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Attitudes and awareness in autonomous decision on medical treatment or inclusion in clinical trials amongst Slovenian adolescents: an online survey

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Abstract

Background In Europe and elsewhere in the world, activities are taking place to improve the awareness of children and adolescents (hereinafter: adolescents) regarding their rights and obligations in autonomous decision-making about their own medical treatment and participation in clinical research.

Methods The cross-sectional survey of adolescents was carried out using an anonymous online questionnaire. We obtained consent from the Commission of the Republic of Slovenia for Medical Ethics. Participating young people were invited through the network of primary and secondary schools, the Society of Dystrophy of Slovenia and through the dissemination of electronic messages. The online questionnaire was open from April 25 to May 6, 2023. Young people aged 13 to 20 joined the survey. The association between several factors and awareness of the minimum age limit was tested by univariate logistic regression. All statistical testing was performed at a significance level of 0.05.

Results The responses of 458 respondents were analysed, of which 281 were male. Only 8.3% of participating adolescents knew the age limit set by law for autonomous decision-making about medical treatment at 15 years old. Most answered that a medical institution should inform them about their rights (62.4%). Only 5.02% responded that they do not need their parents' consent when making decisions; 2.6% of respondents answered that they autonomously decided to undergo treatment without their parents' knowledge. The majority obtained information about treatment from a doctor (more than 70%); 42.8% were in favour of new forms of treatment, especially chronic patients (more than 70%); 44.8% had already heard about clinical research, most of them through the media (55.4%); 70% of the respondents answered correctly about making an autonomous decision about participation in research at the age of 18. About three-quarters (75.6%) of respondents who had heard of clinical research believe that an individual should be paid for participating.

Conclusions Our research showed insufficient awareness of the age limit of adolescents regarding medical treatment decisions and clinical research. The prevailing view is that health professionals should inform young people more about their rights. Most adolescents believe they should be paid to participate in clinical research.

Keywords Decision-making, Competence, Treatment, Clinical research, Informed consent

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Background

Various national and international laws and guidelines emphasise the importance of respecting the development and autonomy of adolescents and their involvement in decision-making about their treatment and participation in clinical research. Activities are also being carried out in Europe and elsewhere to improve adolescents' awareness of their rights and the possibility of participating in clinical research [1–4]. However, there are significant differences in policy and implementation across countries. Efforts are being made towards unifying standards in international environments for respecting children's rights. [5].

The United Nations Convention on the Rights of the Child thus recognises children's right to the highest level of healthcare and medical treatment services [6]. General comment no. 20 to Article 24 of the Convention on the Rights of the Child stipulates that children who are capable of understanding can give their free consent to any treatment, regardless of whether parental consent is required [7].

More specific medical guidelines include the Second Directive of the European Parliament and of the Council of the European Union, which states that clinical trials on minors can only be carried out if the minor has received information in accordance with their capacity to understand [8]. Young people want greater participation in health decisions than they receive, and they are often limited in this by health professionals or parents, so it is essential to accept or implement relevant legislation [9].

There is no universal agreement in the world about the age at which minors should be competent to make autonomous decisions regarding treatment or participation in clinical research [10, 11].

The EU Agency for Fundamental Rights (FRA) has presented on its website the age range in which children in EU member states can autonomously give consent to treatment without the necessary parental consent, ranging between 14 and 18 years or according to the child's level of maturity [12].

When adolescents are involved in clinical research, there are legal obstacles to their autonomous participation in research [13]. In the European Union, for participation in clinical research with a clinical trial of minors who have not yet acquired total legal capacity in a particular country, it is the case that the minor's legal representatives must give their consent to the clinical trial. However, this does not apply to non-interventional studies. If competent, a minor must also give consent [14].

In the United States, the degree of risk, the adolescent's decision-making capacity and the potential benefits to the individual are key factors in deciding whether a young person needs parental consent. Individual laws determine when an adolescent needs parental consent to participate in research. Consent is not required when the risk is minimal or when the young person is mature enough. Restrictions on the participation of young people in research also apply to different categories of research [13].

Several laws and acts in Slovene legislation define rights [14–20]. The age in Slovenia at which a young person can autonomously decide on their own treatment or inclusion in clinical research without a clinical trial is 15. At the same time, exceptions are allowed. An adolescent may be younger for self-determination if the doctor assesses through an exploratory interview with the adolescent that only they are competent, or they must be older if the doctor considers that they are not mature enough to make a decision. In addition to the aforementioned, the Patient's Rights Act (ZPacP) also requires an interview with the parents for doubtful cases—an extended exploratory interview.

In order to be enrolled in a clinical trial in Slovenia, the consent of the legal representative of the adolescent is required before the child reaches the age of 18, and after the age of 15, the consent of the adolescent is also required, if the adolescent is competent to do so [14]. According to the traditional position of the Commission for Medical Ethics of the Republic of Slovenia (KME RS), for all clinical research, in addition to the consent of a young person over 15 years of age, the consent of both their parents or guardians is required. However, there is also a safeguard in Slovene legislation that states that parents are the legal representatives of minors and are responsible for their best interest, so in interpreting laws, one must be careful and consider the age limit only as a framework recommendation, and otherwise adhere to the rule that parents, or the legal representatives of minors, make decisions in their best interest [20]. More details are presented in the Supplementary Fig. 1.

It is essential when including young people in research that their opinion is heard and taken into account, that they can express their views and that they are involved in planning and decision-making [9, 21–24]. They should be given an equal role [25, 26]. Teenagers look at things from different perspectives and ask questions that adults don't even think about. The research questions they formulate fundamentally differ from those of adults, contributing valuable innovative perspectives to research [27–30]. Research shows that an equal relationship of participation in research between young people and adults is optimal for successful research development [31–36].

