

B²-InF



B2-INF BE BETTER INFORMED ABOUT FERTILITY

B2-INF RECOMMENDATION GUIDELINES

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The World Health Organization states that infertility is a global health issue, affecting around 48 million couples and 186 million individuals worldwide.¹ The inability to have children can have social, economic, psychological and physical effects that seriously impact the well-being and quality of life of people affected by infertility. Additionally, institutions such as the Center for Disease Control and Prevention highlight that there are significant inequalities in the prevalence, diagnosis, referral and treatment of infertility (sex, ethnicity, socioeconomic status, etc.), as well as likely health risks for women, men and offspring associated with treatments for infertility.² For all of these reasons, the prevention of infertility and the consequences associated with its treatment is a critical issue from a public health standpoint, and fertility care is key to the promotion of sexual and reproductive health and rights. However, studies that investigate young people's opinions, concerns, and expectations related to infertility and medically assisted reproduction (MAR) are scarce.

B2-INF IS A RESEARCH PROJECT FUNDED BY THE EUROPEAN UNION THROUGH THE EUROPEAN UNION'S HORIZON 2020 RESEARCH AND INNOVATION PROGRAMME (GRANT AGREEMENT NO. 872706), WHICH AIMS TO EXPLORE HOW YOUNG PEOPLE PERCEIVE AND THINK ABOUT MAR, AND HOW MAR CLINICS CAN BETTER ALIGN THEIR SERVICES, RESEARCH AND INFORMATION WITH THE VIEWS, CONCERNS, AND EXPECTATIONS OF CITIZENS.

B2-INF promotes responsible research, innovation and public participation in the field of MAR. Toward this end, B2-INF collected and analysed knowledge, expectations, and concerns about MAR from young people (aged 18 to 30) in eight European countries (Albania, Belgium, Italy, Kosovo, North Macedonia, Slovenia, Spain, Switzerland) for the purpose of transferring this information to clinics and policymakers. In addition, B2-INF collected and analysed information offered by clinics on their websites and compared this information with young people's perceptions and needs. The results of B2-INF will be used to improve the scientific information offered by MAR clinics to society from sociocultural, legal and gender perspectives through the application of citizen-validated national and international guidelines. Furthermore, B2-INF will help to shed light on the evolution of reproductive science and its perception by society in order to promote proactive and anticipatory policy making and to align research developments with

the needs, expectations and values of society.

This document presents the recommendation guidelines drafted by B2-INF based on the results of the sociocultural, gender, and legal analyses carried out by specialized scientific research teams on data obtained from interviews with young populations and information provided by clinics.

First, the general methodology of the project is presented as it was carried out in eight European countries (Albania, Belgium, Italy, Kosovo, North Macedonia, Slovenia, Spain, Switzerland), followed by global recommendation guidelines for all countries of the European Union.

Next, the national guidelines are presented, with recommendations specifically tailored to each country, based on data obtained from interviews with youth and reviews of information provided online by clinics in each country. These guidelines are preceded by a summary of the national context and a description of the fieldwork and sampling methods for each country.

¹ Infertility [Internet]. World Health Organization - Health Topics. 2022 [visited 16 December 2022]. Available in: https://www.who.int/health-topics/infertility#tab=tab_1

² Centers for Disease Control and Prevention. National Public Health Action Plan for the Detection, Prevention, and Management of Infertility. Atlanta, Georgia: Centers for Disease Control and Prevention; June 2014.

In total, 98 semi-structured interviews were conducted, and 38 clinics' websites were explored in Albania, Belgium, Italy, Kosovo, North Macedonia, Slovenia, Spain and Switzerland. All the information was collected in vernacular languages, transcribed verbatim and translated into English. The transcripts of the interviews and the clinics' information were analysed independently following a qualitative thematic and content analysis approach. The analysis was supported by Atlas.ti software v9.1.5.

Based on the data obtained by interviews and reviews of websites, thematic and content analyses were carried out by specialized research teams focussing on the following aspects:

- Sociocultural: Analysis carried out by researchers from the Institut national d'Études démographiques (Ined; France)
- Gender: Analysis carried out by researchers from the University of Antwerp (UA; Belgium)
- Legal: Analysis carried out by researchers from the Universidad Rey Juan Carlos (URJC; Spain).

In addition, the URJC conducted a search of documents to determine the regulation of MAR in the selected countries, including legislation, jurisprudence, and soft law, with respect to: MAR techniques, informed consent, and advertising presented by clinics on their websites. Then, in light of this legal regulation, it conducted a legal analysis of the information offered by clinics.

Once the thematic and content analysis and legal analysis was completed, the University of Navarra (UNAV; Spain) team, responsible for integrating the results,

carried out that work with the collaboration and feedback from the research teams involved.

The guides are organized into two sections that were prepared separately: one that deals with matters related to sociocultural factors and gender, and one that deals with legal questions.

A first draft of the national guidelines was developed during the month of September 2022 and presented at the Internal Workshop held in Pamplona (Spain) on October 6. After several revisions, a new draft was presented prior to the Validation Workshop 2 held in Brussels (Belgium) in October 2022 with 32 young people from the 8 countries selected.

Then, more revisions, feedbacks and modifications were made to the guidelines, based on the comments received from the participants in Validation Workshop 2 and by the research partners involved in B2-InF, resulting in the present document.

GLOBAL RECOMMENDATION GUIDELINES

This section presents a set of global recommendations that were elaborated by the research team by synthesizing the results of investigations carried out in eight European countries (Albania, Belgium, Italy, Kosovo, North Macedonia, Slovenia, Spain, Switzerland). These recommendations are based on the following:

1) data collected over the course of the project through qualitative interviews with youth, a survey of information

found on the webpages of assisted reproduction clinics, and a review of the national and international legal frameworks concerning the object of investigation.

2) scientific analyses of this information carried out by separate teams of the B2-INF consortium composed of experts in the fields of gender, sociocultural context, and law.

SOCIOCULTURAL AND GENDER GUIDELINES

Being better informed about infertility treatment requires that the information provided by clinics are aligned with the concerns and expectations of the public, especially young populations. It also requires that citizens are better educated about infertility, including its causes, prevalence, and treatment. In interviews with young persons from participating countries, the following discrepancies and misalignments were detected:

MAIN GENERAL CONCLUSIONS

- o Young people are concerned that infertility, especially male infertility, remains taboo, partly due to lack of knowledge about prevalence and causes of infertility in society at large.
- o Young people are concerned that women are unfairly burdened by unequal responsibility and blame for infertility; meanwhile information on clinic websites tends to be heavily skewed toward women.
- o Young people seek information about psychological services related to MAR.
- o Young people tend to support equal access to MAR, while many clinics present their services as directed primarily toward white and heterosexual couples.
- o Young people are concerned not only for

improved access to fertility treatment but also for universal access to basic services of primary and reproductive healthcare.

- o Young people expect transparency about costs of MAR, while many clinics do not provide adequate information about prices of treatments and add-ons.
- o Young people mention that surrogacy is often part of a heavily polarized debate in the media, while clinics do not offer information on surrogacy (often due to legal restrictions).

