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Free Informed Consent in ART Clinics: A Case Study of *In Vitro Fertilization* (IVF) Patients Who Consulted a Creighton Model FertilityCare Practitioner

LAISVAS INFORMUOTAS SUTIKIMAS VAISINGUMO KLINIKOSE: *IN VITRO FERTILIZATION* (IVF) PROCEDŪRAS PATYRUSIŲ IR KREITONO METODO MOKYTOJO KONSULTACIJOS IEŠKOJUSIŲ SUTUOKTINIŲ ATVEJO TYRIMAS

SUMMARY. This article presents a qualitative, in-depth, interview-based case study investigating how fertility clinics in Lithuania implement the mandatory free informed consent requirement for patients before in vitro fertilization (IVF) procedures. The study is grounded in Lithuanian legal requirements – specifically the Law on Patients' Rights and the Law on Assisted Reproductive Technology – which detail what information must be provided prior to ART procedures. The theoretical framework draws on internationally established principles of informed consent, including the informational and consent components identified by T. Beauchamp and R. Faden. Participants were three individuals (two spouses and one married woman) who underwent IVF procedures at two Vilnius fertility clinics in 2023–2024 and subsequently contacted a Creighton Model FertilityCare Practitioner seeking to conceive naturally. Data were collected through in-depth interviews and supplemented by analysis of the clinic's written informed consent forms. Content analysis identified six categories: information about the ART procedure itself, effectiveness, risks to women, risks to children,

alternatives to ART, and the fate of surplus embryos. The study found that across all categories, patients received incomplete information: consent forms were signed before being fully read, medical staff did not verify patients' comprehension, and no information on restorative reproductive medicine alternatives was provided. According to participants own assessments, the quality of information received was only satisfactory. These findings reflect broader international patterns and point to a systemic failure to treat informed consent as a genuine dialogue rather than a formality.

SANTRAUKA. Šiame straipsnyje pateikiamas kokybiniu giluminiu interviu grįstas atvejo tyrimas, kuriame nagrinėjama, kaip Lietuvos vaisingumo klinikos užtikrina privalomą laisvą ir informuotą pacientų sutikimą prieš *in vitro* apvaisinimo (IVF) procedūras. Tyrime remiamasi Lietuvos teisine baze – pacientų teisių ir žalos sveikatai atlyginimo įstatymu bei Pagalbinio apvaisinimo įstatymu, kuriuose nustatyta, kokia informacija turi būti suteikta prieš pradėdant pagalbinio apvaisinimo procedūras. Teorinė straipsnio dalis grindžiama tarptautiniu mastu pripažintais informuoto sutikimo principais, tarp jų minimi T. Beauchamp'o ir R. Faden išskirti informacinis ir sutikimo komponentai. Tyrimo dalyviai – trys asmenys (sutuoktiniai ir viena ištekėjusi moteris), kuriems 2023–2024 m. dviejose Vilniaus vaisingumo klinikose buvo atliktos IVF procedūros ir kurie vėliau kreipėsi į Kreitono modelio vaisingumo pažinimo sistemos mokytoją, norėdami pastoti natūraliai. Duomenys rinkti giluminių interviu metodu; papildomai analizuotos klinikų naudojamos rašytinės informuoto sutikimo formos. Taikant turinį analizę nustatytos šešios pacientams teikiamos informacijos kategorijos: apie pagalbinio apvaisinimo procedūrą, jos veiksmingumą, riziką moteriai, riziką vaikui, alternatyvas bei perteklinių embrionų likimą. Tyrimas parodė, kad kiekvienoje iš nustatytų kategorijų pacientams pateikta informacija buvo neišsami: sutikimo formos buvo pasirašomos prieš atidžiai jas perskaičius, klinikos darbuotojai netikrino, ar pacientai suprato pateiktą informaciją, neinformavo apie vaisingumą atkuriančios medicinos alternatyvas. Pačių dalyvių vertinimu, gauta informacija tebuvo patenkinama. Šie rezultatai atspindi platesnes tarptautines tendencijas ir rodo sisteminį informuoto sutikimo proceso nepakankamumą – sutikimas dažniau suvokiamas kaip formalumas, o ne kaip tikras dialogas tarp gydytojo ir paciento.

KEYWORDS: informed consent, assisted reproduction, Naprotechnology, Restorative Reproductive Medicine, *in vitro* fertilization (IVF).

RAKTAŽODŽIAI: laisvas informuotas sutikimas, pagalbinis apvaisinimas, naprotechnologija, atkuriamoji reprodukcinė medicina, *in vitro* apvaisinimas (IVF).

Introduction

In 1997, the Council of Europe adopted the Convention for the Protection of Human Rights and Dignity of Human Beings with Respect to the Application of Biology and Medicine. The convention states that “an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. The person must be given appropriate information beforehand about the purpose and nature of the intervention, as well as its consequences and risks. The person may withdraw consent at any time”¹. The doctrine of free and informed consent (FIC) is rooted in the principles of human dignity, bodily integrity, inviolability, and autonomy².