Various organisations and networks have been established worldwide for better cooperation and inclusion of a larger number of adolescents in research, which helps connect all stakeholders in health research. One such is

the Young Persons Advisory Groups (YPAGs), which help young people to understand clinical research, share their experiences and views, and influence all phases of research, including research question development, research design and implementation, recruitment, and strategies for disseminating results [29]. Young patients, their family members and supporters are brought together by the International Children's Counselling Network (iCAN) [37–39]. It aims to ensure the voice of paediatric patients in decision-making at higher levels, such as regulatory agencies and pharmaceutical companies, in developing clinical trials and treatments. The advantage of such and similar networks is that they enable the acquisition of valuable perspectives from young people on clinical research and healthcare [37] and encourage more adolescents to participate in research [39]. The education of young people about the rights of treatment and clinical research must be carried out in educational institutions at the national level. The adolescent's gender should not be an obstacle to accessing the information. It is also necessary to raise awareness of legal representatives-parents [24].

In order to involve adolescents in research, it is crucial to develop systematic training protocols and organisational practices that enable participation without extensive individual institutional investments [40]. Many examples support youth participation in research, but there is little research documenting methodology with stepwise protocols and impact evaluation [13, 39, 41]. One such study was the research "*Involving young people in participatory research and evaluation*", which illustrated and compared the active participation of young people in research on four examples of research projects. The research systematically provided guidelines for successful participation. It confirmed the benefits of youth involvement and participation in clinical research (Rural HIV Prevention Study, Independent Living Study, Youth and Adult Leaders for Program Excellence, and the UNICEF Project—What Should Every Adolescent Know) [41].

In developed countries, financial compensation is often provided to clinical research participants, encouraging the participation of both adults and children [42–51]. These payments are ethically questionable, especially in paediatrics, and are only acceptable as compensation or reimbursement in cases of low or negligible risk [45–48, 51–55]. In Slovenia and elsewhere in the European Union, financial support for clinical trials is not allowed, except for compensation for direct costs [14].

No research has yet been conducted in Slovenia on adolescents' attitudes and their awareness of autonomous decision-making for treatment or inclusion in clinical research. We assess that Slovene adolescents are insufficiently aware of the age limit of 15 years, which guarantees them decision-making in treatment and 18 years for inclusion in clinical research through a clinical trial, that the majority of adolescents before the age of 18 are not informed about all the negative and positive consequences of treatment or clinical research, indicating a lack of communication with healthcare professionals that adolescents before the age of 18 do not make autonomous decisions about treatment or involvement in clinical research as there may be indifference or uncertainty about how to involve young people in active participation in decisions related to their health care [5, 56] and that disputes between adolescents and their legal representatives-parents are rare, may be due to the superior role of parents [9, 11, 24].

The survey research was focused on investigating the attitudes and awareness of Slovenian adolescents about autonomous decision-making for treatment or inclusion in clinical research.

The research approach also closes the gap in the international environment, as it examines adolescent's awareness of rights and their implementation in health care comprehensively, outside of health settings, and inquiries about their opinion and wishes related to health care, being aware of the importance of including adolescents' voices in health decision-making processes.

The findings from this research can help harmonise Slovenian practice with broader European standards, which ultimately encourages greater respect for the rights of young patients [14, 26] and stimulate further international awareness research and youth participation in a variety of settings outside of health care.

Aim and Hypothesis

The aim of the pilot study was to examine the understanding and attitudes of adolescents towards treatment and clinical research in Slovenia. By surveying elementary and high school students, we checked their experiences. We studied the implementation of their rights to information, participation and independent decision-making in medical treatment, as stipulated in the legislation of the Republic of Slovenia. The aim of the research was also to raise awareness among adolescents, their doctors and medical staff about this.

Working hypotheses were formulated based on ethical and legal aspects related to adolescents in healthcare:

- Hypothesis 1: More than 80% of adolescents are not aware of the age limit at which they can make independent decisions about their treatment.

- Hypothesis 2: More than 80% of adolescents learn the right to make decisions in a medical institution or with a doctor.
- Hypothesis 3: More than 80% of adolescents would like to make independent decisions about their treatment before age 16.
- Hypothesis 4: 80% of adolescents believe that an adolescent under the age of 18 should always be assessed before being allowed to make independent treatment decisions.
- Hypothesis 5: At least 50% of adolescents would ask their parents for advice on any procedure.
- Hypothesis 6: more than 90% of adolescents are involved in treatment or intervention decisions during hospitalisation or treatment of a chronic or rare disease.
- Hypothesis 7: More than 70% of adolescents favour new treatment methods.
- Hypothesis 8: More than half of adolescents have heard of clinical research.
- Hypothesis 9: At least 50% of adolescents who were aware of clinical research believe it would not be necessary to receive payment for participating.

Concerning working hypotheses, we asked ourselves three key questions:

1. about autonomous decision-making for treatment,
2. medical assessment of the adolescent's maturity
3. involvement of parents and adolescents in clinical research, which we discussed in more detail with the established hypotheses.

Methods

This study was designed as a cross-sectional online survey entitled "Decision-Making about Treatment or Inclusion in a Clinical Trial—Adolescents". The aim of the survey was to assess their knowledge and attitudes regarding their rights in treatment decisions and participation in clinical research. The questionnaire is open-ended (quantitative, observational and descriptive research).

The online survey was conducted online using Google Forms and distributed throughout Slovenia. Participants were recruited through several channels, including networks of primary and secondary schools, professional workers in educational institutions, the Dystrophy Association of Slovenia, the Association for Rare Diseases, and electronic communication among adolescents (see Supplementary Fig. 2 for the distribution network). The survey was available for completion from April 25 to May 6, 2023.

Sample size and target population

The target population for this survey was primary and secondary school students from Slovenia. We estimate that there was a 10% response rate from institutions that were aware of the survey and a 10% response rate from individuals reached by the survey. We aimed to obtain a diverse sample of 300 primary and secondary school students.

Inclusion and exclusion criteria

The survey included adolescents between the ages of thirteen and twenty, including thirteen and twenty-year-olds. All adolescents included in the survey had to attend primary or secondary school, live in Slovenia and are users of Slovenian healthcare (they have health insurance in Slovenia). Inclusion criteria included willingness to participate voluntarily, informed consent given by adolescents, and additional consent from parents or guardians for those under 18 years of age. In some educational institutions, consent was obtained following their standard procedures.

