically.

6.1.2 Donation systems

An **opt-in system** requires an affirmative expression of willingness to donate. An **opt-out system** treats donation as authorised when the person has not registered an objection, subject to national

rules. Either model can be administered in a "hard" form, with little or no family discretion, or a "soft" form, in which the family is consulted and practice may not proceed over serious objection.

Presumed consent is not the same as known consent. Its ethical defence depends on public information, accessible refusal, trustworthy registries, fair treatment of people with limited literacy or access, and confidence that procurement follows strict safeguards. Family consultation can provide evidence of the person's wishes and protect trust, but a family veto may also defeat an expressed decision to donate. The legal status of each voice must be checked rather than inferred from the ethical model.

6.1.3 Living donation

Living donation exposes a person without disease to risk for another's benefit. It can be justified when risk is proportionate, expected recipient benefit is reasonable, consent is informed and voluntary, and independent assessment protects the donor. The donor's welfare remains a clinical responsibility; willingness to accept any risk does not oblige the team to proceed.

Voluntariness is difficult within families. Love, duty, fear of blame, financial dependence, and the possibility of a relative's death may influence a donor without an explicit threat. The assessment should occur apart from the recipient and family. The potential donor must be able to withdraw without being required to defend the decision to relatives. An independent donor advocate or team can help separate donor welfare from pressure to secure an organ.

Payment for reasonable expenses differs from buying an organ. Reimbursement aims to prevent the donor from becoming poorer because of donation. A market payment makes the organ the object of a transaction and may recruit people through financial desperation. Proposals for regulated markets claim that oversight could increase supply and reduce unsafe trade; objections concern exploitation, commodification, unequal access, and damage to altruistic systems.

6.1.4 Allocation and justice

Organs are scarce and allocation must use public, clinically relevant criteria. **Utility** supports producing as much health benefit as reasonably possible. **Urgency** gives weight to imminent death without transplantation. **Equity** addresses fair opportunity and disadvantages not captured by prognosis. **Waiting time** can recognise equal claims over time. No single criterion is sufficient in every programme.

Medical factors may legitimately affect priority when they change transplant benefit or safety. A history of substance use, disability, age, social position, wealth, citizenship, fame, or perceived responsibility for illness should not become a proxy for moral worth. If adherence matters clinically, the team should assess present barriers and available support rather than punish a diagnostic label or past conduct.

Table 6.1: Ethical considerations in organ allocation.

Consideration	Relevant question	Misuse to avoid
Urgency	How soon is the candidate likely to die or deteriorate without transplantation?	Allowing the most dramatic case to displace consistent criteria.
Expected benefit	What survival and function are reasonably expected with and without the organ?	Treating uncertain prediction as a judgement of personal worth.
Compatibility	Is the organ clinically suitable for this recipient?	Hiding discretionary social preferences inside technical language.

Consideration	Relevant question	Misuse to avoid
Waiting time	How long has the candidate held an eligible claim?	Ignoring rapid deterioration or unequal access to listing.
Equity	Do rules create avoidable disadvantage for a group or person?	Assuming identical treatment is fair under unequal conditions.

Transparent rules, consistent application, audit, and appeal protect fairness better than bedside intuition. The individual clinician should not secretly redesign allocation criteria for a sympathetic patient.

6.1.5 Transplantation tourism

Transplantation tourism becomes ethically serious when travel involves organ trafficking, commercial exploitation, unsafe procurement, or diversion of local resources. A returning recipient remains a patient and should not be denied necessary care as punishment. Treating complications does not endorse the transaction. Clinicians may also have duties to document concerns, avoid facilitating brokers, and use current reporting channels.

6.2 Ethical framework

6.2.1 Reproductive autonomy and reproductive justice

Reproductive autonomy protects decisions about whether, when, and how to have children or avoid pregnancy. It supports access to information and freedom from forced contraception, sterilisation, pregnancy, abortion, or treatment. Reproductive decisions occur within relationships and institutions, so the exercise of autonomy may affect partners, donors, existing children, and future people.

Reproductive justice asks whether people have the material and social conditions needed to exercise meaningful choice. A nominal right may be weak when care is unaffordable, geographically inaccessible, discriminatory, or unsafe. Justice also concerns freedom from coercive population policies and unequal targeting of marginalised groups.