GUIDELINES

- Clinics should use a common language to describe techniques: they should use the same terms and definitions, the same figures for prevalence of infertility (including by sex), the same success rate unit (live-birth rate is recommended) by technique and according to age (both men and women).
- Clinics websites should be more user-friendly and ergonomic, making information accessible but not excessively detailed, to support good understanding and informed choice.
- Clinics should de-stigmatize infertility and MAR use, specifying that many individuals and couples face infertility issues and use MAR, specifying however that MAR procedure can be long and difficult, and can present psychological challenges.
- Clinic websites should provide information about psychological services, facilitate access to these services (where available), and address this information to all prospective parents (e.g. regardless of gender) and those contributing to reproduction (e.g. donors).
- Clinics should provide systematic, clear and comprehensive information on MAR procedures, techniques, costs, and on relevant legal framework.
- Clinics should present their services in ways that are consistent with legal access in their respective countries and/or clearly explain any legal restrictions on access (e.g. the nullity of surrogacy contracts).
- Information provided by clinics should be more gender-balanced (not focusing only on women and motherhood), in order to avoid contributing to the dominant social representation that infertility is a women's issue and to reduce social pressure on women to conceive. Clinics might avoid using pink on fertility websites and use a more gender-neutral colour.
- Information provided by clinics should be more gender-inclusive (considering single individuals, same-sex couples and also trans and intersex people). In the context of cryopreservation, pre-transition gamete freezing should be named explicitly.
- Clinics should address people with disabilities, who should be kept in mind as possible MAR users.
- Clinics should be less heterocentric (focused on heterosexual couples) and consider the different existing family configurations, including multiple parenthood.
- The information and advertising provided by clinics should reflect the ethnic, cultural, and racial diversity of European citizens. Infertility and its treatment should not be presented as if it were exclusive to certain groups.
- Clinics should be less market-oriented (less use of superlatives to describe their services, experience and performance) and more grounded in social and human reality.
- Clinics should avoid presenting themselves as "dream sellers" to avoid false hopes and should not represent MAR as a condition for happiness in life. They should mention other alternatives for becoming parents.
- Clinics should not contribute to taboos regarding infertility and MAR. They should not avoid speaking of sexuality (sexual intercourse) and masturbation (as the primary way to collect sperm).
- Public information should be available and disseminated in local languages (and not only in English).
- Public information campaigns on infertility (causes, prevalence) and MAR possibilities should be carried out to better inform general population, including young people who appear to have little knowledge of the subject, and to raise awareness.
- Public information campaigns should be gender-balanced and gender-inclusive.

LEGAL GUIDELINES

DEFICIENCIES IN THE INFORMATION PROVIDED BY CLINICS:

All information provided by clinics – through their websites, advertising, and documents of informed consent – is regulated by legal standards for truthful advertising and informed consent. We have found that information provided by clinics about success rates of fertility treatments, add-ons (supplementary procedures offered by clinics for the purpose of improving fertility treatment outcomes), and possible risks associated with MAR does not meet these standards. Accordingly, in the interest of greater transparency, we make the following recommendations for the improvement of this information:

WITH REGARD TO SUCCESS RATES IT IS RECOMMENDED THAT:

- Success rate should be clearly defined as live birth, in alignment with expectations of persons seeking fertility treatment and their main reason for contracting the services of a clinic.
- Information about success rates should be based on best available evidence. Clinics should clarify the strength of this evidence.
- Different success rates should be specified in relation to age, different techniques, and use of egg donation.
- Clinics should provide access to evidence-based sources of data for purposes of verification.
- Information about success rates provided through websites and advertising should match the information provided through informed consent.

WITH REGARD TO ADD-ONS IT IS RECOMMENDED THAT:

- Clinics should provide clear information, based on best available evidence, in support of any claim that add-ons can improve fertility treatment outcomes. If such data is unavailable, clinics should make this clear.
- All risks associated with the use of add-ons should be clearly explained.
- Clinics should provide access to evidence-based sources of data on add-ons for purposes of verification.
- Information about add-ons provided through websites and advertising should match the information provided through informed consent.

WITH REGARD TO POSSIBLE ASSOCIATED RISKS IT IS RECOMMENDED THAT:

- In websites, advertising, and documents of informed consent, clinics should provide complete, clear, and comprehensible information, based on best available evidence, about potential health risks for persons undergoing fertility treatment. Clinics should clarify the strength of this evidence.
- In websites, advertising, and documents of informed consent, clinics should provide complete, clear, and comprehensible information, based on best available evidence, about potential health risks for children conceived through MAR.
- This information should differentiate specific risks associated with different techniques (IUI, IVF, ICSI) and procedures (chemical and physical manipulation of gametes and embryos). Clinics should clarify the strength of this evidence.
- Information about risks should be expressed at two levels: in technical terms that specify the type of risk and its probability, and in nontechnical language that is readily accessible to the public (e.g., using illustrations if necessary).
- Clinics should provide access to evidence-based sources of data for purposes of verification.
- Information about associated health risks to MAR provided through websites and advertising should match the information provided through informed consent.

ADDITIONAL KEY RECOMMENDATIONS AND CONSIDERATIONS

- Clinics should make documents of informed consent available to the public through their websites.
- Clinics should make information sheets and informed consent forms adapted to people with disabilities as required by article 25 of United Nations International Convention on the Rights of Persons with Disabilities.
- Recommended that health authorities create a catalogue of informed consent forms and information sheets that comply with current regulations.
- Clinics can provide information about reproductive health services available in other countries but should avoid promoting travel across borders to obtain these services in ways that implicitly or explicitly circumvent domestic laws (e.g., lack of legal support for surrogacy contracts).
- Widespread concern among young people about “designer babies” points to need for information about ethics and legal regulation of gamete donation.
- Many young people support equal access to MAR, but their positions on surrogacy are diverse, reflecting the ongoing ethical and juridical debate.
- Many young people view parenthood as a right but do not clearly distinguish between claim rights and liberty rights—being entitled vs. being free to have children.
- At the European level there is a possible inconsistency between child’s right to knowledge of biological origins (International Convention on Rights of the Child, art. 8 European Council Recommendation 2156/2019, Recommendations of national bioethics committees, e.g., in Spain and Switzerland) and donor anonymity (domestic regulations).

NATIONAL RECOMMENDATION GUIDELINES

This section presents recommendations that have been elaborated by the research team for each country (Albania, Belgium, Italy, Kosovo, North Macedonia, Slovenia, Spain, Switzerland) based on the following:

1) data collected over the course of the project through qualitative interviews with youth citizens from each country, a survey of information found on the webpages of assisted reproduction

clinics selected from each country, and a review of the national and international legal frameworks concerning the object of investigation. 2) scientific analyses of this information carried out by separate teams of the B2-INF consortium composed of experts in the fields of gender, sociocultural context, and law.

01

ALBANIA

1.1 Introduction

ALBANIAN CONTEXT

The fertility rate in Albania has decreased slightly in recent years to its current level of 1.6 children per woman, but remains slightly above the European average³. The average age of women at first birth is 22 years and can be even younger⁴ among women from rural areas, those with a lower economic level, and in Muslim populations. Albania has not regulated Medically Assisted Reproduction (MAR) to date. In 2002, the Albanian government decided to implement some provisions regarding MAR in the law on "Reproductive Health". This law groups MAR together with other reproductive issues and, as a result, does not address its specific ethical problems.