¹ *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, Oviedo, April 4, 1997, <https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.130089?jfwid=-8xfwh9qxp>.

² Modestas Sriubas, “Informuoto paciento sutikimo pažeidimo atvejai”, *Teisės problemos* 1 (71) (2011): 41, <http://teise.org/wp-content/uploads/2016/10/2011-1-sriubas.pdf>.

Informed consent is a legal, ethical, and moral obligation³. Both the healthcare professional and the patient are responsible for its implementation. Informed consent consists of two requirements. First, there is the duty to disclose information. Second, there is the right to choose⁴. Thomas Beauchamp and Ruth R. Faden identified two key elements of informed consent:

The first is the information component, consisting of the physician's disclosure of information and the patient's or subject's understanding of it. The second is the consent component, consisting of the voluntary decision to undergo the procedure and authorization⁵. As Lewis Vaughn argues, legislation in most countries obligates patients to disclose important information:

1. The nature of the procedure (for example, whether it is a test or treatment, whether it is invasive, and how long it will take to perform);
2. The risks of the procedure (what kind of risks are involved, their seriousness, their probability of occurring, and when they might happen);
3. The alternatives to the proposed procedure – including the option of no treatment (includes information on the options' nature, risks, and benefits);
4. The expected benefits of the proposed treatment, including their extent and their likelihood of being achieved⁶.

In the context of assisted reproduction, informed consent is a critical ethical and legal requirement. It ensures that individuals are fully aware of the procedures, risks, benefits, and implications involved in the reproductive process.

According to the Lithuanian Bioethics Committee's definition, informed consent is considered genuine and valid if the patient is capable of giving consent (i.e., can adequately express his or her will), has been given sufficient information about the treatment or research to make an informed decision, and acts of his or her own free will⁷. Competence is a mandatory condition for free informed consent (FIC). The more important and riskier the decision is, the more competent the patient must be. Assisted reproduction is undoubtedly an ethically significant decision. Therefore, the competence of those who must express consent for assisted reproduction is a prerequisite for their choice to be considered FIC. Assisted reproduction itself raises a number of ethical issues, one of the main ones being the fate of surplus embryos.

³ Edita Gruodytė, and Laura Šalčiūtė-Pratkienė, "Informuoto paciento sutikimo doktrinos samprata ir svarba sveikatos priežiūroje", *Teisės apžvalga* 1 (10) (2013): 136–170.

⁴ *Ibid.*, 149–150.

⁵ Ruth R. Faden and Tom L. Beauchamp, "Informed Consent", in *Bioethics*, 4th ed. (Cengage Learning, 2014), 1682–1687, <https://bioethics.jhu.edu/wp-content/uploads/2022/05/Beauchamp-TL-Faden-RR-Meaning-and-Elements-of-Informed-Consent.pdf>.

⁶ Lewis Vaughn, *Bioethics Principles, Issues, and Cases*, 4th ed. (New York: Oxford University Press, 2020), 224.

⁷ Lietuvos bioetikos komitetas, *Informuoto paciento sutikimas. Kas tai?* (Vilnius, 2013), 3, https://bioetika.lrv.lt/media/viesa/saugykla/2024/1/W_B9BeJ2cGo.pdf.

This article aims to assess whether individuals who wish to have children and have chosen assisted reproduction have received adequate information to make an informed and free choice. The research question of this study is: Did patients of ART clinics in Lithuania receive complete and adequate information required for free and informed consent before undergoing IVF procedures? To answer this question, a qualitative in-depth interview method and content analysis were applied.

1. Principles of free and informed consent for assisted reproduction in Lithuanian law

In Lithuania, two pieces of legislation regulate the free and informed consent of patients: the Law on Patients' Rights and Compensation for Damage to Health (2015) and the Law on Assisted Reproductive Technology (2016). According to Article 15 of the Law on Patients' Rights and Compensation for Damage to Health, which was adopted by the Seimas of the Republic of Lithuania, consent to an intervention is considered informed and appropriate if it fulfils the following four conditions: 1) it is given by a person capable of adequately expressing his or her will; 2) it is given with sufficient, clear information; 3) it is given by the patient (or his or her representative) of his or her own free will; and 4) it complies with the form prescribed by legislation." Article 7⁸ of the Assisted Reproductive Technology Act describes the requirements for informed consent in some detail: it lists the information that must be provided and how it must be provided. Article 7 describes the content of the information to be provided, stating that both spouses/partners must be informed in a comprehensible way about:

- assisted reproduction options;
- the assisted reproductive techniques to be used;
- alternatives;
- benefits;
- the risks, possible medical and psychological consequences of the procedures;
- the risks of multiple pregnancies for the mother and the foetus;
- the likelihood of success of assisted reproduction, indicating the number of clinical pregnancies and births (both generally known in medical practice and specifically achievable in the healthcare facility providing assisted reproduction services) per method envisaged;
- the time limits for storing embryos created but not transferred to a woman in a germ cell bank.