Neither framework establishes an unlimited claim to every reproductive technology. Safety, professional integrity, fair allocation, the welfare of people created through treatment, and the rights of others may justify limits. Those limits require reasons and should not be based on stereotypes about disability, sexuality, marital status, poverty, or "deserving" parenthood.

6.2.2 Contraception and sterilisation

Contraception raises questions about access, informed choice, cultural and religious belief, side effects, partner influence, and confidentiality. The person using the method should make the decision. A partner's preference may matter within the relationship but does not create authority over another person's body.

Sterilisation is intended to be permanent and therefore requires careful consent about alternatives, failure, procedural risk, and the possibility of later regret. Predicted regret alone should not be used to deny a competent adult, especially when that prediction reflects assumptions about age, parity, disability, or future partners. Conversely, a signature obtained during labour, pain, dependency, or external pressure may not establish a voluntary decision.

Sterilisation of a person who cannot consent creates a profound conflict between bodily integrity, protection from pregnancy, caregiving interests, and possible benefit to the person. Convenience

for carers is not sufficient. The applicable legal safeguards and decision-making authority must be identified.

6.2.3 Abortion and moral status

Ethical disagreement about abortion concerns the moral status of the embryo or fetus, the pregnant person's bodily integrity, responsibility, equality, and the state's role. Some positions assign full moral status from conception. Others connect moral status to development, sentience, viability, relationships, or birth. A further argument holds that even substantial fetal moral status does not automatically create a right to use another person's body.

These arguments should be stated accurately. Describing one side as hostile to women or the other as indifferent to life prevents analysis. Gestational age, reason for the request, fetal condition, risk to the pregnant person, social circumstances, and access to support may alter the ethical reasoning, but the current legal position determines which clinical options are available.

Conscientious objection may protect professional integrity within legal limits, but it should not become deception, humiliation, abandonment, or obstruction of urgent care. The clinician should provide accurate information and follow current duties concerning referral or transfer.

6.2.4 Pregnancy and fetal interests

Pregnancy creates a close biological relationship but does not erase the pregnant patient's status as the person whose body undergoes examination and intervention. Fetal welfare can be a strong moral reason for counselling and support. It does not automatically authorise forced treatment of a patient with capacity.

The term **maternal-fetal conflict** can misleadingly frame the woman and fetus as adversaries. Many disagreements arise from fear, previous trauma, communication failure, or different estimates of risk. The team should assess capacity, explain urgency, address pain and language barriers, explore the reason for refusal, and offer less intrusive alternatives where possible. Family members cannot consent to surgery on behalf of a competent adult.

6.2.5 Assisted reproduction

Assisted reproduction includes methods intended to overcome infertility through clinical handling of gametes, fertilisation, embryos, or insemination. Ethical questions concern access, effectiveness, risk to the patient and future child, multiple pregnancy, use of donor material, storage, consent, parentage, commercial interests, and allocation of publicly supported treatment.

Gamete donation creates interests for donors, recipients, and donor-conceived people. Anonymity may protect donor privacy and family stability; access to identifying or medical information may support identity, health, and avoidance of accidental consanguinity. The ethical balance depends partly on what was promised and on current law. Clinics should not guarantee permanent anonymity when legal or technological change may make it impossible.

Cryopreserved embryos are not well described as ordinary property or as patients. Different ethical positions assign them full moral status, special respect because of their developmental potential, or a status tied chiefly to the projects of the people who created them. Storage agreements should address duration, withdrawal of consent, separation, death, donation, research, and disposal before conflict arises. One person's wish to reproduce must be weighed against another's wish not to become a genetic parent.

Preimplantation genetic testing may help avoid serious inherited disease, but it raises questions about disability, selection, acceptable indications, error, discarded embryos, and the future child's welfare. Selection for non-medical traits or tissue compatibility adds further concerns. The fact that a test is technically available does not establish that its use is clinically justified or socially fair.

6.2.6 Surrogacy

Surrogacy separates gestation from intended parenthood and may be altruistic or commercial, traditional or gestational. Supporters appeal to reproductive autonomy and the possibility of family life. Critics emphasise exploitation, unequal bargaining power, health risks, commodification, and conflicts when intentions change.