Exclusion criteria included surveys of adolescents who did not attend primary or secondary school. Although we wanted to include all adolescents between the ages of 13 and 20, only 10 participants in the sample were students, unemployed or employed. This group of participants was too diverse and too small to adequately represent all students, employed and unemployed between the ages of 13 and 20, and were therefore excluded from the final analysis.

After applying these criteria, out of a total of 468 surveys received, we analysed the answers of 458 adolescents who attended primary or secondary school; the difference is represented by 10 who did not have the status of primary or secondary school.

Ethical aspects

We obtained consent from The National Medical Ethics Committee of the Republic of Slovenia to conduct the research (no. of co: 0120–171/2023/3, date of consent May 9, 2023).

Informed consent was obtained from all participants. Additional written consent from parents or guardians was required for children under 18. The parental consent contained a clear statement that they agreed with their child's participation in anonymous research and that they were adequately informed about the nature, purpose and goals of the study. Participants and parents were required to send consent to a specific email address or submit it in

accordance with the institutional protocols of the schools where the research was conducted.

The informed consent included a brief description of the research, which emphasised that the research would be conducted anonymously, voluntarily, for academic purposes and without commercial interest and that it aimed to improve the awareness of adolescents about their rights in relation to treatment and clinical research. The survey questionnaire was available for inspection in the schools where the research was conducted, ensuring complete transparency.

The anonymity of the participants was fully guaranteed; no personally identifiable information was collected or stored. The completed survey questionnaires were treated strictly confidentially, and the results were analysed only in aggregate form, which additionally guarantees the participants' privacy.

Filling in the survey questionnaires on medical topics can create risks and burdens for the people involved. To avoid this, we emphasise that participation in the research was voluntary, and participants could withdraw from participation or omit individual questions at any time without consequences.

We assume that the survey will benefit respondents who have not thought about this topic until now; it will encourage them to become familiar with the rights discussed in medical treatment or inclusion in clinical research.

Questionnaire development and validity

The questionnaire was developed in a multidisciplinary manner with renowned Slovenian experts in the fields of medicine, psychology, education, law, and ethics. Cooperation was based on open and transparent communication, the purpose of which was to ensure the adequacy of the questionnaire by considering different perspectives. These experts checked the content validity of the questionnaire to ensure that it accurately covered the topics covered.

The research has a participatory approach, as one of its authors is also a young person with many years of experience as a user of hospital services due to a neurological illness. His active participation in the preparation of the questionnaire made it possible to include in the research the aspects and experiences that are important for adolescents who are directly connected to health services.

Pilot testing was carried out on a sample of 17 adolescents, including some with chronic diseases, which allowed for the obtaining of diverse feedback regarding the clarity and comprehensibility of the questions and the functionality of the entire questionnaire. Based on this feedback, adjustments were made to the questionnaire, which mainly related to visual corrections for a better user experience; only one question was restructured to improve the comprehensibility and orientation of the respondents. Also, some originally designed options for additional enrolment were excluded. The survey lasted between 6 and 10 min, depending on the participants' familiarity with specific terms such as "clinical research" or their experiences with diseases or hospitalisation. The invitation to participate contained a brief content and the purpose of the research.

The final questionnaire contained 42 questions in eight sections. The questionnaire was designed with exclusionary questions, resulting in all respondents answering 20 questions and respondents with more knowledge or more health problems up to 42 questions.

Structure of the research by headings with the number of questions:

1. Demographic data (5 questions) – This set includes questions about gender, age, status, regions of residence and frequency of visits to the doctor.
2. Hospitalisation (4 questions) – The questions refer to the number of hospitalisations and decision-makers in treatment.
3. Chronic diseases (3 questions) – This set covers questions about chronic diseases and who made treatment decisions.
4. Rare diseases (3 questions) – Questions refer to the presence of rare diseases and treatment decisions.
5. Age limit (8 questions) – The questions in this section deal with awareness and opinions about age limits for independent decision-making about treatment.
6. Influences on decision-making (6 questions) – This section focuses on young people's opinions about who should inform them about age limits and who should decide on their treatment.
7. Favourability of new forms of treatment (1 question) – The question assesses adolescents' favourability towards new treatment forms.
8. Clinical research (12 questions) – This set's questions refer to adolescents' experiences, attitudes and willingness to participate in clinical research.

The entire Survey Questionnaire can be seen in Supplementary Attachment 1.

Data analysis

Categorical variables were described by frequencies and percentages and continuous with means and standard deviations. The comparison in shares of sample and population characteristics was performed using the goodness of fit chi-square test, while the association between several factors and awareness of minimum age limit for

consenting to treatment or several factors and being in favour of new medical treatments was tested using univariate logistic regression analysis. All the statistical testing was performed at a 0.05 level of significance. Statistical analysis was performed using SPSS version 28.

There was only one continuous variable in the questionnaire—the age of the respondents, which was described by the mean and standard deviation. The normality of the distribution of this variable was examined by calculating the coefficient of skewness and kurtosis, both of which were in the range between -1 and 1, indicating approximately normal distribution of the variable [57]. More rigorous testing of the non-normality was not applied as the variable was not used in statistical testing, assuming the normality of the distribution. All other variables used in the statistical analysis were categorical. The statistical tests appropriate for categorical variables were therefore used. This analysis has no assumptions regarding the normality of the distribution of the continuous variable that might be included as a predictor variable.

Results

Demographic characteristics of respondents and their medical history are summarised in Table 1. Overall, 458 primary and secondary school pupils were included in the survey. Of those, 281 (61.4%) were males, 351 (76.6%) were secondary school pupils, and 150 (32.8%) lived in the central region of Slovenia. The mean age of respondents was 16.2 years ± 1.5 years. There was a statistically significantly higher share of secondary school pupils than in the Slovene population ($p < 0.001$). According to the Statistical Office of Slovenia, there were 28% of secondary school pupils in 2022. There was a statistically significantly higher share of male pupils in the sample ($p < 0.001$) than in the whole Slovene population (51%). There was a significantly higher share of pupils from the central region ($p = 0.016$) in the sample than in the whole Slovene population (28%).