Since 2002, no regulation has been adopted in order to implement special legal provisions. Because of this lack of regulation, the legal situation in Albania is characterized by uncertainty regarding the status of the donor, the rights of the child, and especially the criteria settled by the health providers for users⁵.

There are 11 clinics in the country performing MAR treatments, and all of them are private. The government of Albania does not provide public funding for this type of treatment and there is no national register of MAR activity in the country. Albania is a destination for cross-border reproductive care⁶, but Albanians are also travelling to other countries, especially Greece and North Macedonia, to use MAR.

³ Fertility rate, total (births per woman) - Albania | Dating [Internet]. [cited 2022 Jan 24]. Available from: <https://data.worldbank.org/indicator/SP.DYN.TFRT.IN?locations=AL>

⁴ Talukder A, Khan ZI, Khatun F, Tahmida S. Factors associated with age of mother at first birth in Albania: application of quantile regression model. *Helyon* [Internet]. 2021 Mar 1 [cited 2022 Jan 24];7(3):e06547. Available from: <https://www.sciencedirect.com/science/article/pii/S2405844021006502>

⁵ Calhaz-Jorge C, De Geyter CH, Kupka MS, et al. Survey on ART and IUI: legislation, regulation, funding and registries in European countries: The European IVF-monitoring Consortium (EIM) for the European Society of Human Reproduction and Embryology (ESHRE). *Hum Play Open* 2020(1): hoz044. doi:10.1093/hropen/hoz044

⁶ The European IVF-Monitoring Consortium (EIM) for the European Society of Human Reproduction and Embryology (ESHRE), Wyns C, De Geyter C, Calhaz-Jorge C, Kupka MS, Motrenko T, et al. ART in Europe, 2017: results generated from European registries by ESHRE. *Human Reproduction Open* [Internet]. 2021 Jun 1 [cited 2021 Oct 25];2021(3). Available from: <https://doi.org/10.1093/hropen/hoab026>

FIELDWORK DESCRIPTION

INTERVIEWS

Interviewees were recruited through a convenience sample technique. Individuals were identified through by Health Grouper (B2-Inf partner). Researchers identified individuals who complied with the required demographic and social characteristics and invited them to participate. Most of those invited accepted the invitation.

In total, 11 interviews were carried out between May and September 2021, all of them conducted in Albanian language. In relation to the geographical distribution, most of the interviewees came from Tirana, the country's capital. Although one third of the sample were currently located in Tirana, they were originally from different areas of the country.

Three out of 11 interviews were conducted remotely, and 8 interviews took place face-to-face. One of the three remote interviews was done by phone call and the other two by WhatsApp call. No section of the interviews had to be skipped due to embarrassment or other difficulties. Sometimes it was necessary to ask the interviewee the same question more than once in order to collect better and more articulated opinions.

CLINICS

Due to the low number of MAR clinics in Albania, a Google tool search was performed using keywords such as "IVF Centres" or "Assisted Reproduction Centres", and the five centres that appeared first were selected. Subsequently, the selection of centres was checked with local experts in health services research. Local language and country were set up as preferred for every search that was conducted. Other sources such as journals or blog articles that were not from IVF centres were excluded.

Data collection was carried out by Medistella during November and December 2021. Websites from selected MAR clinics were explored in local language (Albanian) and then translated into English. All the information was collected and organized by specially designed templates. Once the template was completed, it was reviewed by an English native speaker. Approximately 140 pages were collected from Albanian MAR clinics' websites.

1.2 Recommendation guidelines

SOCIOCULTURAL AND GENDER GUIDELINES

Being better informed about infertility treatment requires that the information provided by clinics is aligned with the concerns and expectations of the public, especially young populations. It also requires that citizens are better educated about infertility, including its causes, prevalence, and treatment.

- To educate citizens, infertility should be the focus of a public information and awareness-raising campaign directed by public health authorities. The campaign should de-stigmatize infertility by providing information about the prevalence and causes of infertility in both men and women. It should provide information about the full range of methods available to couples and individuals for becoming parents.
- Clinics should provide more gender-inclusive information, and less female-centred information, to counteract the social representation that infertility is a women's issue (include, for example, ICSI and sperm donation in the techniques for dealing with infertility in men).
- Clinics should present information and advertising (e.g., photos) in a manner that reflects the ethnic, racial, and cultural diversity of Albanian citizens, and should provide information on options for all genders and/or sexual orientations.
- Clinics should reassure future patients in face of society's critical view of Medically Assisted Reproduction (MAR).
- Clinics should provide psychological support.
- Clinics should provide information that is consistent with and adapted to the country's laws.
- Clinics should provide more detailed information about the costs of fertility treatment and success rates according to age, and about the legal framework (for instance, who has access to MAR in Albania).
- The government should be aware that young people are concerned not only for improved access to fertility treatment but also for universal access to basic services of primary and reproductive healthcare.

LEGAL GUIDELINES

The availability and adequacy of information provided by clinics depends in part on the state of the relevant legal frameworks: laws that regulate fertility treatments and health services in general, laws that regulate informed consent and the use of personal data, laws that regulate advertising, as well as laws that affect marriage and paternity.

WEAKNESSES OF THE LEGAL FRAMEWORK IN ALBANIA:

- Poor legal framework: Law 8876 On Reproductive Health (2002) is now 20 years old, needs developing and updating to conform to European Court of Human Rights case law.
- No national commission for oversight of MAR; Albanian law does not provide for it.
- Although surrogacy contracts are considered null and void, and Albanian law determines parentage in favour of the woman who gives birth, Albania has become a common destination for cross-border surrogacy programmes originating in Russia and Ukraine, leading to increased risk of reproductive exploitation and vulnerability of intended parents during the current conflict in Ukraine.
- Lack of clarity about access: art. 30 establishes right for individuals and couples to have access to MAR, but same article links access to existence of fertility problems in couple.
- Legal restriction of fertility treatment to infertile couples does not account for the fact that according to European Court of Human Rights case law (*Costa Pavan v. Italy*, 2012), access must be guaranteed to couples carrying genetic diseases.
- No law specifically establishes obligation to report on MAR, but this is implied by regulation of sexual and reproductive health (art. 3).
- Possible inconsistency between child's right to knowledge of biological origins (*Child Convention*, art. 8; *European Council Recommendation 2156/2019*) and donor anonymity.
- No detailed regulation of informed consent, clinics do not make this info public.

DEFICIENCIES IN THE INFORMATION PROVIDED BY CLINICS:

All information provided by clinics – through their websites, advertising, and documents of informed consent – is regulated by legal standards for truthful advertising and informed consent. We have found that information provided by clinics about success rates of fertility treatments, add-ons (supplementary procedures offered by clinics for the purpose of improving fertility treatment outcomes), and possible risks associated with MAR does not meet these standards. Accordingly, in the interest of greater transparency, we make the following recommendations for the improvement of this information:

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- Success rate should be clearly defined as live birth, in alignment with expectations of persons seeking fertility treatment and their main reason for contracting the services of a clinic.
- Information about success rates should be based on best available evidence. Clinics should clarify the strength of this evidence.
- Different success rates should be specified in relation to age, different techniques, and use of egg donation.
- Clinics should provide access to evidence-based sources of data for purposes of verification.
- Information about success rate provided through websites and advertising should match the information provided through informed consent.