⁸ Lietuvos Respublikos pagalbinio apvaisinimo įstatymas Nr. XII-2608, 2016 m. rugsėjo 14 d., 7 str., <https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/f31c44c27bd711e6a0f68fd135e6f40c/otaYeykZcG?jfwid=-1dgu4gdrf>.

This information must be provided in writing before the start of assisted reproduction on an informed consent form dedicated to this purpose, which the spouses/partners must complete and sign. Before signing the form, both spouses/partners must be informed in writing of the estimated cost of the entire procedure and the conditions under which consent takes effect and can be withdrawn. The law does not specify which alternatives to PABs must be presented to patients or which risks must be disclosed.

2. Assisted reproduction alternatives and availability in Lithuania

In many developed Western countries, Restorative Reproductive Medicine (RRM)⁹ is offered as a scientifically and ethically sound alternative to assisted reproduction technology. RRM is based on the view that infertility is not a definitive diagnosis but rather a manifestation of a specific medical disorder¹⁰. By treating the underlying causes of the disorder, it is possible to restore natural fertility function¹¹. RRM methods help women and couples understand their fertility and collaborate with their doctors to address the causes of infertility. During treatment, couples learn to monitor fertility signs (biomarkers) to identify cycle phases, hormone imbalances, ovulation problems, and other possible infertility factors¹².

RRM methods are also applied by certified doctors in Lithuania. At least two RRM methods are currently available: NaProTechnology (Natural Procreation Technology) and FEMM (Fertility education and medicine management). NaProTechnology (NaPro) is a holistic infertility treatment system based on the work of US scientist Thomas W. Hilgers. It is described as a new science of women's health, designed to monitor and maintain a woman's procreative and gynecological health. The approach is based on therapeutic/surgical treatment of the couple (both man and woman) and knowledge of the woman's fertility, using the Creighton Model Fertility Care System (CrMS). CrMS "is the first and only family planning system that is completely integrated with a woman's health. It is based upon objective and standardized vulvar observations of biological markers and it is the foundational system to the new women's health science of NaProTechnology"¹³. NaPro does not create embryos, is non-invasive and conception occurs naturally. CrMS is suitable for both couples seeking to have children and couples wishing to delay pregnancy.

FEMM (Fertility Education & Medical Management) is a health programme that helps women understand and monitor their hormonal expression during the

⁹ International Institute for Restorative Reproductive Medicine, "What is Restorative Reproductive Medicine?"; accessed January 18, 2026, <https://iirm.org/what-is-rrm/>.

¹⁰ Ibid.

¹¹ Ibid.

¹² Ibid.

¹³ T. William Hilgers, "The new women's health science of NaProTECHNOLOGY", *Archives of Perinatal Medicine* 17 (4) (2011).

menstrual cycle using natural biomarkers¹⁴. The programme combines fertility awareness and medical diagnosis to identify cycle disorders (e.g. polycystic ovary syndrome, thyroid dysfunction, etc.), diagnose the causes of infertility, and address hormonal imbalances without hormonal contraception.

FEMM doctors rely on observations of the woman, so treatment is personalised, ethical and physiologically based. The programme also allows women to plan or postpone pregnancy naturally, without hormonal means.

FEMM-certified doctors work in Lithuania. This is one of the branches of Reproductive Reproductive Medicine (RRM)¹⁵. Consultations with certified doctors are available both remotely and by contact. There is also the International Institute for Reproductive Medicine (IIRRM), which connects professionals worldwide, including Lithuania¹⁶.

Benefits of Restorative Reproductive Medicine. RRM as an alternative to ART is particularly important for couples seeking an ethical, holistic approach to fertility challenges based on the natural functioning of the body. RRM offers long-term health restoration. It is worth knowing for anyone considering assisted reproduction or looking for alternatives. Benefits of RRM¹⁷:

- treating the cause of infertility, not the symptoms,
- human dignity is respected, and natural sexual intercourse is maintained as an integral part of conception,
- has no side effects, does not require invasive interventions, and is based on the natural mechanisms of the human body, i.e. the observation of a woman's menstrual cycle,
- couples take an active part in the treatment, learning to understand their body's signals.

The challenge of ensuring adequate patient information in ART is not unique to Lithuania. Similar findings have been reported in other countries. A qualitative study conducted in Australia – “The silent world of assisted reproduction” – found that IVF patients frequently encountered communication gaps regarding the emotional and

¹⁴ Meghan Grizzle Fischer, “The Case for FEMM: White Paper”, Femmhealth.org, October 2013, <https://femmhealth.org/wp-content/uploads/2020/12/FEMM-White-Paper.pdf>.

¹⁵ “Kas yra FEMM”, NaPro.lt, accessed January 18, 2026, <https://napro.lt/kas-yra-femm/>.