Approximately half of respondents (236; 51.5%) visit the family physician once a year or less frequently. There were 42 (9.2%) respondents with a chronic disease and 14 (3.1%) with a rare disease included in the sample. More than half (53.9%) of respondents had been hospitalised at least once.

Overall, 202 (44.1%) of respondents claimed to know the minimum age requirement for consenting to medical treatment (Table 2); however, only 38 (18.8%) of those stated the correct age limit of 15 years. The share of respondents in the sample knowing the minimum age requirement was, therefore 38 (8.3%). This is statistically significantly lower than 20% ($p < 0.001$). Of those who correctly stated the minimum age requirement, more than one-third (36.8%) obtained this information from their family. More than half (53.5%) of respondents claimed their parents were aware of the age limit; however, only 33 (7.2%) claimed that their parents provided the correct age limit to them. Respondents would like to obtain information about the minimum age limit from three sources: medical institutions (62.4%), educational institutions (60.6%) and family (50.8%). More than two-thirds of adolescents believe that assessing an adolescent's maturity should be necessary

Table 1 Demographic characteristics and medical history

	n **= 458 (%)**
Male gender	281 (61.4)
Secondary school student	351 (76.6)
Age (mean ± SD years)[a]	16.2 (1.5)[a]
Central Region	150 (32.8)
Family physician visit	
Once a year or less	236 (51.5)
2 – 3 times a year	158 (34.5)
4 times a year or more	64 (14)
Hospitalisation	247 (53.9)
Frequency of hospitalisation	
1 – 2	174 (70.4)
3 – 5	58 (23.5)
6 or more	15 (6.1)
Chronic disease	42 (9.2)
Rare disease	14 (3.1)

Legend: [a]mean (SD-standard deviation)

Table 2 Minimum age requirement for consenting to medical treatment

	n **= 458 (%)**
Aware of the minimum age requirement	202 (44.1)
Knowing min. age requirement 15 yrs (*n* = 202)	38 (18.8)
Source of information (*n* = 38)	
Friends	2 (5.3)
Web	4 (10.5)
Nowhere	7 (18.4)
Educational institution	6 (15.8)
Family	14 (36.8)
Medical institution	5 (13.2)
Parents aware of minimum age consent—general	245 (53.5)
Parents aware of 15 yrs limit	33 (7.2)
Desired source of information (*n* = 457)	
Family	232 (50.8)
Educational institution	277 (60.6)
Medical institution	285 (62.4)
On their own	1 (0.2)
Assess adolescent's maturity	38 (69.4)

before obtaining their consent to treatment or medical procedure.

Experience with informed consent during hospitalisation and treatment of chronic or rare diseases is summarised in Table 3. About half of respondents reported that they had been included in the decision on their medical treatment or procedure during hospitalisation or treatment of a chronic or rare disease. The majority (more than 70%) obtained information about the effect of treatment from the physician.

Respondents would like to consult with parents about their medical treatment when deciding about medium (23.8%) or severe (30.1%) treatment procedures or every time (36.2%) (Table 4). Twelve (2.6%) respondents underwent a medical treatment or procedure without their parents' knowledge. Most (63.5%) would like their parents to decide on their treatment when they were unable to participate in the decision themselves. Seventy (15.3%) respondents disagreed with at least one party (parents, physician) about their treatment or procedure. Half of them (51.4%) were against the proposed treatment, and more than half (57.1%) underwent it despite their reluctance.

Less than half (196, 42.8%) of respondents favoured new treatments (Table 5). The number (%) of patients with chronic and rare diseases in favour of new treatment was 23 (54.8%) and 9 (64.3%) (data not shown). There were 205 (44.8%) respondents who had already heard of clinical studies, more than half (55.4%) from the media or the Internet, and more than three-quarters (76.6%) answered that both ill and healthy people could be included in studies. Twenty-six (12.7%) respondents who had heard of clinical studies had been invited to participate, and 19 (9.3%) had been included in one. Of the latter, 4 (21.1%) had been informed about the treatment effects. Of those who had heard about clinical studies ($n=205$), 24 (11.7%) would never participate in a clinical trial, 65 (31.7%) were unsure whether they would participate, while 15 (7.3%) would always participate in a clinical study. Willingness to participate was mainly conditioned on treatments that would improve their condition (30.7%). Rather, more than 70% (71.2) of respondents who were aware of clinical studies stated that the minimum age requirement for an autonomous decision about inclusion in such a study is 18 years. A minority of respondents (12; 5.9%) stated that the minimum age requirement is 15 years. Of 17 respondents who had been included in a clinical trial and were willing to provide the source of information about the treatment, more than half (52.9%) stated

Table 4 Consultation and disagreement about medical treatment

	***n*=458 (%)**
Consultation with parents in case of:	
Easy medical intervention or treatment	22 (4.8)
None	23 (5)
Medium medical intervention or treatment	109 (23.8)
Severe medical intervention or treatment	138 (30.1)
All	166 (36.2)
Intervention or treatment unknown to parents	12 (2.6)
The preferred person making a treatment-related decision	
Trusted adult	17 (3.7)
Parent	291 (63.5)
Do not care	27 (5.9)
Physician	123 (26.9)
Experience with treatment disagreement	70 (15.3)
Adolescent against treatment	36 (51.4)
Adolescent for treatment	34 (48.6)
Adolescents' compliance against will	40 (57.1)

Table 3 Experience with informed consent

	Hospitalisation *n*=247 (%)	**Chronic disease *n*=42 (%)**	**Rare disease *n*=14 (%)**
Treatment decision			
Parents	194 (78.5)	31 (73.8)	11 (78.6)
Self	139 (56.3)	22 (52.4)	7 (50)
Physician	171 (69.2)	33 (78.6)	11 (78.6)
Treatment effects			
Parents	111 (45.3)	12 (29.3)	6 (46.2)
Self	31 (0.1)	4 (9.8)	1 (7.7)
Physician	177 (72.2)	34 (82.9)	11 (84.6)
Other healthcare employee	28(11.4)	3 (7.3)	-
Other adult	4 (1.6)		-
Noone	24 (9.8)	2 (4.9)	-