The pregnant surrogate remains a person with authority over medical decisions during pregnancy. A contract cannot ethically predetermine every intervention or remove the right to consent or refuse. After birth, the child's welfare and legal identity require protection regardless of whether adults breached domestic rules. Cross-border arrangements create particular risks when jurisdictions disagree about parentage, payment, citizenship, and enforceability.

A combined decision method

1. **Identify each body, role, and decision.** Separate donor from recipient, pregnant patient from fetus, donor from intended parent, and clinical team from allocation authority.
2. **Establish valid consent.** Assess capacity, information, voluntariness, withdrawal, dependency, and any legally required authorisation.
3. **Specify benefits and burdens.** Include direct clinical effects, psychosocial effects, long-term follow-up, and burdens transferred to less powerful people.
4. **Apply fair criteria.** Ask whether the rule is relevant, public, consistent, reviewable, and free from judgements of social worth.
5. **Check professional and legal limits.** Identify the Bulgarian authority and current rule; do not import a foreign solution.
6. **Plan communication and review.** Protect confidentiality, document reasoning, provide independent advice, and state what new fact would change the decision.

Current Bulgarian and EU rules

EU law sets quality and safety requirements for organs, tissues, and cells, while Bulgarian law governs consent, procurement, allocation procedures, assisted reproduction, pregnancy termination, and parentage. Official sources were checked on 17 August 2026, including a 2025 Bulgarian draft amendment concerning transplantation. Exact claims about family objections, donor eligibility, surrogacy, embryo use, and abortion procedures require the current consolidated national rules and specialist advice.

6.3 From principle to practice

Transplant conversations should separate determination of death from donation. Families need a clear explanation that death has been established according to the applicable standard before discussion of procurement. Living donors should have private consultations, independent assessment, and a safe route to withdraw. Recipient teams should not receive unnecessary explanations for a donor's refusal.

Allocation decisions should be documented through the authorised programme rather than negotiated with status, media pressure, or personal appeals. When a patient is ineligible, the team should state the clinical criterion, available support, route for reassessment, and appeal. A risk factor should not be treated as a moral fault.

Reproductive consultations should distinguish clinical information from moral counselling and legal conditions. The clinician can explore values and consequences without imposing a personal view. Where disagreement concerns embryos, donor information, or cross-border parentage, early

legal and ethics advice is safer than promising an outcome that the clinic cannot deliver.

6.4 Case workshop

6.4.1 Case 1: The reluctant sibling donor

Mila, aged 26, is the only medically compatible sibling of a brother with advanced kidney disease. In a private consultation she says that she does not want surgery but will agree because her parents have told her that refusal would make her responsible for his death. She asks the transplant physician to tell the family that she is medically unsuitable. Her physical assessment shows no contraindication, and her brother does not know about her reluctance.

6.4.1.1 Questions for discussion

1. Which forms of influence are present, and do they undermine voluntariness?
2. What duties does the team owe separately to Mila and her brother?
3. Is a confidential "medical exit" ethically defensible, and what should be recorded?
4. Which independent assessment and support should be offered?
5. What should the team communicate to the family without revealing Mila's confidential decision?

6.4.2 Case 2: One liver, two candidates

Two patients have comparable urgency and expected transplant benefit. Candidate A is a 38-year-old teacher with two children who joined the waiting list six months ago. Candidate B is a 44-year-old unemployed man receiving stable treatment for opioid dependence who joined the list twelve months ago. A committee member argues that Candidate A contributes more to society and is less responsible for the illness. The published allocation criteria include medical urgency, compatibility, expected benefit, and waiting time, but not occupation, parenthood, or moral responsibility.

6.4.2.1 Questions for discussion

1. Which facts are ethically and clinically relevant under the published criteria?
2. Why are occupation and parenthood poor measures of moral worth?
3. When may substance-use history be clinically relevant without becoming punishment?
4. How should equal benefit and different waiting time be handled?
5. What decision process would remain defensible if the candidates' social descriptions were reversed?

6.4.3 Case 3: The purchased kidney

Mr Dobrev returns from an overseas private clinic after paying for a kidney supplied by an unknown living donor. He has fever, wound infection, and possible rejection but no reliable records. His nephrologist is angry about probable exploitation and worries that treating the graft makes the Bulgarian service complicit. Delay would place Mr Dobrev at serious risk. The team is also uncertain whether any reporting duty applies.