¹⁶ Rita Simonaitytė, “Apie mane”, Unikaklinika.lt, accessed January 18, 2026, <https://unikaklinika.lt/komanda/rita-simonaityte/>; “Akvilė Esmantiene”, NaPro.lt, accessed January 18, 2026, <https://napro.lt/akvile-esmantiene/>; “Kalniečių padalinio komandoje – nauja gyd. endokrinologė Jūratė Antanavičienė”, Kauno miesto poliklinika, April 6, 2023, <https://kaunopoliklinika.lt/2023/04/06/kalnieciu-padalinio-komandoje-nauja-gyd-endokrinologe-jurate-antanaviciene>.

¹⁷ International Institute for Restorative Reproductive Medicine, “With Infertility Rates Rising in U.S., Restorative Reproductive Medicine Gains Prominence as Promising Option”, May 29, 2025, <https://iirm.org/with-infertility-rates-rising-in-u-s-restorative-reproductive-medicine-gains-prominence-as-promising-option/>; Phil C. Boyle, Agnes Tóth, Linda O'Neill, and Craig J. Turczynski, *Restorative Reproductive Medicine: An Emerging New Treatment Process and a Prerequisite to Assisted Reproductive Technology for Treatment of Infertility*, Preprint, January 8, 2024, <https://doi.org/10.20944/preprints202401.0624.v1>.

long-term aspects of treatment, and that the commercial context of fertility clinics can discourage extended, honest conversations with patients¹⁸. A qualitative study with 130 IVF patients in the United States likewise revealed that informed consent processes in ART are often undermined by bureaucratic consent documents that patients sign without fully understanding their content – a finding that closely mirrors the experiences reported by participants in the present study¹⁹. A recent normative analysis across eight European countries (B2-InF project) found significant inconsistencies in how ART clinics present information online, with particular concerns regarding transparency about success rates, associated risks, and treatment alternatives²⁰. These international findings suggest that the inadequacies in informed consent identified in Lithuanian ART clinics reflect a broader, systemic challenge rather than a country-specific phenomenon.

3. Methodology for the study “Informed consent for assisted reproduction: a case study of spouses after IVF in Lithuania”

The provision of FIC to patients who chose ART was assessed using a qualitative in-depth interview method. Qualitative studies do not use survey samples. The validity and meaningfulness of the qualitative study’s results are more related to the richness of the information provided by the selected cases and the researcher’s analytical skills than to the sample size²¹.

Limitations of the study: The main limitation of this study is the **small sample size (n=3)**. Due to the small number of participants, the results cannot be generalized to the entire population, but only reflect the specific, individual experiences of these individuals. It is likely that due to the small number of interviews, full **data saturation** was not achieved. Further research with a larger sample size could reveal additional insights or subthemes that may have been overlooked in this study. The small sample size is explained by two factors: first, qualitative research, by its nature, does not require a large sample, as it prioritises the depth and richness of the data over statistical representativeness; second, the highly sensitive and personal nature of the topic meant

¹⁸ Louis Taffs, Ian Kerridge, and Wendy Lipworth, “The Silent World of Assisted Reproduction: A Qualitative Account of Communication Between Doctors and Patients Undergoing In Vitro Fertilisation in Australia”, *Health Expectations* 26, no. 6 (2023): 2340–2348, <https://doi.org/10.1111/hex.13839>.

¹⁹ Jody L. Madeira and Barbara Andracka-Christou, “Paper Trails, Trailing Behind: Improving Informed Consent to IVF Through Multimedia Applications”, *Journal of Law and the Biosciences* 3, no. 1 (2016): 2–38, <https://doi.org/10.1093/jlb/lsv054>.

²⁰ Marta Albert, Rosa Tapia, Juana Farfán, et al., “Information and Misinformation on Assisted Human Reproduction Techniques in Europe: A Normative Analysis of the Information Provided on the Websites of Medically Assisted Reproduction Clinics”, *BMC Medical Ethics* (2026), <https://doi.org/10.1186/s12910-026-01388-5>.

²¹ Inga Gaižauskaitė, and Natalija Valavičienė, *Socialinių tyrimų metodai: kokybinis interviu* (Vilnius: Registru centras, 2016), 36.

that few individuals were willing to share their experiences. Participant recruitment was purposive: only individuals who had undergone ART and subsequently contacted a NaProTechnology specialist were eligible, which further limited the available pool of participants.

The study participants were individuals who sought help from a Creighton Fertility Care System teacher and a physician who uses the principles of NaProTechnology to get pregnant naturally. All participants underwent ART procedures at two assisted reproduction clinics in Vilnius between 2023 and 2024 (see Table 1).