Table 5 Clinical studies

	n **= 458**
In favour (> 3)	196 (42.8)
Aware of clinical studies	205 (44.8)
Source of information (*n* = 204)	
Media or Internet	113 (55.4)
Educational institution	51 (25)
Medical institution	62 (30.4)
Friends and colleagues	36 (17.6)
Family	72 (35.3)
who included (*n* = 205)	
Ill	21 (10.2)
Healthy	27 (13.2)
Both	157 (76.6)
Ever invited (*n* = 205)	26 (12.7)
Ever included (*n* = 205)	19 (9.3)
Asked (*n* = 19)	15 (78.9)
Informed about treatment effects (*n* = 19)	4 (21.1)
Willingness to participate (*n* = 205)	
Ethically approved	38 (18.5)
No other possibilities for treatment	41 (20)
Treatment improves condition	63 (30.7)
Payment	28 (13.7)
Help science and others	39 (19)
Never	24 (11.7)
Always	15 (7.3)
Do not know	65 (31.7)
Minimum age requirement (*n* = 205)	
13	3 (1.5)
14	4 (2)
15	12 (5.9)
16	23 (11.2)
17	8 (3.9)
18	146 (71.2)
19	2 (1)
20	7 (3.4)
Source of information (*n* = 17)	
Themselves	2 (11.8)
No one	3 (17.6)
Physician	9 (52.9)
Other healthcare employee	4 (23.5)
Parents	6 (35.3)
Other adult	2 (11.8)
Obligatory payment (*n* = 205)	155 (75.6)

they had been informed about the study by their physician. About three-quarters (75.6%) of respondents who had already heard of clinical studies believed a person should receive payment for participation.

There were lower odds of being aware of the age limit requirement for giving consent to a treatment for older pupils (OR [95% CI]: 0.78 [0.61–1]) and higher for pupils having more frequent medical appointments, having a chronic disease or having parents who were aware of the correct age limit (Table 6). Students who visit their physician 4-times a year or more frequently had ~ 3-times (1.33 – 7.04) higher odds of knowing the age limit compared to those who visit their physician once a year or less often. Students with chronic disease had ~ 4-times (1.93 – 9.71) higher odds of being aware of the age limit. Students whose parents were aware of the correct age limit had about 7-times (3.24 – 16.77) higher odds of being aware of the minimum age requirement for giving consent to a medical treatment or procedure. Age, gender, being a primary or secondary school pupil, region, having a rare disease, frequency of hospitalisation or source of information about the age limit were not statistically significantly associated with the awareness of pupils of the minimum age requirement.

Age, gender, region, being a primary or secondary school pupil, and frequency of visits to physicians or hospitalisations were not statistically significantly associated with favouring new medical treatments (Table 7). Only pupils who had heard of clinical studies had about 1.6 (1.11 – 2.35) higher odds of favouring new medical treatments.

Discussion

The research revealed that health workers in the Republic of Slovenia do not consistently inform young people about their rights established by legislation; such a practice can also be detected elsewhere in the world [16–19, 56, 58]. Adolescents have the right, as enshrined in the Convention on the Rights of the Child, to give their own free consent to any treatment without the consent of their parents if they are capable of understanding [7]. This is generally not implemented in practice. Parents usually participate in minors' decision-making about their treatment or inclusion in clinical research by their signed consent [5, 9, 24].

In Slovenia, the Patient Rights Act (ZPacP) specifies a fundamental limit of 15 years. A presumption of autonomous decision-making capacity applies to a child who has already reached the age of 15 unless the physician exceptionally assesses otherwise, in which case the parents are generally consulted. A child under the age of 15 is presumed to be incapable of self-determination if, based on the child's maturity, the physician does not consider that they are capable of doing so and, as a rule, the parents or guardian are consulted about the circumstances that speak of the ability to make decisions about themselves.

Table 6 Association between demographic and medical history factors and awareness of minimum age requirement for consenting to treatment (results of univariate logistic regression)

	No (*n* = 420)	Yes (*n* = 38)	OR (95% CI)	P
Male gender	259 (61.7)	22 (57.9)	0.85 (0.44—1.68)	0.648
Mean age (SD)	16.1 (1.5)	15.6 (0.9)	0.78 (0.61—1)	0.046
High school	323 (76.9)	28 (73.7)	0.84 (0.39—1.79)	0.654
Central Region	136 (32.4)	14 (36.8)	1.22 (0.61—2.43)	0.575
Frequency of visits to physician				
1 Once a year or less	221 (52.6)	15 (39.5)	1	
2—3 times a year	146 (34.8)	12 (31.6)	1.21 (0.55—2.66)	0.634
4-times a year or more	53 (12.6)	11 (28.9)	3.06 (1.33—7.04)	0.009
Frequency of hospitalisation				
No	193 (46)	18 (47.4)	1	
1—2—times	157 (37.4)	17 (44.7)	1.16 (0.58—2.33)	0.674
More than 2-times	70 (16.7)	3 (7.9)	0.46 (0.13—1.61)	0.224
Chronic disease	32 (7.6)	10 (26.3)	4.33 (1.93—9.71)	< 0.001
Rare disease	12 (2.9)	2 (5.3)	1.89 (0.41—8.77)	0.417
Parents aware of the age limit	22 (5.2)	11 (28.9)	7.37 (3.24—16.77)	< 0.001
Source of information about age limit (*n* = 202)				
Nowhere	28 (17.1)	7 (18.4)	1.15 (0.41—3.23)	0.797
Family	65 (39.6)	14 (36.8)	0.99 (0.42—2.31)	0.976
Medical institution	16 (9.8)	5 (13.2)	1.43 (0.44—4.67)	0.552
Other sources	55 (33.5)	12 (31.6)	1	