6.4.3.1 Questions for discussion

1. What immediate duties are owed to Mr Dobrev despite the suspected unethical transaction?
2. Does treating a complication endorse or facilitate organ trafficking?

3. Which information should be sought, and how should uncertainty about donor risk be managed?
4. What confidentiality and reporting questions require current legal verification?
5. How can the team oppose transplantation tourism without using treatment as punishment?

6.4.4 Case 4: Refusal during labour

Mrs Stefanova, aged 28, is in labour at term. Monitoring suggests acute fetal compromise, and the obstetric team recommends an emergency caesarean section. She is alert and can repeat the predicted risks, but refuses because a previous operation was traumatic and she fears anaesthesia. Her husband demands that the team operate, saying the baby's life matters more than her refusal. There is little time, but an anaesthetist and senior obstetrician can speak with her immediately.

6.4.4.1 Questions for discussion

1. What should be done to support and reassess Mrs Stefanova's decision under time pressure?
2. How do fetal interests affect counselling without replacing her authority over surgery?
3. What role may her husband have, and what authority does he lack?
4. Which alternatives or changes to anaesthesia might address the reason for refusal?
5. If she continues to refuse with capacity, what ethical recommendation follows and which Bulgarian rule must be confirmed?

6.4.5 Case 5: The embryos after separation

Maria and Ivan created six embryos during fertility treatment. Two were transferred and four remain in storage. After separation, Maria wants another transfer because her chance of creating new embryos is low. Ivan withdraws his agreement and says that he does not want another genetic child. Their original consent form addresses storage fees but is unclear about separation and withdrawal. The clinic is asked to proceed before the current storage period expires.

6.4.5.1 Questions for discussion

1. Which interests and forms of reproductive autonomy are in conflict?
2. What moral status should the embryos have in this decision, and what follows from each main position?
3. Does Maria's limited future opportunity outweigh Ivan's objection to genetic parenthood?
4. How should the inadequate consent process affect the clinic's response without manufacturing consent retrospectively?
5. Which current Bulgarian rules on assisted reproduction, consent, storage, and parentage must be verified?

6.5 Applied class exercise

Divide into an allocation committee and a reproductive ethics committee. The allocation committee must develop four publicly defensible tie-breakers for Case 2 and reject two social-worth criteria with reasons. The reproductive committee must propose a clinic policy for embryo storage agreements covering separation, death, withdrawal, research, donation, and disposal.

Exchange policies. Each group should identify one rule that appears neutral but may disadvantage a particular population. Revise the rule and state how the revision improves fairness without promising an outcome that current Bulgarian law may not permit.

6.6 Self-check

1. Why must determination of death be independent of the need for organs?
2. Distinguish reimbursement of donation expenses from purchase of an organ.
3. Why is a donor's family pressure relevant even when no explicit threat is made?
4. Give two legitimate allocation considerations and two prohibited social-worth judgements.
5. How does reproductive justice differ from reproductive autonomy?
6. Choose one workshop case and write a recommendation of no more than 180 words. Identify each person's authority, the strongest benefit and burden, the fairness issue, and the current Bulgarian rule that must be verified.

7 Experimental ethics: research involving humans and animals and ethical codes

A physician invites a patient to enter a trial comparing standard treatment with a new drug. The patient hears the invitation as a personal recommendation and assumes that the experimental drug was selected for them. In another laboratory, animals are exposed to a painful procedure even though a validated non-animal method may answer the question. Both studies may be scientifically interesting, but scientific interest does not establish ethical acceptability.

Research asks questions intended to produce knowledge beyond the needs of one patient. It may expose participants or animals to burdens that ordinary clinical care would not impose. Ethical review must therefore examine the value and validity of the question, selection of subjects, consent, risk, independent oversight, and what will happen when the study ends.

> **Class focus**
>
> This class prepares you to distinguish research from care, use major ethical codes without treating them as interchangeable laws, and assess whether a human or animal study is justified before asking whether its procedures were followed correctly.

7.1 Essential concepts

7.1.1 Research and clinical care

Clinical care is directed primarily towards the health needs of an individual patient. **Research** is a systematic activity designed to produce generalisable knowledge. A patient may benefit from a study, but the protocol, randomisation, comparison group, sampling schedule, and data collection are chosen to answer the research question rather than tailored solely to that patient.