Table 1. Description of the study participants

Participant	Ages	Assisted reproduction experience	Excess embryos remaining after the ART procedure	Participant code
Spouses: Male Woman	40 y 37 y	2 IVF procedures: First in 2023 – ended in early miscarriage. The second one in 2024 – ended with a timely birth.	No longer available.	V1 M1
Female (married)	33 y	3 unsuccessful ART procedures. The exact number of embryos created is unknown.	There were frozen embryos left after the ART which had already been destroyed at the time of the interview.	M2

3.1. Survey data collection

In-depth interviews were used for data collection. The interviews took place on 24 and 25 February 2025. The duration of each interview was 1-1.5 hours. A pre-designed question guide was used for the interviews. The question guide was developed in accordance with Article 7 of Law of the Republic of Lithuania on Assisted Reproductive Technology. The criteria of point 1 of the Free Informed Consent in the Law:

1. What was explained to you about the ART procedure?
2. What ART probability have you been given?
3. What are the possible risks of ART for a woman that were mentioned to you before the ART procedure:
4. What possible risks of ART to the embryo and, if successful, to the child, were mentioned to you before the ART procedure
5. Which ART alternatives have you been introduced to?
6. What was your decision on the fate of surplus frozen embryos?

Additional questions were used to clarify or clarify where necessary. The ART Clinic Free Informed Consent Form provided by the study participants, which was signed by the study participants prior to the ART procedure and voluntarily shared with the investigators, was also assessed as a written information.

3.2. Research ethics

The study was conducted according to high ethical standards. Each participant was given the opportunity to provide informed consent to participate in the study. This consent form clearly stated that participation was voluntary. By signing the document, participants acknowledged that they had been informed of the study's objectives, methods, and data protection policy. The consent form also indicated that participants had the right to terminate their participation at any time or refuse to answer certain questions without facing negative consequences. All the necessary information was provided, including the name of the study, its purpose, the researchers, how the data would be used, and whom to contact with any questions about the study. These measures ensured the rights and privacy of the participants while respecting ethical principles. Each interview began with open-ended questions about the participants' experiences with assisted reproduction and asked them to identify the most positive and negative aspects of their experiences.

3.3. Method of data analysis

The interviews of the study participants were tape-recorded and transcribed. The data were processed using the method of content analysis, which allows to diagnose how the situation is perceived by the research participants, what difference exists between the theoretical description of the phenomenon under study and its expression in real life. Content analysis is a creative process of interpretation, which is carried out in sequential steps. The following steps are applied in text analysis: 1) multiple reading of the text, 2) identification of categories, 3) decomposition of the content of categories into sub-categories, 4) interpretation of categories and sub-categories, and justification of the text's claims.

3.4. Analysis and discussion of the survey data

The content analysis of the transcribed interviews identified the following categories 1) information provided about the ART procedure, 2) information provided about the effectiveness of ART, 3) information provided about the physical and mental risks of ART for the woman, 4) information provided about the risks of ART for the child, 5) information provided about the alternatives to ART, and 6) the number of embryos created and the fate of surplus embryos.

1) Category: *Information on assisted reproductive technology* (ART). This category identifies the sub-categories that were supported by the statements found in the interview text (see Table 2).

Table 2. Subcategories and supporting text for 1 Category *Information provided on assisted reproduction*

Subcategories of 1 Category	Confirmatory text
The ART method itself is explained more, less	<p>“It’s, you know, probably more or less everything about what comes after what, how it will work, what will follow, what needs to be done, probably more or less everything is explained, what comes after what, how it will work, what will follow, what needs to be done – it’s explained in a very basic way...” (M2).</p> <p>“The procedure itself was told... I was looking at the wall, I was looking at the poster, well, I’m always good with images” (M2).</p>
Suggested to read online for yourself	<p>“He didn’t say specifically how it would work, what we would do, to be precise – nothing, absolutely nothing. Ai, he said, read it on the internet, it’s all there” (M2).</p>
Explained in a way that makes no sense	<p>“Perhaps in general, what I missed was the explanation of those medical terms. Punctuation. Well, ok, let’s sign, but you have to sit down and say, ok, there is a puncture. If it’s not there, then you’re just led by that doctor <...> Insufficient ovarian response. Up to three per cent response. That’s quite a lot. Well, what is it? What is the consequence of this inadequate ovarian response?” (V1).</p>
The documents have been sent for consultation	<p>“There were documents sent out for reading, familiarisation and so on” (M1).</p>
The content of the documents was not discussed	<p>“What is written has not been discussed. <...> it’s practically after you sign it that you read it” (V1).</p> <p>“More often than not, I’ve asked what it is. Ai, they said, look it up on the internet, it’s clearly written there” (M1).</p>
Documents are read after signing	<p>“Documents are signed when everything has been decided and read after they have been signed” (M1).</p> <p>“And when are the documents signed? When everything is decided and it’s post facto, you’re practically reading after you’ve signed” (V1).</p>

As can be seen, the study participants said that they were given more or less information about the procedure and the steps to be taken during it. Visual aids were also used for this purpose. They were encouraged to read more on their own. However, many questions remained because the explanations were unclear, and the doctors used medical terms that the patients did not understand. The participants stressed the lack of information about the procedure and possible scenarios, especially in the initial

phase. They noted that they only read the documents they signed more carefully after the insemination and that these documents were not discussed before the procedure.