Table 7 Association between demographic and medical history factors and favourable opinion about new treatment methods (results of univariate logistic regression)

	No (*n* = 262	Yes (*n* = 196)	OR (95% CI)	P
Male gender	156 (59.5)	125 (63.8)	1.2 (0.82—1.75)	0.357
Mean age (SD)	16 (1.5)	16.1 (1.5)	1.04 (0.92—1.19)	0.502
High school	196 (74.8)	155 (79.1)	1.27 (0.82—1.98)	0.286
Central Region	91 (34.7)	59 (30.1)	0.81 (0.54—1.2)	0.296
Frequency of visits to physician				
1 Once a year or less	133 (50.8)	103 (52.6)	1	
2—3 times a year	95 (36.3)	63 (32.1)	0.86 (0.57 – 1.29)	0.458
4 times a year or more	34 (13)	30 (15.3)	1.14 (0.65 – 1.98)	0.645
Frequency of hospitalisation				
No	123 (46.9)	88 (44.9)	1	
1—2—times	98 (37.4)	76 (38.8)	0.86 (0.57—1.29)	0.458
More than 2-times	41 (15.6)	32 (16.3)	1.14 (0.65—1.98)	0.645
Chronic disease	19 (7.3)	23 (11.7)	1.7 (0.9—3.22)	0.103
Rare disease	5 (1.9)	9 (4.6)	2.47 (0.82—7.5)	0.11
Heard of clinical studies	104 (39.7)	101 (51.5)	1.62 (1.11—2.35)	0.012

These practices are essential for balancing the need to protect minors while recognising their developing capacities and rights to participate in health-related decisions [9]. The process aligns with practices in other European countries and worldwide, which require an assessment of the adolescent's maturity before allowing them to make independent decisions [10, 56]. However, age limits are set differently, because there is no

universal agreement on what age minors should be considered competent to make decisions [10]. Setting an age limit in legislation is not only inaccurate, but can often be too restrictive [24, 59].

Slovenian legislation also provides for a child's right to consent after instruction. The child is given explanations appropriate to their development and age. The physician is responsible for assessing the child's decision-making ability and is not bound by the parents' opinion.

The doctor must be qualified to assess the child's decision-making capacity. Clear guidelines and training of healthcare workers increase their competence [10, 24, 56]. A multidisciplinary approach of experts is recommended for the assessment of children's competencies [10]. Involving adolescents in decision-making processes is practically and ethically demanding [24]. The physician must not wait for the adolescent to ask for their rights under Article 35 of Patient Rights Act or assert these rights but must also explain the content of the law and the child's rights [7]. In order to protect minors, clinical drug trials on persons under the age of 18 can only be carried out with the consent of the parents or legal representative and with the minor's expressed presumed will [14, 15]. Obtaining dual informed consent from parents and children capable of giving consent is in accordance with International Ethical Standards [26].

In relation to the research questions, we asked ourselves three questions regarding autonomous decision-making for treatment, medical assessment of an adolescent's maturity and involvement of parents and adolescents in clinical research.

Autonomous decision-making about treatment

Our research showed that 91.7% of the adolescents interviewed were not informed about the statutory age limit at which they can make autonomous decisions about their treatment, i.e.,15 years, which is a pivotal point in terms of responsibility and decision-making related to treatment, and decision-making and involvement in the treatment process. In terms of whether they knew the critical age, 202 (44.1%) young people answered that they knew it, but only 38 (18.8%) knew the correct age. Hypothesis 1, which states that more than 80% of adolescents are not informed about the age limit at which they can independently decide on their treatment, was confirmed.

The odds of knowing the age limit for consenting to treatment were lower for older pupils (OR [95% CI]: 0.78 [0.61–1]), while the odds were higher for pupils with more frequent medical visits, chronic disease or parents who know the correct age limit.

We found that only 5 (13.2%) adolescents had learned about the age limit in a healthcare institution, and more than a third had learned about it in the family circle. Only 33 (7.2%) of adolescents stated that their parents correctly indicated this age limit. Most of those surveyed (62.4%) believed they should be informed about this right by a medical institution, which is also stipulated by law [7]. Hypothesis 2, which states that more than 80% of adolescents learn about their decision-making rights in a healthcare institution or from a doctor, was not confirmed. Our findings corroborate that education about health care and clinical research rights should be implemented in the programs of national educational institutions [24]. Respondents put an educational institution in second place, followed by the home environment and others.

It is also interesting to note that they would like to have the right to make an autonomous decision about treatment at 18 (31%), and only (10%) of young people decided on this at 15. These results rejected Hypothesis 3, which states that more than 80% of adolescents would like to decide on their treatment before age 16 independently.

The result is surprising because most cognitively developed adolescents achieve the possibility of abstract thinking at the age of 15 and also have the same decision-making ability as adults [10]. However, according to the profession's experience, emotional maturity appears later in adulthood. Therefore, it is necessary to provide suitable support to adolescents when they are making decisions [9, 10] and are too emotionally unstable [60, 61]. The age limit varies among European countries [12]. We consider that the age limit in Slovenia is set low compared to other European countries, mainly because the age limit is set at 15, regardless of the complexity of the treatment [12, 18]. However, the findings must be understood with the awareness that parents are the guardians of a minor child and the set limit is arbitrary, so, in most cases, in addition to the adolescent, parents or guardians are also co-signatories.

Medical assessment of the maturity of adolescents and the involvement of parents

In the survey, 69.5% of the respondents answered that the maturity of a young person under the age of 18 should always be assessed and, based on the assessment, they should be allowed to make autonomous decisions. Hypothesis 4, that 80% of adolescents believe that a minor under the age of 18 should always be assessed before being allowed to make independent treatment decisions, was rejected. The assessment of the decision-making competencies of adolescents makes sense, as they differ depending on the development and the individual's circumstances [10]. In Slovenia, an evaluation of the competence of young people is not carried out consistently for the entire population. According to the experience of an adolescent with SMA, chronically ill adolescents with

various deficiencies are tested multidisciplinary and often with the ABAS-3 method at the Clinical Department for Child, Adolescent and Developmental Neurology at UKC Ljubljana [62–64]. Other methods, e.g., MacCAT [65, 66] and Gillick's competence, are used elsewhere. For the latter, in the UK, parents cannot override children assessed as competent by this method [23, 27, 67].