WITH REGARD TO ADD-ONS IT IS RECOMMENDED THAT:

- Clinics should provide clear information, based on best available evidence, in support of any claim that add-ons can improve fertility treatment outcomes. If such data is unavailable, clinics should make this clear.
- All risks associated with the use of add-ons should be clearly explained.
- Clinics should provide access to evidence-based sources of data on add-ons for purposes of verification.
- Information about add-ons provided through websites and advertising should match the information provided through informed consent.

WITH REGARD TO POSSIBLE ASSOCIATED RISKS IT IS RECOMMENDED THAT:

- In websites, advertising, and documents of informed consent, clinics should provide complete, clear, and comprehensible information, based on best available evidence, about potential health risks for persons undergoing fertility treatment. Clinics should clarify the strength of this evidence.
- In websites, advertising, and documents of informed consent, clinics should provide complete, clear, and comprehensible information, based on best available evidence, about potential health risks for children conceived through MAR.
- This information should differentiate specific risks associated with different techniques (IUI, IVF, ICSI) and procedures (chemical and physical manipulation of gametes and embryos). Clinics should clarify the strength of this evidence.
- Information about risks should be expressed at two levels: in technical terms that specify the type of risk and its probability, and in nontechnical language that is readily accessible to the public (e.g., using illustrations if necessary).
- Clinics should provide access to evidence-based sources of data for purposes of verification.
- Information about associated health risks to MAR provided through websites and advertising should match the information provided through informed consent.

ADDITIONAL KEY RECOMMENDATIONS FOR CLINICS:

- Clinics should make documents of informed consent available to the public through their websites.
- Clinics should make information sheets and informed consent forms adapted to people with disabilities as required by article 25 of United Nations International Convention on the Rights of Persons with Disabilities.
- Clinic websites should describe the conditions for receiving governmental support (e.g., through the public health system) for fertility treatment (e.g., age of the woman, etc.) and should provide information about alternative methods.
- Clinic websites should clarify that surrogacy contracts are not legally supported in Albania.
- Clarification of access is needed: art. 30 establishes right for individuals and couples, but same article links access to existence of fertility problems in couple. Does not mention couples who are carriers of genetic disease.
- Strict compliance with principles of authenticity and truthfulness: advertising should be clearly identifiable as such and should not be incomplete or otherwise misleading (Law 97/2013 art. 43, LAW Nr.9902, dated 17.4.2008 on consumer protection).

CONSIDERATIONS FOR THE IMPROVEMENT OF PUBLIC INFORMATION:

- It is recommended that health authorities create a catalogue of informed consent forms and information sheets that comply with current regulations.
- Persons seeking fertility treatment should be informed of available alternatives to MAR, including adoption and the possibility of treating infertility through biomedical intervention.
- A national registry of clinics should be created that provides standardized, up-to-date information about success rates.
- Citizens should be informed of the legal definition and conditions of parenthood and of the rights that are implicated by fertility treatment (rights of parents, rights of donors, rights of offspring).
- Public information campaigns need support from government and health authorities: Albania does not have a national commission for MAR; a National Bioethics Committee exists but has no website.
- Obligation to report on MAR is implied by Law 8876 art. 3: public information campaign recommended.

BELGIAN CONTEXT

The fertility rate in Belgium has been declining since 2010. In that year, the fertility rate was 1.85 children per woman, whereas in 2020 the total fertility rate decreased to 1.55 children per woman⁷. Since 1998 the average age of mothers at birth in Belgium has increased, from 29 in 1998 to 31 years in 2020⁸. There are differences among regions, with a significantly higher average age in Brussels (32 years) than in Flanders and Wallonia (31 years old).

Regarding legislation, MAR in Belgium is regulated by the law of 6 July 2007. The techniques allowed in Belgium are: intrauterine insemination (IUI), in vitro fertilization (IVF), intracytoplasmic sperm injection (ICSI), egg and sperm donation, egg freezing, and preimplantation genetic diagnosis (PGD). Egg and sperm donation can be anonymous or non-anonymous, but embryo donation is only anonymous⁹. No specific law regulates surrogacy in the current Belgian legislation.

With regard to accessibility, MAR techniques in Belgium are accessible for heterosexual couples, single women, female couples and, on a case-by-case basis, for male couples. MAR is covered by social insurance for Belgian women up to 43. Because of the wide accessibility to MAR techniques, Belgium is considered an 'open state' and a frequent destination of cross-border reproductive care¹⁰.

The Medically Assisted Reproduction (MAR) data from Belgium has been recorded by the Belgian Register for Assisted Procreation (BELRAP) since 1989¹¹. According to this registry, 39,489 cycles were performed in 2018 and 5,954 children were born through MAR¹².

The number of centres that provide MAR in Belgium is limited by law¹³. There are 17 medical centres which diagnose and treat infertility but do not have a MAR laboratory; and there are 18 medical centres with a MAR laboratory. There are no completely private MAR centres in Belgium.

⁷ Statbel. Sharp drop in births in 2020 [Internet]. [cited 2022 Jan 12]. Available from: <https://statbel.fgov.be/en/news/sharp-drop-births-2020>

⁸ Statbel. A still declining birth rate and fertility rate [Internet]. 2019 [cited 2022 Jan 12]. Available from: <https://statbel.fgov.be/en/news/still-declining-birth-rate-and-fertility-rate>

⁹ Pennings G. Belgian Law on Medically Assisted Reproduction and the Disposition of Supernumerary Embryos and Gametes. *Eur J Health Law* [Internet]. 2007 Jan 1 [cited 2022 Jan 11];14(3):251-60. Available from: https://brill.com/view/journals/ejhl/14/3/article-p251_4.xml

¹⁰ Merchant J, editor. *Access to Assisted Reproductive Technologies: The Case of France and Belgium*. New York; 2020.

¹¹ BELRAP[web] [cited 2022 Jan 11]. Available from: <https://www.belrap.be/Public/Default.aspx?Lg=En>

¹² Anagnostou E, Blockeel MC, Delbaere MA, member Devreker AF, Vandekerckhove MF, Belmans A, et al. Assisted Reproductive Technology National Summary Report Belgium 2018. *College of Physicians Reproductive Medicine* [Internet]. 2021 [cited 2022 Jan 11]. Available from: www.belrap.be.

¹³ Calhaz-Jorge C, De Geyter C h, Kupka MS, Wyns C, Mocanu E, Motrenko T, et al. Survey on ART and IUI: legislation, regulation, funding and registries in European countries. *Hum Reprod Open*. 2020 Jan 1;2020(1).

FIELDWORK DESCRIPTION

INTERVIEWS

The recruitment of participants was organized through two recruitment offices, one in the Francophone area and the other one in the Flemish region of the contracted company based in Belgium.

15 interviews were carried out in Belgium during June 2021. Eight interviews were conducted in French and seven in Dutch. One of the interviews carried out in Dutch was removed from the sample because it met the exclusion criteria. The young people who took part in the interviews mainly came from Antwerp and the province of Antwerp, Brussels, Brussels-Capital Region, the province of Walloon Brabant and the province of Liège in order to ensure a good distribution between Flanders and Wallonia. Because of the COVID-19 pandemic, all interviews took place online through video call via Whereby platform.