The clinic’s “Informed Patient Consent for Assisted Reproductive Technology” form, signed by the study participants, focused on describing the ART procedure. Based on the participants responses indicating a lack of information, as well as the fact that they were offered the opportunity to find the information themselves, and that they only read the written information more carefully after the procedure, it can be concluded that the clinic’s medical staff did not assess their patients’ understanding of the written information provided. This is an integral part of FIC.

2) Category: Information provided on the effectiveness of ARTs. This category identifies the sub-categories that were supported by the statements found in the text (see Table 3).

Table 3. Sub-categories of information provided on the effectiveness of ARTs and supporting text for 2 Category

Subcategories of 2 Category	Confirmatory text
Conflicting data on the likelihood of success of the procedure	<i>“They said 80 percent. But then where, in the office table, it’s less. Then I started to look online, and that’s another figure” (V1).</i>
	<i>“I think something was said about probability. Percentage-wise, I’m now afraid of jinxing something. Well, now I’m afraid to say, could it be 30 percent?” (M2).</i>
The delivered efficiency is lower than expected	<i>“The probabilities were discussed, but in reality they are lower than expected” (M2).</i>
Inadequate reporting of statistics	<i>“We really need more of those statistics, I mean, based on some kind of number” (V1).</i>

Participants in the study shared the impression that the treatment’s effectiveness was presented as having a certain probability of success, though this was not stated precisely. After seeing the tables posted in the clinic and conducting additional independent internet searches, they found that the probability was much lower than what the clinic’s staff presented. During the interviews, the participants expressed dissatisfaction with the clarity of the information about the probabilities of success. They said they would like more statistical information to better assess the effectiveness of assisted reproduction. However, the clinic’s “Informed Patient Consent for Assisted Reproduction” form, signed by the study participants, contains a fairly detailed description of the “Probability of success of assisted reproduction in the IVF procedure” in point 8. This section presents the clinic’s assisted reproduction results. It discusses what factors influence success and what hinders or helps efficiency. It also presents statistics on the success of ART

procedures published by ESHRE for 17 European countries in 2016. Therefore, it can be assumed that the study participants had access to written information.

3) Category: Information provided on ARTs to a woman at physical and mental risk. This category identifies the sub-categories that were supported by the statements found in the text (see Table 4).

Table 4. Subcategories of information provided on ARTs for women at physical and mental risk and supporting text for 3 Category

Subcategories of 3 Category	Confirmatory text
Insufficient information about the consequences	<p><i>“But maybe they don’t tell you about some of the consequences. What, well, for example, as far as I’ve had some interest now, that they can then trigger both cancers, and the likelihood of breast enlargement, and ovarian cancer. Well, at least that’s what the literature says. So nobody is saying that, but it’s probably normal that they don’t say it, because every kind of medical thing can always have consequences too, so not everybody is going to go and tell it and scare those people” (M2).</i></p> <p><i>“Nobody at the clinic emphasised those (physical and mental risks – aut. ed.)” (M1).</i></p> <p><i>“Well, there were a couple of sentences. Well, that, for example, as I recall now, there was a certain percentage added to recovery. That for a woman there might be some kind of a harder recovery and some kind of difficulties for a second birth. Well, those were general things to say, something more detailed, not really” (V1).</i></p>
Self-searched information on consequences	<p><i>“Actually, now I remember that it was very serious, the consequences and so on, when I was reading the documents, I realised that there are much, much, much, much, much, much more risks than we were presented with in the clinic, everything was painted in rainbow colours. And that there are such nuances and consequences, what is written is not discussed” (V1).</i></p>
Consequences should be given more attention	<p><i>“But I would say it should be more focused here, in more detail, where the risks are” (M2).</i></p> <p><i>“And when are the documents signed? When everything is decided and post facto, no, you read it practically after signing. It’s really, in terms of information, if out of ten, I would give a maximum of 7” (V1).</i></p>
Psychological consequences are only mentioned in documents	<p><i>“There is no mention of the psychological consequences” (M2).</i></p> <p><i>“There was one other point in the documents about the psychological consequences” (V1).</i></p>

As mentioned above, the Law of the Republic of Lithuania on Assisted Reproductive Technology requires the identification of potential risks caused by ART as a precondition for FIC. In response to the question about risks, however, the study