Only 5.02% of the respondents would not seek a discussion with their parents or guardians about treatment or intervention. The vast majority of respondents would ask their parents for advice in the case of an at least moderately difficult procedure. Hypothesis 5 that at least 50% of adolescents would ask their parents for advice regarding any procedure, was confirmed. Many studies show that the role of parents or legal representatives in making decisions about health services and taking care of children's health is as important, as support or protection [5, 9, 24]. Parents, with their control over their children, can disproportionately interfere in their children's healthcare decisions [24]. In hospital settings, they often mediate between their children and health professionals [5].

In the United States, the law provides that adolescents before the age of majority can autonomously decide to receive treatment or enter clinical research when this represents a minimal risk, as it relates to various categories of research and, at the same time, they are mature enough to make a decision [13]. In Slovenia, adolescents have the legal basis for autonomous decision-making about treatment and non-interventional clinical research at the age of 15, unless it has been proven that they are incapable of doing so, and at the age of 18 for clinical research with a clinical trial [14, 15, 18]. At the same time, the Family Code stipulates to parents that they are responsible for their children until they reach the age of majority [20], which limits children's right to autonomy, which is stipulated by Patient's Rights Act (ZPacP). Unclear guidelines can be the reason for the reduced realisation of the rights of adolescents, as well as their participation and self-determination.

It is interesting to note that almost 45% of adolescent girls would consult their parents for all treatments or interventions, while only a little over 30% of adolescent boys would do so. Twelve (2.6%) respondents had undergone treatment or intervention without their parents' knowledge.

The concern of young people at home and around the world about the involvement of parents or guardians is understandable since there are cases in which a young person needs healthcare, for which he wishes to maintain privacy, or when obtaining parental consent is a problem (personal hardship, religious reasons, worldview, parents' education etc.) [13].

Adolescent confidentiality is essential in all health care, especially in sensitive health issues related to sexual and reproductive health, where autonomy and privacy are highly valued [29]. An unpleasant situation arises because the doctor in the Slovenian environment is obliged to inform the parents or Legal representatives about the child's health condition and to obtain permission from them regarding possible diagnostics and treatment [68].

On the other hand, when acting in the child's best interest, parental consent protects the adolescent. Parents also have the right to be informed, and last but not least, they are responsible for the adolescent's decisions before they reach the age of majority. The rapid development of technology and medical science presents us with new complex dilemmas [21, 23, 25] concerning giving consent. We would highlight the area of paediatric biobanking, with which repeated, deferred and prospective consent come into play. Critical ethical issues include the need for renewed consent as the adolescent's developmental autonomy increases over time [21, 27, 69]. Deferred consent addresses the difficulties of conducting research in emergencies, particularly in time-constrained circumstances and limited parental capacity in a stressful environment [67, 70, 71]. Prospective consent allows the expression of wishes regarding healthcare or research if the individual later loses the capacity to express a will [27].

About half of respondents reported being involved in decision-making regarding their treatment or intervention during hospitalisation or treatment for a chronic or rare disease. The majority (more than 70%) obtained information about the effect of treatment from a physician, which means that in most cases, physicians take into account the adolescent's right to be informed [8, 18]; however, the physician is not only obliged to answer the questions posed by adolescents related to treatment or inclusion in clinical research but must also give them information on his own, consistently and on his initiative [18].

Such a proactive approach aligns with international ethical guidelines and emphasises the importance of obtaining informed consent from children and adolescents [26]. Hypothesis 6, that adolescents are involved in more than 90% of the treatment process or decisions about procedures during hospitalisation or treatment of a chronic or rare disease, was not confirmed.

Autonomous inclusion of adolescents in clinical research

There were 196 (42.8%) respondents in favour of new forms of treatment, this percentage being higher among chronic patients 23 (54.8%) and patients with a rare

disease 9 (64.3%). However, Hypothesis 7, which states that more than 70% of adolescents favour new treatment methods, was not confirmed. Among adolescents with special needs who are regular users of health services, there is a noticeable preference for new treatments, as well as a desire to participate in health decisions [28, 72].

Among the respondents, 205 (44.8%) had already heard about clinical research, and more than half (55.4%) had learned about it through the media or the Internet. Hypothesis 8, which states that more than half of the respondents have heard about clinical research, was not confirmed. We believe that the general public, adolescents and their parents should know the importance of clinical research [13, 37]. The expanding network YPAG (European Young Person's Advisory Group Network) [29] recommends the use of youth-relevant [73] online communication platforms such as social media to inform youth about health, treatment and clinical research [30].

Most adolescents (71.2%) believed that 18 is the cut-off age at which they do not need legal guardians' consent to participate in clinical research. A smaller proportion of respondents (5.9%) stated that the minimum age is 15.

Out of all the respondents, 20 had already been involved in clinical research, representing a little over 4% of all respondents. Most of the respondents, 52.9%, had been informed about participation by a physician, 9 out of 17. Fifty per cent of respondents enrolled in clinical research had been enrolled for treatment. Willingness to participate was primarily conditioned by therapies that would improve their condition (30.7%).

This finding is surprising and contrary to international ethical guidelines, which explicitly require informed consent [26], and legislation, which clearly states that a clinical trial on minors can only be carried out if they received information in accordance with their capacity of understanding, after the age of 15, if they are competent and their consent is given [9, 10, 14, 15, 18].

About three-quarters (75.6%) of respondents who had heard of clinical research believe that an individual should be paid for participating. Hypothesis 9, which states that at least 50% of adolescents who were informed about clinical research believe that payment is not necessary for participation, was not confirmed. Payments for participation in clinical research are one of the established and effective incentives in developed countries and in paediatrics [42–48]. However, this form of incentive is ethically controversial [46, 54, 55, 65]. European and Slovene legislation prohibits rewards or any other financial support to minors and their legal representatives for participation in clinical trials, except for compensation for direct costs (transportation costs, etc.) incurred due to the involvement in the research [14, 15].