Respondents were very willing to cooperate, spoke openly and answered all questions. Only the interview with an unmarried Muslim woman was slightly more complicated because sexuality and fertility are issues that she would not normally discuss.

CLINICS

A thematic search was performed with the tool Google TRENDS in order to select the most used/common keywords among the population when searching MAR clinics.

Top 5 keywords (1.PMA; 2.FIV; 3.Fecondation; 4.Fertilité; 5.ICSI) were selected and used one by one and searched in Google to choose the 5 most popular clinics that appeared in the first place for each keyword search. Local language and country were set up as preferred when every search was conducted. Other sources, such as journals or blog articles; that were not from IVF centres were excluded.

Data collection was carried out by Medistella during November 2021. Websites from selected MAR clinics were explored in local language (French) and then translated into English. All information was collected by a specially designed template. Once the template was completed, it was reviewed by an English native speaker. Belgian MAR clinics provide very extensive information in their websites. In total, almost 300 pages were collected.

In addition, Medistella contacted Belgium MAR clinics directly as well as by "mystery shopping", in order to collect extra information (e.g., leaflets and consent forms) and one clinic provided information about prices. Three of the five facilities had the consent forms available online.

2.2 Recommendation guidelines

SOCIOCULTURAL AND GENDER GUIDELINES

Being better informed about infertility treatment requires that the information provided by clinics is aligned with the concerns and expectations of the public, especially young populations. It also requires that citizens are better educated about infertility, including its causes, prevalence, and treatment.

- To educate citizens, infertility should be the focus of a public information and awareness-raising campaign directed by public health authorities. The campaign should de-stigmatize infertility by providing information about the prevalence and causes of infertility in both men and women. It should provide information about the full range of methods available to couples and individuals for becoming parents.
- The topic of infertility should be included in school curricula in accordance with governmental standards and guidelines (e.g., as part of existing curricula on human reproduction or sexuality).
- Clinics websites should be more ergonomic, with simpler and more well-synthesized information (to avoid confusion), with less medical terms and details.
- Clinics should provide a separate section on LGBTQ+ access and options for Medically Assisted Reproduction (MAR), with special attention to trans and intersex fertility.
- Clinics should be more transparent about costs of treatment, providing information about prices of different techniques and add-ons.
- Information on clinics website should be more gender-balanced. Parenthood should not be presented as assumed for heterosexual couples vs. a “choice” for same-sex couples. Treatment should be presented without taboos (for instance, with sperm collection).
- The government should be aware that young people are concerned not only for improved access to fertility treatment but also for universal access to basic services of primary and reproductive healthcare.

LEGAL GUIDELINES

The availability and adequacy of information provided by clinics depends in part on the state of the relevant legal frameworks: laws that regulate fertility treatments and health services in general, laws that regulate informed consent and the use of personal data, laws that regulate advertising, as well as laws that affect marriage and parenthood.

STRENGTHS OF THE LEGAL FRAMEWORK IN BELGIUM:

- Law obliges clinics to notify Belgian Assisted Procreation Registry of results indicators.
- Detailed regulation of informed consent (Patient Rights Law 2002).
- Belgian law of August 22, 2022, on medical assisted procreation, guarantees patient's right to clear and complete information (art. 7) and protection of personal data (art. 10).
- The MAP law prescribes a duty for clinics to provide counselling (psychological support) during the process (art. 6).
- Possibility of non-anonymous gamete donation guarantees the future child's right to know its biological origins. On the other hand, young people have expressed concern that this may lead to eugenic manipulation of gamete selection (which is banned by art. 23 MAP Law).

WEAKNESSES OF THE LEGAL FRAMEWORK IN BELGIUM:

- Possible inconsistency between child's right to knowledge of biological origins (Child Convention, art. 8; European Council Recommendation 2156/2019) and donor anonymity (allowed by Belgian law).
- No clear and consistent definition of success rate.
- No detailed regulation of informed consent; clinics do not make this info public.

DEFICIENCIES IN THE INFORMATION PROVIDED BY CLINICS:

All information provided by clinics – through their websites, advertising, and documents of informed consent – is regulated by legal standards for truthful advertising and informed consent. We have found that information provided by clinics about success rates of fertility treatments, add-ons (supplementary procedures offered by

clinics for the purpose of improving fertility treatment outcomes), and possible risks associated with MAR does not meet these standards. Accordingly, in the interest of greater transparency, we make the following recommendations for the improvement of this information:

WITH REGARD TO SUCCESS RATES IT IS RECOMMENDED THAT:

- Success rate should be clearly defined as live birth, in alignment with expectations of persons seeking fertility treatment and their main reason for contracting the services of a clinic.
- Information about success rates should be based on best available evidence. Clinics should clarify the strength of this evidence.
- Different success rates should be specified in relation to age, different techniques, and use of egg donation.
- Clinics should provide access to evidence-based sources of data for purposes of verification.
- Information about success rates provided through websites and advertising should match the information provided through informed consent.

WITH REGARD TO ADD-ONS IT IS RECOMMENDED THAT:

- Clinics should provide clear information, based on best available evidence, in support of any claim that add-ons can improve fertility treatment outcomes. If such data is unavailable, clinics should make this clear.
- All risks associated with the use of add-ons should be clearly explained.
- Clinics should provide access to evidence-based sources of data on add-ons for purposes of verification.
- Information about add-ons provided through websites and advertising should match the information provided through informed consent.

WITH REGARD TO POSSIBLE ASSOCIATED RISKS IT IS RECOMMENDED THAT:

- In websites, advertising, and documents of informed consent, clinics should provide complete, clear, and comprehensible information, based on best available evidence, about potential health risks for persons undergoing fertility treatment. Clinics should clarify the strength of this evidence.
- In websites, advertising, and documents of informed consent, clinics should provide complete, clear, and comprehensible information, based on best available evidence, about potential health risks for children conceived through MAR.
- This information should differentiate specific risks associated with different techniques (IUI, IVF, ICSI) and procedures (chemical and physical manipulation of gametes and embryos). Clinics should clarify the strength of this evidence.
- Information about risks should be expressed at two levels: in technical terms that specify the type of risk and its probability, and in nontechnical language that is readily accessible to the public (e.g., using illustrations if necessary).
- Clinics should provide access to evidence-based sources of data for purposes of verification.
- Information about associated health risks to MAR provided through websites and advertising should match the information provided through informed consent.

ADDITIONAL KEY RECOMMENDATIONS FOR CLINICS:

- Clinics should make documents of informed consent available to the public through their websites.
- Clinics should make information sheets and informed consent forms adapted to people with disabilities as required by article 25 of United Nations International Convention on the Rights of Persons with Disabilities.
- Information provided by clinics should be consistent with CNB Report 18/2002 (Opinion of the Comité consultative de Bioéthique de Belgique), which forbids marketing of embryo and its consideration as object.
- Clinic websites should describe the conditions for receiving governmental support (e.g., through social security) for fertility treatment (e.g., age of the woman, etc.) and should provide information about

alternative methods.

- It is recommended that information provided by clinics does not contradict or obscure the fact that surrogacy contracts in Belgium are null and void and the fact that parentage is determined legally in favour of the woman who gives birth (art. 315 Cc). Although there may be other grounds for establishing parenthood of contracting parties, information provided by clinics should not give the false impression that filiation can be established by a surrogacy contract.
- Strict compliance with Principle of Advertising Authenticity, as described in art. 7 of ICC 2018 Code: all advertising should be clearly recognizable as such
- Testimonials should comply with art. 13 ICC 2018 Code, ensuring veracity of content and source.