participants stressed that the potential physical and psychological risks associated with ART procedures were not clearly communicated prior to undergoing the procedure. While the degrees of risk associated with childbirth and postnatal care were discussed, the long-term physical and psychological consequences were not presented. In particular, there was a lack of information on the risk of cancer for women. While research participants were aware of the risks, they did not always have a clear understanding of what they might entail. The information on possible side effects was incomplete. The participants were interested in the various health risks that the procedures could cause, such as an increased risk of cancer. The clinic’s “Informed Patient Consent for Assisted Reproductive Technology” form, which was signed by the study participants, briefly mentions the risks for the mother under point 9, “Risks of Assisted Reproductive Technology, Possible Consequences for the Mother and the Fetus in the IVF Procedure”: “An increased likelihood of multiple gestation pregnancies, a twofold increase in the likelihood of preterm delivery, placental abruption, gestational diabetes, and high blood pressure.” However, ART consent forms from fertility clinics abroad are freely available online and list potential risks to women in far greater detail. For example, the “Informed Consent For Assisted Reproduction” from Northwestern Medicine Clinic devotes an entire section to potential risks for women, including ovarian hyperstimulation syndrome, cancer, and multiple pregnancy, as well as a comparison of risks for women who have had a natural versus an assisted pregnancy²². In light of the above, it can be argued that the subjects were not given sufficient information about the risks to the woman.

4) Category: Information Provided on ART Child Risk. This category identifies the sub-categories that were supported by the statements found in the text (see Table 5).

Table 5. Subcategories of the 4 Category Child Risk Information Provided and supporting text

Subcategories of 4 Category	Confirmatory text
Risks of having twins	“The potential risk of twins is dangerous” (M 2).
Uncertain risks to the child after PAB	“Uncertain risks to the child after IVF” (V1).
Little mention of the risk of birth defects	“Well, he said a couple of sentences that, well, there might be more malformations there, that sort of thing” (M1). “For some future, when there might be a possibility that the child might be weaker or with something, it’s definitely not. Well, no information” (M1).

²² Northwestern Medicine Center for Fertility and Reproductive Medicine, *Informed Consent for Assisted Reproduction*, published March 6, 2020, https://fertility.nm.org/uploads/1/2/7/0/127099700/b2a_informed_consent_for_assisted_reproduction_7.5.19.pdf.

When asked about the information provided regarding potential risks to the child, participants noted that the risk of a twin birth was mentioned. However, there was no mention of long-term risks to the child. Under point 9 of the clinic's "Informed Consent for Assisted Reproductive Technology" form, which was signed by the participants in the study, two sentences were devoted to fetal risks: "The rate of fetal malformations increases by one-third (in the general population, it is 2–4%), and the perinatal mortality rate is four times higher". Considering the verbal and written information provided in the form, it can be concluded that the subjects were not given sufficient information for their consent to be considered informed.

5) Category: Information Provided on ART Alternatives. This category identifies the sub-categories that were supported by statements found in the text (see Table 6).

Table 6. Subcategories of 5 Category Information Provided on Alternatives and supporting text

Subcategories of 5 Category	Confirmatory text
Ovarian stimulation is an alternative to IVF	<p><i>"There have been other places where it's not IVF, but where they inject drugs into the abdomen and then tell you when to be in a relationship and then try. Ovarian stimulation" (M1).</i></p> <p><i>"Before that I tried ovarian stimulation. But it's clear nothing there helped" (M2).</i></p>
Lack of information on alternatives	<p><i>"There was a lack of information on alternatives to treat my identified cause of infertility" (M2).</i></p>
Alternatives (e.g. NaPro) were not considered	<p><i>"No, absolutely not about NaPro. We found the information ourselves – we saw the article by Linas Adomaitis (article in "Žmonės" portal – author's note) and decided to go there. There is one in Kaunas. So we took the initiative and that's how we found the doctor" (M1).</i></p> <p><i>"I say, I say, I have both, I say, I have options in nutrition and endobiogenics, and they laughed, they laughed, they were angry, they said, you can read whatever you want, medicine is medicine, it's world-validated, it's not just some medicine. Well, maybe five years ago I would have believed it, now I'm too enlightened that there are these alternatives, there are plenty of friends around" (M2).</i></p>

When asked about the alternatives to ART they had been introduced to, the subjects replied that ovarian stimulation was mentioned and that some patients had been offered IVF (*in vitro* fertilization) as an option after unsuccessful stimulation.

All three research participants confirmed that they were not introduced to any alternatives, particularly since no information about RRM (Restorative Reproductive Medicine) was provided. Alternative methods, such as holistic medicine and NaPro, were not discussed in the clinic but were discovered by the participants themselves.

The medicine staff did not shy away from expressing their skepticism toward holistic medicine. The clinic’s “Informed patient consent form for assisted reproduction”, signed by the subjects, includes a section titled “Alternative Assisted Reproductive Treatment Methods and Other Alternatives”. This section lists principles such as healthy eating, physical activity, and acupuncture. It also mentions adoption or fostering of children without parental care as an alternative to ART. Unfortunately, measures such as healthy eating, physical activity, and adoption are not treatment methods. Therefore, the verbal and written information provided to ART patients can be considered insufficient and misleading.

