Informed consent

Ethical and legal aspects

Practical Class 2 · Social Medicine and Medical Ethics I · 2026/2027

Chief Assistant Professor Kostadin Kostadinov, MD, PhD

Department of Social Medicine and Public Health

Core questions

- Ethical foundations and conditions for valid consent.
- Information, understanding and voluntariness.
- Decision-making capacity and legal representation.
- Bulgarian legislation: Health Act, Arts. 87–92; Ordinance No. 8/2018.
- Refusal, emergencies and documentation.

Five questions about one decision

1. Ethical foundations of consent
2. Decision-making capacity
3. The Bulgarian legal framework
4. Refusal, emergencies and legal exceptions
5. Applying the rules in clinical practice

What informed consent means

> The patient's free and informed authorisation of a specific healthcare intervention after receiving and understanding the relevant information.

- Moral basis: respect for the person.
- Legal conditions: who decides, about what, and through which process.
- Clinical process: communication, choice and documentation.

Ethical foundations of consent

A good aim also needs a good decision

Autonomy

The patient decides about their own body.

Beneficence

The clinician offers justified care.

Non-maleficence

Consider harms of intervention and of refusal.

Justice

Language, disability and poverty must not exclude participation.

Autonomy includes values and relationships

- An autonomous choice expresses the person’s own values.
- Dependence on care does not erase the right to participate.
- Family involvement may support a decision when the patient wants it.
- Freedom of choice does not oblige a clinician to offer an unjustified intervention.

Paternalism and professional recommendation

Recommendation

A reasoned opinion that leaves room to decline.

Paternalism

Restricting choice for the patient's presumed benefit.

"I know what is best" is not sufficient authority to intervene.

Support where understanding is impaired requires individual assessment and an applicable legal basis.

Five conditions for an informed decision

1	2	3	4	5
Information	**Understanding**	**Capacity**	**Voluntariness**	**Specific choice**

The patient authorises a **specific intervention** after a meaningful discussion.

A signature records a decision; it does not create its preconditions.

Expressing consent and defining its scope

Form	Meaning
Express oral	Clear verbal agreement after information
Express written	Documented agreement; mandatory where legislation requires it
Through conduct	Unambiguous action in context; never a substitute for required written consent

Silence or lack of resistance does not establish an informed choice.

The conversation starts before the form

1	2	3	4	5
Offer	**Explain**	**Listen**	**Check**	**Confirm**

- Discuss the aim, alternatives and personal priorities.
- Allow time and support for a decision.
- Confirm the choice and its scope.
- Revisit consent when the plan or circumstances change.

What must the treating doctor explain?

The condition

Diagnosis, nature of illness and prognosis.

The proposal

Purpose, nature and expected outcomes.

The options

Reasonable alternatives and consequences of refusal.

The risks

Possible complications, adverse effects, pain and burdens.

In good time, with an appropriate amount and form of information.

Relevant information is patient-specific

Probability

How often does the complication occur?

Severity

What happens if it occurs?

Personal priorities

What does it mean for work, family and daily life?

Uncertainty

What cannot be predicted reliably?

Explain benefits and harms in a balanced way, using understandable comparisons.

Check how well you explained it

> “To check that I explained this clearly: how would you describe what we are offering and what other options you have?”

- “What do you expect if you choose to wait?”
- “Which risk matters most to you?”
- Clarify gaps and check again.

Support preserves freedom of choice

Persuasion

Explain the reasons for the recommendation.

Support

Involve someone close if the patient wishes.

Pressure

Threats, shame or making care conditional on obedience.

Check

Speak privately: “Is this what you want?”

Case 1 · The signed form

A patient is admitted for elective surgery. The doctor is busy and asks the nurse to bring the form. The patient understands little Bulgarian and signs. Before anaesthesia, the patient says: “I thought this was just a test.”

- Which condition for consent is missing?
- What must happen before surgery?

Decision-making capacity

Legal status and clinical capacity

Legal status

Age and the applicable rules governing legal representation.

Decision-making capacity

A clinical assessment for this intervention at this time.

A diagnosis, age or disagreement with the clinician does not, by itself, establish incapacity.

Four questions for clinical assessment

Understand?