The distinction is not always sharp. A clinician may also be an investigator, and a trial may provide access to promising treatment. The ethical safeguard is not to pretend that the roles are identical. The physician-researcher should explain which procedures are required for care, which are required by the protocol, what alternatives exist outside the study, and which interests or payments may influence recruitment.

Therapeutic misconception occurs when a participant misunderstands research as personalised treatment and believes that every procedure was selected for their direct benefit. It differs from **therapeutic optimism**, which may be a hopeful but informed belief that the participant will benefit. The investigator should correct misconception without removing reasonable hope.

Clinical equipoise is honest professional uncertainty within the relevant clinical community about the comparative merits of trial interventions. It helps justify randomisation because no arm is known to be inferior. Debate continues about its exact scope and whether a physician's individual judgement or community uncertainty should control. Whatever account is used, a trial should not knowingly assign participants to avoidably inferior care merely to obtain a cleaner comparison.

7.1.2 Social value and scientific validity

Research that cannot answer a worthwhile question cannot justify risk. **Social value** concerns the importance of the knowledge expected and the realistic prospect that it will be used. **Scientific validity** concerns whether the design, sample, methods, analysis, and reporting can produce reliable knowledge. These are ethical requirements, not only technical matters.

An underpowered study, biased comparison, redundant animal experiment, or plan that suppresses unfavourable results exposes subjects without a defensible return. A scientifically valid study may still be unethical if risk is excessive, selection is unfair, or consent is invalid. Ethics review should therefore examine validity and protection together.

7.1.3 Risk, benefit, and fair selection

Risks include physical injury, psychological distress, stigma, loss of privacy, financial burden, and group harm. Benefits should be separated into possible direct clinical benefit, benefits of monitoring or contact, and the social value of knowledge. Payment is not a clinical benefit and should not be used to make an unfavourable risk-benefit balance appear favourable.

Participant selection should follow the scientific question and distribute burdens fairly. Recruitment from prisons, institutions, emergency departments, low-income communities, or dependent clinical relationships may be convenient but creates risks of exploitation. Exclusion can also be unjust: routine exclusion of children, older people, pregnant people, or those with disabilities may leave them without evidence relevant to their care. Inclusion requires safeguards appropriate to the risk and reason for studying the group.

7.2 Ethical framework

7.2.1 Historical sources and ethical codes

Modern research ethics developed partly through responses to systematic abuse. Nazi medical experiments involved coercion, torture, and killing. The Tuskegee study deceived Black men with syphilis and withheld effective treatment. The Willowbrook studies exposed institutionalised children to hepatitis in circumstances of dependency and constrained parental choice. These examples differ in severity and context, but each shows how scientific aims, institutional power, racism, disability discrimination, and weak oversight can combine.

Historical cases should not be used to suggest that abuse belongs only to the past or to exceptional individuals. Ordinary incentives can also distort research: pressure to publish, commercial deadlines, professional hierarchy, competition for grants, and access to populations with little power. Ethical codes provide standards, but they require institutions willing to enforce them.

Table 7.1: Major instruments in human research ethics.

Instrument	Main contribution	Authority and limitation
Nuremberg Code (1947)	Voluntary consent, scientifically justified design, avoidance of unnecessary suffering, qualified investigators, and freedom to stop participation.	Historical international code arising from a judicial judgement; highly influential but not a complete modern regulatory system.

Instrument	Main contribution	Authority and limitation
Declaration of Helsinki (2024)	Ethical principles for medical research involving human participants, identifiable material, and data; independent review, consent, vulnerability, registration, dissemination, and post-trial considerations.	World Medical Association policy; professionally authoritative but not itself a statute in every country.
Belmont Report (1979)	Respect for persons, beneficence, and justice linked to consent, risk-benefit assessment, and selection.	United States report with broad educational influence; not Bulgarian or EU law.
CIOMS International Ethical Guidelines	Detailed guidance on vulnerability, community engagement, low-resource settings, data, biological materials, and public-health research.	International guidance; application depends on the study and governing law.
Oviedo Convention	Human rights and dignity in biology and medicine, including conditions for research and protection of persons unable to consent.	Binding treaty for states that have ratified it; Bulgaria is a party.

The 2024 Declaration of Helsinki is the current version. Earlier versions remain historically informative but should not be presented as the active WMA standard. Ethical codes overlap, yet their wording, audience, and legal force differ. Citing a famous code does not remove the need to identify Bulgarian and EU requirements.