6) Category: Number of embryos created and fate of surplus embryos. Within this category, sub-categories have been identified which are supported by the statements found in the text (see Table 7):

Table 7. Number of embryos created and fate of surplus embryos sub-categories of 6 Category and supporting text

Subcategories of 6 Category	Confirmatory text
The number and fate of surplus embryos is uncertain	<p><i>“It was frozen, but there was no explanation of what would happen to the rest of the... I asked how long will it be able to stay there?” (V1).</i></p> <p><i>“You know, I know that maybe about five straws, I don’t know how many straws there are, but there was” (M2).</i></p> <p><i>“Yeah, there were seven. They pulled out eleven and then they call the next day, so that’s seven left, and then four of those seven. Four and finally the healthy ones to put down it was two. That is the remaining question. Gone, dead, but the truth is that nobody has told us anything to explain what happened” (M1).</i></p>
Embryo destruction authorisation was influenced by a conversation with a psychologist	<p><i>“Now, at the end of the year, we had to come and talk to a psychologist. We could have donated. But we asked them, we didn’t feel sorry for them, but we asked them ourselves, is this normal? And then they said that it would not be normal anyway, because nobody knows if they will go to my cousin, for example. That there is no control. That there is no control in that, and it could be incest. So we say, of course, then there is no need. We do not want any donations. And then by our decision they thawed them and destroyed them” (M2).</i></p>

During the interviews, the participants, a married couple, shared that they had not been clearly informed of the number of remaining surplus embryos or their fate. They lacked information about the stages of embryo development and what would happen to them after procedures or long-term storage. A conversation with the clinic psychologist was crucial in convincing the participants to agree to destroy the surplus embryos.

Studies have shown that patients with frozen embryos have mixed experiences with them. A study by Anne Drapkin Lyerly, Karen Steinhauser, and others²³ found seven main themes in the decision-making process regarding the fate of the embryos: family and personal issues, trust, embryo definition, future responsibility, responsibility to society, information adequacy, and lack of acceptable options. Our study also identified a lack of information.

The data obtained in this study, while limited in scope, are informative, original and ethically significant. Several cross-cutting observations deserve broader discussion. First, across all six categories, a recurring pattern emerges: written information was formally provided but not adequately communicated or verified. Research participants consistently noted that consent forms were signed before being fully read, and that medical staff did not check whether the content was understood. This is a fundamental violation of the FIC doctrine, which requires not merely the provision of information but also the assurance of comprehension. Second, the findings highlight a structural imbalance in the doctor–patient relationship: research participants felt pressured or guided toward the ART procedure, with little encouragement to explore alternatives or to ask questions. This is particularly evident in the category concerning alternatives, where RRM methods – which are legally required to be disclosed – were not mentioned at all. Third, the emotional and psychological dimensions of the ART process were systematically under-represented in the information provided, both orally and in writing. The participants' accounts suggest that the psychological consequences of ART – including the emotional burden of decision-making about surplus embryos – received little attention during the consent process. Taken together, these findings indicate that the problem is not merely one of incomplete paperwork, but of a broader failure to treat informed consent as a genuine, ongoing dialogue between clinician and patient, as required by both Lithuanian law and international bioethical standards.

Conclusions

Informed consent is a legal, ethical, and moral obligation that is the responsibility of both the healthcare professional and the patient. The Lithuanian legal system regulates the conditions for implementing FIC in assisted reproduction procedures. The Lithuanian Law on Assisted Reproductive Technology contains a chapter that details what is covered by FIC and explains when and how it is signed.

A situational analysis of informed consent in assisted reproduction showed that participants lacked information about the ART process and were encouraged to find information themselves. Participants only read the written information provided on

²³ Anne Drapkin Lyerly, Karen Steinhauser, Emily Namey et al., “Factors that affect infertility patients’ decisions about disposition of frozen embryos,” *Fertility and Sterility*, Vol. 85, no. 6 (2006): 1623–1630.

the clinic's ART form carefully after the procedure. This suggests that clinic staff did not determine how patients understood the written information. This is an integral part of FIC.

During the interviews, research participants expressed dissatisfaction with the clarity of the information regarding the probability of a successful pregnancy and said they would like more statistical information to better assess the effectiveness of ART. However, the clinic's "Informed Consent for Assisted Reproductive Technology" form, signed by the study participants, describes the "Probability of success of assisted reproductive technology in IVF" quite thoroughly. Therefore, it can be concluded that the clinic's medical staff did not ascertain how their patients understood the written information.

Regarding the risks of ART for women and children, the study participants reported a lack of oral and written information. Patients tried to find information on their own. According to the responses of the survey participants, the alternatives were not made known. No information on modern methods of restorative reproductive medicine was provided, either orally or in writing. Participants found this information on their own via the internet.

According to the results of the study participants lacked information about the fate of embryos. They were not told how many embryos had been created or how many remained. According to the study, it can be concluded that consent for the ART procedure was obtained from patients who were not fully informed. In answer to the research question posed in the introduction, the study reveals that patients of ART clinics in Lithuania did not receive complete and adequate information required for free and informed consent before undergoing IVF procedures. According to the patients' own assessment, they rated the information as only satisfactory. To improve the information provided to patients before assisted reproduction, a more detailed study should be conducted.

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