What is proposed, and why?

Retain?

Can the person retain information long enough to decide?

Use and weigh?

Can they consider consequences for themselves?

Communicate?

By speech, writing, gesture or an appropriate aid.

A clinical framework from UK guidance; not a standalone Bulgarian legal test.

First make decision-making possible

1	2	3	4
Communication	**Relief**	**Time**	**Reassess**

- Interpreter, glasses, hearing aid and accessible information.
- Identify and treat reversible causes of confusion.
- Choose the right time; defer when clinically safe.
- Involve the patient as fully as possible.

Representation and family involvement

- Address reversible causes and support communication.
- Defer the elective intervention when safe.
- Verify the legal basis for any representative’s authority.
- Relatives can explain the patient’s values and preferences.

Kinship alone does not create general authority to consent for an adult.

The Bulgarian legal framework

Identify the kind of rule

Source	Role
Bulgarian legislation	Health Act, Arts. 87–92: consent, information, form, refusal
Oviedo Convention	Rights and safeguards for healthcare interventions
Professional ethics	WMA: principles governing professional conduct
Overseas guidance	GMC: a useful clinical reference from the UK

Start with the adult patient

Situation	General Health Act rule
Able to decide	The patient gives consent
Limited interdiction	Patient’s consent plus that of the appointed curator
Legal incapacity	Consent by the legal representative under Art. 87(4)
Mental disorder with established incapacity	Specific provisions: Art. 87(7); Art. 89(3)

Specific rules for mental disorders

- A mental disorder and established inability to consent are distinct conditions.
- Article 87(7) refers to persons designated through Article 162(3).
- Interventions under Article 89(1) also engage the specific procedure in paragraph 3.
- A diagnosis alone does not authorise treatment against the person’s will.

Age changes the general rule

Age	Who participates in consent?
Under 14	Parent or guardian; involve the child according to maturity
14 to under 18	Patient plus parent or curator
From age 16	Exception for specified counselling, preventive examinations and tests under Ordinance No. 8/2018

Ordinance No. 8/2018: scope from age sixteen

Health counselling

Behavioural risk; mental, sexual, reproductive and dental health; navigating healthcare.

Tests

Specified infection tests, preventive blood and urine tests, pregnancy testing.

Preventive examinations

Within the specified scope; dental examination and specialist preventive assessment.

Boundary

No parental consent for the listed activities; not an exemption for every treatment.

Ordinance No. 8/2018: notification

> Article 5 requires the doctor to notify the parent or curator in a timely manner if an abnormality or illness is identified during activities covered by the Ordinance.

- Separate consent to the activity from information-sharing rules.
- Explain confidentiality limits in advance.
- Do not promise absolute secrecy in every circumstance.

The child participates according to maturity

Legal consent

Who may authorise the intervention under the applicable law?

Participation and assent

What does the child understand, and how do they express agreement or objection?

Assent: active agreement appropriate to the child's abilities.

For ages 14–17, the patient's own consent under Article 87(2) is a legal requirement, not merely an ethical courtesy.

When is written consent required?

- **Surgery** and **general anaesthesia**.
- Invasive and other diagnostic/therapeutic methods involving increased risk to life or health, or temporary alteration of consciousness.
- Article 89(1) requires both the information and the consent in written form.

A written record does not replace the conversation.

The choice not to know is also personal

> A relative says: “Do not tell her the diagnosis.” The patient has not yet been asked what she wants to know.

- Establish the patient’s own preferences.
- Article 92(2)–(3) permits declining specified information and requires a written record.
- Written authority to receive information is not general authority to decide for the patient.

Consent authorises a defined intervention

- Define the type and scope of the proposed intervention.
- Discuss foreseeable extensions in advance.
- A new elective intervention requires a new discussion and the required form.
- An unexpected immediate danger is assessed against Article 89(2).

Anaesthesia does not turn limited consent into blanket permission.

Case 2 · Counselling or intervention?

A 16-year-old asks for contraceptive counselling without a parent present. Afterwards, she asks whether an intrauterine device can be inserted today. There is no emergency and no identified illness.

- Do the conversation and the procedure follow the same rule?
- What can be promised about confidentiality?