7.2.2 Consent to research

Research consent requires disclosure, understanding, voluntariness, capacity, and explicit agreement for the study. The participant should understand the purpose, methods, randomisation or placebo where relevant, foreseeable risks and benefits, alternatives outside the study, confidentiality, compensation or treatment for injury, commercial interests, withdrawal, and whom to contact.

A long information sheet can still fail to inform. Investigators should use plain language, allow time, invite questions, and check understanding of the features most likely to be misunderstood. Recruitment by a treating physician may create perceived pressure, especially when the patient depends on continued care. A neutral recruiter or delayed decision may reduce this influence.

Withdrawal should not normally threaten ordinary care or earned benefits. Participants should be told what will happen to data and samples already collected because complete deletion may be scientifically or legally impossible after anonymisation or inclusion in an analysis.

7.2.3 Vulnerability, children, and impaired capacity

Vulnerability is not a permanent label attached to a group. It arises when a person faces increased risk of wrong or harm because of impaired decision-making, dependency, poverty, institutional control, emergency, serious illness, language barriers, or limited alternatives. Safeguards should address the actual mechanism rather than exclude everyone in the category.

Research involving children requires a scientifically justified reason why adults cannot answer the question, proportionate risk, permission from the authorised adult, and the child's assent according to development. A child's dissent carries strong weight, particularly when the study offers no direct benefit. Research involving an adult who cannot consent requires a lawful route, a question relevant to that population, and protection against burdens that cannot be justified by potential benefit or minimal-risk knowledge.

An emergency exception used to provide necessary clinical treatment does not automatically authorise enrolment into research. Emergency research needs the specific safeguards and legal basis

applicable to research, including prior review, strict eligibility, necessity of the emergency setting, and consent from the participant or representative as soon as possible where required.

7.2.4 Placebo and standard of care

Placebo controls may be scientifically useful, but withholding established effective treatment can expose participants to avoidable harm. A placebo may be easier to justify when no proven intervention exists, when it is added to standard care, or when withholding treatment creates no serious or irreversible risk and the scientific reason is compelling. Convenience, lower cost, or regulatory simplicity is not enough.

In international research, using a lower local standard can exploit communities that cannot access the best proven care. The protocol should explain which comparator is ethically defensible, whether the research responds to local health needs, and whether participants or communities can reasonably benefit from successful results.

7.2.5 Independent review and research governance

A research ethics committee examines whether a study is ethically acceptable before recruitment and throughout material changes or safety concerns. Review does not transfer all responsibility from investigators. The committee should have appropriate scientific and ethical expertise, independence, management of conflicts, access to the full protocol, and authority to require changes or stop approval.

EU clinical trials of medicinal products are governed by Regulation (EU) No 536/2014 and use the Clinical Trials Information System. Bulgarian national authorities and the Ethics Committee for Clinical Trials have defined roles. Other human research may follow different national routes. Students should not assume that every service evaluation, audit, innovative treatment, biobank project, and clinical trial has the same review process.

Registration and reporting protect participants because hidden negative results distort future care. Investigators should follow the protocol, report adverse events, preserve data integrity, disclose conflicts, and make results available in a responsible form. Authorship or sponsor pressure does not justify fabrication, falsification, selective outcome reporting, or suppression.

7.2.6 Privacy, data, and biological material

Research using records, images, genetic data, or tissue can create risk without physical contact. Pseudonymisation reduces but does not eliminate identification risk. Consent may be specific to one project or broad enough for a governed range of future research; broad consent is not blanket permission for any use.

Secondary use should be examined for compatibility with the original consent, ethical approval, legal basis, identifiability, commercial involvement, return of results, withdrawal, and effects on groups. Genetic findings may concern relatives, but research laboratories should not promise clinical interpretation or return without a validated pathway.

Biobanks require continuing governance rather than a one-time signature. Access committees, data security, audit, transparent policies, and review of new uses help maintain trust. The confidentiality principles in Practical Class 3 and the consent principles in Practical Class 2 remain applicable, but research adds questions about future unknown use and public value.