CONSIDERATIONS FOR THE IMPROVEMENT OF PUBLIC INFORMATION:

- It is recommended that health authorities create a catalogue of informed consent forms and information sheets that comply with current regulations.
- Belgian law limits embryos/transfers from same donor (art. 26 MAP Law) to avoid consanguinity but there is no centralized registry of donors. Its creation is recommended.
- Persons seeking fertility treatment should be informed of available alternatives to MAR, including adoption and the possibility of treating infertility through biomedical intervention.
- Citizens should be informed of the legal definition and conditions of parenthood and of the rights that are implicated by fertility treatment (rights of parents, rights of donors, rights of offspring).
- Recommend greater visibility of equal access for women regardless of marital status and sexual orientation, specific regulations that pursue equal access for female same-sex couples (modification in Feb 23, 2022 of art. 9 of July 7, 2007 with respect to generating new embryos or use of oocytes).
- Public information should avoid appeals to “right to parenthood” as there is no right to parenthood at the European level (see *Paradiso Campanelly v. Italy* 25358/12, 2017, *Valdís Fjölnisdóttir and others vs. Iceland* 71552/17, 2021).
- Information campaigns should include the legal regulation of techniques, and this information should cover biological, legal, ethical and economic aspects of the use of techniques.

ITALIAN CONTEXT

Italy's fertility rate has been declining since 2008. Italy currently has one of the lowest fertility rates in Europe¹⁴: in 2020, the average fertility rate was 1.24 children per woman¹⁵. Furthermore, together with Spain, Italy is one of the European Union countries with the highest maternal age¹⁶: in 2020 the average maternal age at the first birth was 31 years.

Medically Assisted Reproduction (MAR) is regulated by Law 40/2004. According to this law, MAR techniques can only be used by heterosexual couples, married or cohabiting, with a medical diagnosis of sterility or infertility. MAR is not accessible to single individuals and same-sex couples. Therefore, Italian legislation on MAR has been described as one of the most restrictive in Europe¹⁷.

The MAR techniques allowed in Italy are: intrauterine insemination (IUI), in vitro fertilisation (IVF), intracytoplasmic sperm injection (ICSI), egg and sperm donation, egg freezing. Preimplantation Genetic Diagnosis (PGD) is permitted only for serious illnesses. Embryo donation and surrogacy are not allowed. Egg donation and sperm donation are strictly anonymous. The maximum legal age for women to use MAR is 50 years.

In 2005, the National Health Institute (Istituto Superiore di Sanità - ISS) established the National Register on Assisted Reproductive Technology (MAR) procedures¹⁸. All the Italian MAR centres are compelled to share their data, which allows annual complete reports on all MAR performed in the country. According to the Italian registry, there are 330 fertility centres, of which 97 are public and 233 private. In 2018, a total of 58,407 treatment cycles were initiated and 12,646 children were born as a result of these techniques¹⁹. The publicly funded MAR techniques cover 3 cycles of IUIs and 3 cycles of IVF/ICSI. Medication costs might be covered, at least partially, depending on regional health authority. Due to restrictions, some Italian individuals and couples cross borders in seek MAR in other countries.

¹⁴ The World Bank. Fertility rate, total (births per woman) - European Union | Data [Internet]. [cited 2021 Jul 15]. Available from: https://data.worldbank.org/indicator/SP.DYN.TFRT.IN?contextual=min&locations=EU&most_recent_value_desc=false

¹⁵ Istituto Nazionale di Statistica. Natalità i fecondità della popolazione residente - Anno 2020 [Internet]. 2021 [cited 2022 Jan 4]. Available from: <https://www.istat.it/it/files//2021/12/REPORT-NATALITA-2020.pdf>

¹⁶ Eurostat. Women are having their first child at an older age - Products Eurostat News [Internet]. 2020 [cited 2021 Jul 15]. Available from: <https://ec.europa.eu/eurostat/web/products-eurostat-news/-/ddn-20200515-2>

¹⁷ Hanafin P. Rights, bioconstitutionalism and the politics of reproductive citizenship in Italy. <https://doi.org/10.1080/136210252013851144> [Internet]. 2013 [cited 2022 Jan 10];17(8):942-55. Available from: <https://www.tandfonline.com/doi/abs/10.1080/13621025.2013.851144>

¹⁸ Istituto Superiore di Sanità. Registro Nazionale Procreazione Medicalmente Assistita - Centri in Italia [Internet]. [cited 2022 Jan 10]. Available from: <https://w3.iss.it/site/RegistroPMA/PUB/Centri/CentriPma.aspx>

¹⁹ Registro Nazionale de Procreazione Medicalmente Assita. Monitoring the activity and outcomes of Italian Assisted Reproductive Technology Centers 2018. 2018.

FIELDWORK DESCRIPTION

INTERVIEWS

Recruitment of interviewees was organised by a contracted company based in Italy. This company contacted by email a selection of the relevant age group of young people in its panel and then contacted respondents by phone for specific questions.

Interviews were carried out during June 2021. The interviewees were from the region of Lombardia, most of them from Milan, where the company is based. All the interviews were conducted in Italian and took place online via Zoom because of COVID-19 pandemic. No issues related to internet connections or respondents were reported, and participants were willing to cooperate and speak openly.

CLINICS

A thematic search was performed with the tool Google TRENDS in order to select the most used/common keywords among the population when searching MAR clinics.

Five keywords were selected (1.PMA; 2.Fecondazione assistita; 3.Inseminazione; 4.Infertilita; 5.In vitro) and searched in Google one by one. For each keyword search, the clinic that appeared first was selected, leading to a total of five clinics. Local language and country were set up as preferred for each search. Other sources such as journals or blog articles that were not from IVF centres were excluded.

Data collection was carried out by Medistella during September and October 2021. Websites from selected MAR clinics were explored in local language (Italian) and then translated into English. All the information was collected by a specially designed template. Once the template was completed, it was reviewed by an English native speaker. Italian MAR clinics provide very extensive information on their websites. In total, almost 350 pages were collected.

In addition, Medistella contacted Italian MAR clinics directly as well as by "mystery shopping", in order to collect extra information provided to patients such as leaflets or consent forms. No further information was collected by email other than that extracted from the websites.

3.2 Recommendation guidelines

SOCIOCULTURAL AND GENDER GUIDELINES

Being better informed about infertility treatment requires that the information provided by clinics is aligned with the concerns and expectations of the public, especially young populations. It also requires that citizens are better educated about infertility, including its causes, prevalence, and treatment.

- To educate citizens, infertility should be the focus of a public information and awareness-raising campaign directed by public health authorities. The campaign should de-stigmatize infertility by providing information about the prevalence and causes of infertility in both men and women. It should provide information about the full range of methods available to couples and individuals for becoming parents.
- Influencers and other public figures could also act to raise awareness and de-stigmatise infertility.
- Information provided by clinics should be more gender-neutral, to avoid contributing to social pressure on women and the stigma of infertility among women.
- For clarity, clinics should avoid using overly technical terms to describe techniques.
- Clinics should be more transparent about costs of treatment, providing information about prices of different techniques and add-ons.
- Clinics should provide information in a manner that is consistent with ethnic, racial, and cultural diversity of Italian citizens, and should provide information on Medically Assisted Reproduction (MAR) options for all genders and/or sexual orientations.
- Clear information on MAR possibilities and access in Italy should be made publically available through public campaigns (to avoid confusion and to better inform about the available options for different populations).
- The government should be aware that young people are concerned not only for improved access to fertility treatment but also for universal access to basic services of primary and reproductive healthcare.