Refusal, emergencies and legal exceptions

Refusal also needs a conversation

1	2	3	4
Clarify	**Inform**	**Offer**	**Record**

- Check understanding, capacity, voluntariness and reasons.
- Discuss consequences and acceptable alternatives.
- Record refusal with a signature; if unable or unwilling to sign, the doctor and a witness attest it.
- The patient may change their decision; care continues.

Article 90: recording a refusal

Situation	Record
The person signs	Refusal is recorded in the medical documentation with that person’s signature.
Unable or unwilling to sign	The treating doctor and a witness attest the refusal.
Refusal is withdrawn	This may happen at any time; record the new decision and subsequent actions.

Article 89(2): immediate danger

- **An immediate threat to the patient's life.**
- The physical or mental condition prevents expression of informed consent.
- Consent cannot be obtained in time from a representative where legally required.
- The exception concerns Article 89(1) interventions for the patient's health benefit.

Article 90(4): refusal with life at risk

> When treatment is refused and the patient's life is threatened, the head of the healthcare establishment may decide on life-saving treatment.

- The provision identifies a specific decision-maker.
- Disagreement is not thereby classified as incapacity.
- Application requires assessment of the facts, rights and scope of intervention.

Two different legal situations

Article 89(2)	Article 90(4)
Immediate threat to life; the patient cannot express informed consent.	An expressed refusal and a threat to the patient’s life.
Consent cannot be obtained in time from a legally required representative.	The head of the healthcare establishment may decide on life-saving treatment.
Exception to written consent for the interventions in paragraph 1.	Not automatic authority for every clinician to override refusal.

Article 91: care against a patient’s will

Care against a patient’s will is permissible only in cases provided for by law.

- Ethical concern does not, by itself, create legal authority.
- Hospital rules cannot independently create a new exception.
- For a special regime, verify the legal basis, competent authority and procedure.

Previously expressed wishes

- Article 9 of the Oviedo Convention requires previously expressed wishes to be taken into account.
- This matters when the patient cannot express their wishes at the time.
- Check the content, applicability and reliability of the information.
- Do not automatically import another country’s advance-directive regime.

Case 3 · Refusal with life at risk

An adult refuses a proposed blood transfusion because of personal beliefs. The patient clearly explains the risks, including death, and consistently confirms the choice. Bleeding increases, and the team identifies a threat to life.

- Which facts support an autonomous refusal?
- What does Article 90(4) add to the legal analysis?

Applying the rules in clinical practice

Who bears the duty to inform?

Treating doctor

Provides Article 88 information and fulfils Article 92 duties.

Healthcare team

Supports preparation, interpretation, accessibility and recording.

The allocation of practical tasks does not turn a form into a substitute for the doctor’s discussion.

Consent does not waive responsibility for negligence or departures from professional standards.

The record should show the decision

What was discussed?

Intervention, benefits, risks, alternatives and refusal.

What did the patient choose?

Priorities, questions, scope and limits.

What support was provided?

Interpretation, aids, time and capacity assessment.

What happens next?

Date, participants, required form and reassessment.

Revisit consent when circumstances change

- The proposed intervention or its scope changes.
- New relevant information emerges about risks or alternatives.
- The condition, capacity or preferences change.
- The patient adds limits or withdraws consent.

A previous signature does not remove the need to establish current wishes.

Care and research are separate decisions

Clinical care

Aim: care for this patient. Consent to the proposed intervention.

Research

Aim: generate knowledge. Separate information, free choice and ethics oversight.

Declining participation must not undermine standard care.

The emergency exception for treatment is not blanket permission to enrol someone in research.

Shared decision-making

The clinician

Explains the options, evidence and uncertainty.

The patient

Expresses goals, values and acceptable treatment burdens.

The discussion brings these perspectives together.

Consent authorises the intervention; shared decision-making describes how the choice is reached.

Five questions before intervention

1. **Who decides?**
2. **Do they understand?**
3. **Is the choice free?**
4. **What is authorised?**
5. **How is it recorded?**

If consent is refused or cannot be obtained: establish urgency and the specific legal basis.

Informed consent starts with a conversation.

It leads to a decision the patient understands.