Reviewing a human study

1. **Question and value.** Is the question important, answerable, and responsive to a genuine health need?
2. **Design.** Can the methods produce reliable knowledge, and is the comparator ethically defensible?
3. **Selection.** Why are these participants included or excluded, and are burdens and potential benefits distributed fairly?
4. **Risk and benefit.** Separate direct benefit, social value, payment, and each foreseeable burden; specify monitoring and stopping rules.
5. **Consent and vulnerability.** Test understanding, voluntariness, capacity, assent, dependency, and lawful representation.
6. **Governance.** Check independent review, privacy, conflicts, registration, safety reporting, compensation, dissemination, and post-trial arrangements.

7.3 From principle to practice

7.3.1 Moral status and animal research

Animals used in research are capable of interests that matter morally, especially avoidance of pain, distress, fear, and lasting harm. Ethical positions disagree about whether animal and human interests have equal weight, whether species membership has moral relevance, and when expected knowledge can justify animal use. Current practice does not require agreement on one theory, but it does require that animal suffering be counted rather than treated as a technical inconvenience.

The **Three Rs** provide the central practical framework. **Replacement** uses a scientifically satisfactory method that does not require a live protected animal where possible. **Reduction** uses the minimum number consistent with a valid design; too few animals can be as wasteful as too many if the study cannot answer the question. **Refinement** changes procedures, housing, handling, analgesia, training, and endpoints to reduce pain, distress, and lasting harm.

The Three Rs operate together. A poorly validated replacement may fail to protect humans or animals. Reduction must not create an underpowered study. Refinement should not be ignored because the animal will eventually be killed. Researchers must search for alternatives, justify species and numbers, and revise the protocol when better methods become available.

7.3.2 Severity and humane endpoints

A **humane endpoint** is a pre-defined point at which an animal is treated, removed, or killed to prevent avoidable suffering before death becomes the experimental endpoint. Criteria may include weight loss, tumour size, ulceration, inability to eat or drink, abnormal behaviour, respiratory distress, or a validated clinical score. They should be objective enough for trained staff to act without waiting for the principal investigator's convenience.

Death as an endpoint requires exceptional justification when earlier measures can provide the needed information. Analgesia should be withheld only when it would invalidate an essential objective and no refined design can answer the question; the ethical and scientific reasons must be reviewed. Veterinary staff and animal-welfare bodies need authority to intervene when actual suffering exceeds the approved severity or protocol.

Directive 2010/63/EU places replacement, reduction, refinement, project evaluation, authorisation, severity classification, and welfare structures within the EU legal framework. Bulgarian implementation adds national procedures. Ethical approval is not permanent permission to ignore unexpected harm.

Codes, guidance, and binding rules

The 2024 Declaration of Helsinki, Nuremberg Code, Belmont Report, and CIOMS Guidelines are not interchangeable sources of law. The Oviedo Convention, EU Clinical Trials Regulation, EU animal-research directive, and Bulgarian legislation have different legal effects. Their current official status was checked on 17 August 2026. Every real protocol must follow the exact route applicable to its intervention, population, institution, and species.

7.4 Case workshop

7.4.1 Case 1: The paediatric leukaemia trial

An investigator invites a 12-year-old with relapsed leukaemia to a phase I dose-escalation trial. The study's main purpose is to identify toxicity and a suitable dose, although some participants may experience tumour response. The child's parents describe it as "the treatment that will save her" and do not want the investigator to discuss the small chance of direct benefit because she may lose hope. The child asks whether the new drug is known to work and says she is tired of procedures.

7.4.1.1 Questions for discussion

1. Which statements show possible therapeutic misconception?
2. What must the parents and child understand about purpose, benefit, toxicity, alternatives, and withdrawal?
3. What ethical weight should be given to the child's dissent?
4. How does the treating team's dual role affect voluntariness?
5. What changes to recruitment or consent would make enrolment more defensible?

7.4.2 Case 2: The placebo-controlled study

A sponsor proposes a trial of a new treatment for a painful chronic condition. An effective standard treatment exists but is expensive. Participants in the control group would receive placebo alone for twelve weeks; rescue medication is permitted only after a severe symptom threshold is reached. The sponsor argues that placebo will produce a clearer result and speed regulatory approval. The trial is planned mainly in hospitals serving low-income communities.