LEGAL GUIDELINES

The availability and adequacy of information provided by clinics depends in part on the state of the relevant legal frameworks: laws that regulate fertility treatments and health services in general, laws that regulate informed consent and the use of personal data, laws that regulate advertising, as well as laws that affect marriage and paternity.

STRENGTHS OF THE LEGAL FRAMEWORK IN ITALY:

- Legal regulation of informed consent (art. 6 law 40/2004 DECREE 28 December 2016, n. 265) is thorough and well-articulated: model of good practice.
- Obligation by 2016 decree to inform centres about pathology in mother or child that could be caused by techniques, even if a long period has elapsed since birth.
- Decree 2016 specifically mandates information about risks based on available scientific evidence.
- Some clinics make informed consent forms public and a few meet the requirements established by art. 6 law 40/2004 though not all the requirements established later by the 2016 decree.

WEAKNESSES OF THE LEGAL FRAMEWORK IN ITALY:

- In last 20 years, numerous laws and decisions apply specifically to MAR; legal framework is unusually complex and needs consolidation in single text.
- Cryopreservation and suppression of embryos both prohibited by art. 14.1 of law 40, however the Corte Costituzionale (CC) has declared unconstitutional the limitation of implants.
- Possible inconsistency between child's right to knowledge of biological origins (Child Convention, art. 8; European Council Recommendation 2156/2019) and donor anonymity (established by Italian law).

DEFICIENCIES IN THE INFORMATION PROVIDED BY CLINICS:

All information provided by clinics – through their websites, advertising, and documents of informed consent – is regulated by legal standards for truthful

advertising and informed consent. We have found that information provided by clinics about success rates of fertility treatments, add-ons (supplementary procedures offered by clinics for the purpose of improving fertility treatment outcomes), and possible risks associated with MAR does not meet these standards. Accordingly, in the interest of greater transparency, we make the following recommendations for the improvement of this information:

WITH REGARD TO SUCCESS RATES IT IS RECOMMENDED THAT:

- Success rate should be clearly defined as live birth, in alignment with expectations of persons seeking fertility treatment and their main reason for contracting the services of a clinic.
- Information about success rates should be based on best available evidence. Clinics should clarify the strength of this evidence.
- Different success rates should be specified in relation to age, different techniques, and use of egg donation.
- Clinics should provide access to evidence-based sources of data for purposes of verification.
- Information about success rates provided through websites and advertising should match the information provided through informed consent.

WITH REGARD TO ADD-ONS IT IS RECOMMENDED THAT:

- Clinics should provide clear information, based on best available evidence, in support of any claim that add-ons can improve fertility treatment outcomes. If such data is unavailable, clinics should make this clear.
- All risks associated with the use of add-ons should be clearly explained.
- Clinics should provide access to

evidence-based sources of data on add-ons for purposes of verification.

- Information about add-ons provided through websites and advertising should match the information provided through informed consent.

WITH REGARD TO POSSIBLE ASSOCIATED RISKS IT IS RECOMMENDED THAT:

- In websites, advertising, and documents of informed consent, clinics should provide complete, clear, and comprehensible information, based on best available evidence, about potential health risks for persons undergoing fertility treatment. Clinics should clarify the strength of this evidence.
- In websites, advertising, and documents of informed consent, clinics should provide complete, clear, and comprehensible information, based on best available evidence, about potential health risks for children conceived through MAR.
- This information should differentiate specific risks associated with different techniques (IUI, IVF, ICSI) and procedures (chemical and physical manipulation of gametes and embryos). Clinics should clarify the strength of this evidence.
- Information about risks should be expressed at two levels: in technical terms that specify the type of risk and its probability, and in nontechnical language that is readily accessible to the public (e.g., using illustrations if necessary).
- Clinics should provide access to evidence-based sources of data for purposes of verification.
- Information about associated health risks to MAR provided through websites and advertising should match the information provided through informed consent.

ADDITIONAL KEY RECOMMENDATIONS FOR CLINICS:

- Clinics should make documents of informed consent available to the public through their websites.
- Clinics should make information sheets and informed consent forms adapted to people with disabilities as required by article 25 of United Nations International Convention on the Rights of Persons with Disabilities.
- Clinic websites should describe the conditions for receiving governmental support (e.g., through the public health system) for fertility treatment (e.g., age

of the woman, etc.) and should provide information about alternative methods.

- If clinic websites mention surrogacy, they should clarify that surrogacy contracts are not legally supported in Italy (ECHR, Paradiso Campanelli v. Italy, 2017).
- Strict compliance with principles of authenticity and truthfulness: advertising should be clearly identifiable as such and should not be incomplete or otherwise misleading (2006/114/EC and The Self-Regulatory Code of Commercial Communications art.1 and art. 2).
- Testimonials should comply with principle of truth (The Self-Regulatory Code of Commercial Communications Code art. 4, art. 6).

CONSIDERATIONS FOR THE IMPROVEMENT OF PUBLIC INFORMATION:

- It is recommended that health authorities create a catalogue of informed consent forms and information sheets that comply with current regulations.
- Persons seeking fertility treatment should be informed of available alternatives to MAR, including adoption and the possibility of treating infertility through biomedical intervention.
- A national registry of clinics should be created that provides standardized, up-to-date information about success rates.
- Citizens should be informed of the legal definition and conditions of parenthood and of the rights that are implicated by fertility treatment (rights of parents, rights of donors, rights of offspring).
- Because of unusual complexity of legal framework, it is recommended that health authorities draft and distribute a single text that consolidates up-to-date information about legal regulation of MAR in Italy.

KOSOVAR CONTEXT

Kosovo's fertility rate decreased significantly from 1984 to 1997. The average number of children per woman in Kosovo in 2019 was 1.97, higher than the European average fertility rate²⁰. This year, the average maternal age at the first birth reached 29²¹

Medically assisted reproduction (MAR) is regulated by the Law for Reproductive Health (Law No. 02/L-76) since 2006. Assisted reproduction corresponds to free choice and couple parental request to have a child and is intended for treatment of infertility due to medical causes or to prevent transmission of diseases from parents to child.

In Kosovo, Medically Assisted Reproduction (MAR) techniques allowed by law are: assisted insemination; in-vitro fertilization (IVF) and other equivalent techniques. Couples and individuals shall be informed about procedures' success or failure rates and about women and children's risks associated to the treatments. They shall be evaluated for their motivation, and informed about the legal opportunities to adopt a child^{22, 23}.

A lack of public information about MAR has been identified in Kosovo. There is a shortage of information available online from the Kosovar state, and there is no clear information regarding the provision of public funding. In addition, there is no active national registry of MAR in Kosovo.