Limitations

All Slovene regions were invited to participate in the survey, the most significant number of which were covered by two regions, namely the Central Slovenia and Savinja regions. The non-uniformity of the regions covered could represent a bias in the analysis of the results.

Another source of bias is non-random sampling, which was used as well as self-selection. Those who decided to participate in the study could have differed from those who did not. As secondary school students were oversampled, this could also influence the obtained conclusions based on the provided data. Nevertheless, this is the first research on the topic in Slovenia and could serve as a pilot study for all proceeding studies.

The response rate to the survey questionnaire was around 10%.

Conclusions

The information and attitudes of adolescents about their rights and duties and knowledge about treatment or inclusion in clinical research are poorly researched worldwide; no comparable scientific articles are available.

Our research showed a significant gap in the realisation of the rights of children and adolescents in the healthcare field and the lack of information of adolescents and their parents about treatment and participation in clinical research in Slovenia.

The results of our study indicate that school-going adolescents from 13 to 20 years old are insufficiently aware of their rights, nor are their parents aware of them. Adolescents and their parents are mostly unaware of the critical age limit of 15 years; in most cases, they associate all rights with reaching adulthood. An alarming result of our survey-based research is that only 8.3% of respondents correctly know the age limit for autonomous decision-making.

Results indicate that health professionals do not consistently educate adolescents about their rights and duties or do not give the information the correct meaning.

The findings are similar to studies from other countries investigating adolescent participation in the healthcare systems and show that adolescents often lack the information to participate fully in treatment decisions or clinical research [5, 10, 24]. These findings indicate the need for better awareness and education of health professionals [5, 56], children, adolescents and their parents [5, 24].

The point of view of adolescents that most fifteen-year-olds do not feel mature enough to make decisions related to treatment or participation in clinical research is surprising, especially given that in the developed world, there are significant youth initiatives for participatory involvement in health, where young people at this age

actively engage in participatory research with their initiatives and perspectives and take on mentoring roles for younger children [37–39, 74]. This discrepancy highlights the need to empower adolescents to make decisions.

However, it should be noted that in other countries, this area has not been comprehensively researched or presented, so we do not have data on the extent to which the rights of children and adolescents in this field are realised in practice, how well-informed adolescents and their parents are, and what their views are on topics related to their participation.

We can only infer these insights from partial studies, which have most often been conducted within healthcare settings. Our research, however, has shown that adolescents with more health issues who visit the doctor more frequently are better informed about the age threshold and participation in decision-making.

The research showed that most adolescents do not feel competent at 15. Most of them would set the threshold at 18 years. The majority of children want parental support when making decisions. Other studies conducted in international contexts also confirm the vital role of parents in supporting children in decision-making [9, 24].

Most adolescents feel they should always be assessed for their decision-making competence. The rationale for assessing adolescents' competence in deciding whether to treat or involve them in clinical research is reasonable and justified [10, 24].

On the other hand, some adolescents stated that their parents or guardians were not aware of their treatment, which confirms the need for adolescents to have the right to make their own decisions when they are mature enough to do so, or the law allows them to do so. Requiring parental involvement in all medical decisions of adolescents, despite the adolescent's competence to make the decisions that concern them, is unreasonable and may interfere with the integrity and autonomy of the mature adolescent.

Most adolescents who had heard about clinical research believed that participation in clinical research should require payment, which is controversial from an ethical point of view. These results show a misconception about financial incentives, legislation and ethical guidelines that only allow financial compensation for expenses and lost income directly resulting from participation in the clinical trial. Payment for participation in research is ethically questionable as it could increase the fragility of children and adolescents[14, 45–48, 51–55].

Experience from abroad shows that initiatives and networks of organised lay people, with the involvement of paediatric patients, help to improve information. It is also in our interest to improve treatment outcomes and increase adolescents' participation in clinical research through a participatory approach since these are important for society as a whole and even more so for children.

A review of Slovenian legislation has revealed inconsistencies in the health care for adolescents in terms of their participation in decision-making related to their treatment or inclusion in clinical trials. Clear legal guidelines are needed in this area to be implemented in practice. [17–20].

We can conclude that a comprehensive education approach and explicit legislative provisions are needed to support the autonomy of children and adolescents in healthcare. It is also necessary to consider the implementation of protocols in medical practice that assess the maturity of adolescents in making decisions.

The results show a lot of room for healthcare professionals and health policies to improve their work in this area.

The research lays the groundwork for future studies in Slovenia on adolescent participation in healthcare decisions and clinical research, as well as on exploring the implementation of international ethical guidelines and rights established by law. It also makes a significant contribution to this field in the global context.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12909-024-06164-w.

Additional file 1 - Supplementary Figure 1: Legislation in Slovenia that defines the rights of children and adolescents

Additional file 2 - Supplementary Figure 2: Distributive network of survey dissemination (CAA – Children and adolescents; PS – Primary school; SS – Secondary school)

Additional file 3 - Supplementary Attachment 1: Survey Questionnaire

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Informed consent
The Medical Ethics Committee of Republic Slovenia approved the anonymous online survey. Informed, written consent was obtained from both the parent/caregiver prior to participation in the study.

Authors' contributions
MLČ and ŠG conceived the study. MLČ, ŠG and VE developed the data to be included conception and design. MLČ, ŠG and VE approved the conception and design of the study. VE provided statistics. MLČ collected all data and conducted the survey. MLČ and ŠG wrote the manuscript. SG obtained funding. All authors provided critical feedback and helped shape the research, analysis and manuscript. All authors have read and approved the manuscript.

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Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
Ethical approval was obtained by the National Ethics Committee (No: 0120–171/2023/3; date: May 9, 2023.)." for studies involving humans.
All methods were carried out in accordance with relevant guidelines and regulations (declaration of Helsinki).

Consent for publication
NA.

Competing interests
The authors declare no competing interests.

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