7.4.2.1 Questions for discussion

1. What scientific question requires placebo rather than an active comparator?
2. What harms may result from withholding established treatment, and are they reversible?
3. Does recruitment from low-income communities create exploitation, fair inclusion, or both depending on design?
4. Which rescue, monitoring, and stopping rules are required?
5. Is the proposed comparator ethically defensible, and what alternative design should be considered?

7.4.3 Case 3: Research during an acute stroke

Mr Marinov arrives with a severe acute stroke, cannot communicate, and has no representative available within the treatment window. A randomised study compares standard intervention with standard intervention plus an experimental drug carrying additional bleeding risk. The study has

ethics approval for emergency enrolment under specified conditions. A junior investigator assumes that the clinical emergency exception to consent is sufficient and prepares the study drug without checking the protocol's research-specific safeguards.

7.4.3.1 Questions for discussion

1. Why does authority to provide urgent treatment not automatically authorise research enrolment?
2. Which protocol, legal, and ethics conditions must be checked before enrolment?
3. How should risk, potential direct benefit, and the necessity of the emergency population be assessed?
4. What information should be given later to Mr Marinov or his representative?
5. What should the junior investigator do if there is insufficient time to verify eligibility?

7.4.4 Case 4: The diabetes biobank

Ten years ago, patients donated blood and data for a study of diabetes. The consent referred only to that project. A commercial company now seeks access to pseudonymised samples and records to develop a patentable risk test for obesity and cardiovascular disease. Re-contact is possible for many but not all donors. The hospital expects licensing income, and the access committee includes investigators who would receive research funding from the company.

7.4.4.1 Questions for discussion

1. Does the original consent cover the proposed purpose, commercial involvement, and linked data?
2. What does pseudonymisation protect, and which risks remain?
3. When might re-consent, waiver, exclusion, or a different governance route be justified?
4. How should conflicts of interest within the access committee be managed?
5. What policies are needed for withdrawal, return of findings, benefit sharing, and public transparency?

7.4.5 Case 5: The avoidable rabbit test

A manufacturer proposes a skin-irritation study using thirty rabbits for a new cleaning product. Similar compounds have extensive existing data, and a validated reconstructed human epidermis method may answer the regulatory question without live animals. The company argues that its established rabbit protocol is familiar to staff and that changing methods may delay launch. The animal-welfare body has not been given the literature search for alternatives.

7.4.5.1 Questions for discussion

1. Has the scientific and regulatory need for live animals been established?
2. How do replacement and reduction apply before refinement is considered?
3. What evidence should the investigator provide about alternatives and existing data?
4. Does commercial delay justify animal pain or uncertainty about method validation?
5. What decision should the review body make and what further information, if any, should it request?

7.4.6 Case 6: The tumour endpoint

A mouse study of a cancer drug uses death as the endpoint. Several animals develop ulcerated tumours, marked weight loss, reduced movement, and respiratory distress. The approved protocol requires daily monitoring but does not give numerical stopping criteria. The veterinarian recommends immediate euthanasia and amendment of the protocol. The principal investigator refuses because early euthanasia will alter the survival analysis and delay publication.

7.4.6.1 Questions for discussion

1. Which observations indicate that actual severity may exceed what was ethically acceptable?
2. What humane endpoints could have been defined before the study?
3. How can scientific validity be preserved while refining the endpoint and analysis?
4. What authority and duties do the veterinarian, animal-welfare body, and institution have during the active study?
5. Should the study be paused, modified, or terminated, and how should that decision be justified?

7.5 Applied class exercise

Form a research ethics committee with clinical, methodological, participant, legal, and animal-welfare perspectives. Review either Case 2 or Case 6. Produce one of three decisions: approve, require modifications, or reject. State the scientific question, moral subjects, main risk, expected value, required safeguard, and condition that would stop the study.

The committee must then defend its decision against a sponsor who argues that delay will waste money and postpone useful knowledge. Revise any condition that is ethically desirable but too vague to monitor in practice.

7.6 Self-check

1. Distinguish research from clinical care and therapeutic misconception from therapeutic optimism.
2. Why are social value and scientific validity ethical requirements?
3. What makes a population vulnerable in a particular study?
4. When may placebo use be ethically defensible?
5. Explain why reduction does not mean using the smallest imaginable number of animals.
6. Choose one workshop case and write a committee decision of no more than 180 words. State whether the study should be approved, modified, or rejected; identify the decisive reason; and name the current code, professional rule, or law that must be verified.