²⁰ The World Bank. Fertility rate, total (births per woman) - Switzerland | Data [Internet]. [cited 2022 Jan 21]. Available from: https://data.worldbank.org/indicator/SP.DYN.TFRT.IN?locations=CH&most_recent_value_desc=false

²¹ Kosovo Agency of Statistics. Birth Statistics in Kosovo, 2019 [Internet]. cited 2022 Jan 21]. Available from: <https://ask.rks-gov.net/en/kosovo-agency-of-statistics/add-news/birth-statistics-in-kosovo-2019>

²² Assembly of Kosovo. Law No. 02/L-76 Law on reproductive Law. [Internet] [cited 2022 Jan 21]. Available from: https://msh.rks-gov.net/wp-content/uploads/2020/03/2006_02-L76-On-Reproductive-Health.pdf

²³ Selmani-Bakiu A, Elezi J. Assisted reproduction and reproductive rights - comparative aspects between Republic of North Macedonia and republic of Kosovo. [Internet]. 2020 Dec. 31 [cited 2022 Jan. 21];4(3):52-60. Available from: <https://prizrenjournal.com/index.php/PSSJ/article/view/197>

FIELDWORK DESCRIPTION

INTERVIEWS

The recruitment of participants was carried out through snowballing method and word of mouth by Health Grouper (B2-Inf partner). The researchers also used their personal networks to find participants.

In total, 19 interviews were carried out between June and July 2021. Regarding language, all interviews were conducted in Albanian. Most of the participants were from Prishtina, the capital city of Kosovo, but some interviewees came from other areas outside the capital.

All interviews were conducted face to face, because at that time COVID measures were lifted in Kosovo. All participants were very proactive in talking about the topic, but sometimes participants did not understand questions and researchers made extra efforts to explain them.

CLINICS

Due to the low number of MAR clinics in Kosovo, a Google tool search was performed using keywords such as “IVF Centres” or “Assisted Reproduction Centres”, and the five centres that appeared first were selected. Subsequently, the selection of centres was checked with local experts. Local language and country were set up as preferred for every search. Other sources such as journals or blog articles that were not from IVF centres were excluded.

Data collection was carried out by Medistella during November and December 2021. Websites from selected MAR clinics were explored in local language (Albanian) and then translated into English. All the information was collected in a specially designed template. Once the template was completed, it was reviewed by an English native speaker. Around 120 pages were collected from Kosovar MAR clinics’ websites.

In addition, Medistella contacted Kosovar MAR clinics directly as well as by “mystery shopping” to collect extra information (e.g., leaflets, consent forms) but no clinic provided additional material. Extra materials available online were included in templates and downloaded for further analysis.

4.2 Recommendation guidelines

SOCIOCULTURAL AND GENDER GUIDELINES

Being better informed about infertility treatment requires that the information provided by clinics is aligned with the concerns and expectations of the public, especially young populations. It also requires that citizens are better educated about infertility, including its causes, prevalence, and treatment.

- To educate citizens, infertility should be the focus of a public information and awareness-raising campaign directed by public health authorities. The campaign should de-stigmatize infertility by providing information about the prevalence and causes of infertility in both men and women. It should provide information about the full range of methods available to couples and individuals for becoming parents.
- Clinics should not focus only on women. They should consider men as well, so as not to promote the stigmatisation of female infertility, excessive blame of women for infertility of couples, and the taboo of male infertility. They should avoid representing infertility as if it were a women's issue only.
- Clinics should provide simpler and more well-synthesised information, to avoid confusion and to make information more accessible and understandable.
- Clinics should provide information adapted to the country; local branches of international groups need to adjust their data to the local situation.
- Clinics should provide information and advertising in a manner that is consistent with ethnic, racial, and cultural diversity of Kosovan citizens, and should provide information on Medically Assisted Reproduction (MAR) options for all genders and/or sexual orientations.
- Clinics should systematically provide information on MAR options for trans or intersex people.
- Public information, like the platform suggested by young people, should be available to better inform general population about causes of infertility, the MAR legal framework, and accessibility and success rates.
- Clinics should be more transparent about costs of treatment, providing information about prices of different techniques and add-ons.
- The government should be aware that young people are concerned not only for improved access to fertility treatment but also for universal access to basic services of primary and reproductive healthcare.

LEGAL GUIDELINES

The availability and adequacy of information provided by clinics depends in part on the state of the relevant legal frameworks: laws that regulate fertility treatments and health services in general, laws that regulate informed consent and the use of personal data, laws that regulate advertising, as well as laws that affect marriage and paternity.

WEAKNESSES OF THE LEGAL FRAMEWORK IN KOSOVO:

- Law 2/76 On Reproductive Health (2008) provides regulatory framework but has not been developed as required by art. 25.
- There is no National Bioethics Committee, and no national commission that acts as coordinating and supervisory body for MAR (see art. 24 of Law 2/76).
- Access is legally configured for heterosexual couples by art. 18, but art. 4 implies access for individuals.
- No detailed regulation of informed consent; clinics do not make documents of informed consent public.
- Possible inconsistency between child's right to knowledge of biological origins (Child Convention, art. 8; European Council Recommendation 2156/2019) and donor anonymity.

DEFICIENCIES IN THE INFORMATION PROVIDED BY CLINICS:

All information provided by clinics – through their websites, advertising, and documents of informed consent – is regulated by legal standards for truthful advertising and informed consent. We have found that information provided by clinics about success rates of fertility treatments, add-ons (supplementary procedures offered by clinics for the purpose of improving fertility treatment outcomes), and possible risks associated with MAR does not meet these standards. Accordingly, in the interest of greater transparency, we make the following recommendations for the improvement of this information:

WITH REGARD TO SUCCESS RATES IT IS RECOMMENDED THAT:

- Success rate should be clearly defined as live birth, in alignment with expectations of persons seeking fertility treatment and their main reason for contracting the services of a clinic.
- Information about success rates should be based on best available evidence. Clinics should clarify the strength of this evidence.
- Different success rates should be specified in relation to age, different techniques, and use of egg donation.
- Clinics should provide access to evidence-based sources of data for purposes of verification.
- Information about success rates provided through websites and advertising should match the information provided through informed consent.

WITH REGARD TO ADD-ONS IT IS RECOMMENDED THAT:

- Clinics should provide clear information, based on best available evidence, in support of any claim that add-ons can improve fertility treatment outcomes. If such data is unavailable, clinics should make this clear.
- All risks associated with the use of add-ons should be clearly explained.
- Clinics should provide access to evidence-based sources of data on add-ons for purposes of verification.
- Information about add-ons provided through websites and advertising should match the information provided through informed consent.

WITH REGARD TO POSSIBLE ASSOCIATED RISKS IT IS RECOMMENDED THAT:

- In websites, advertising, and documents of informed consent, clinics should provide complete, clear, and comprehensible information, based on best available evidence, about potential health risks for persons undergoing fertility treatment. Clinics should clarify the strength of this evidence.
- In websites, advertising, and documents of informed consent, clinics should provide complete, clear, and comprehensible information, based on best available evidence, about potential health risks for children conceived through MAR.
- This information should differentiate specific risks associated with different techniques (IUI, IVF, ICSI) and procedures (chemical and physical manipulation of gametes and embryos). Clinics should clarify the strength of this evidence.
- Information about risks should be expressed at two levels: in technical terms that specify the type of risk and its probability, and in nontechnical language that is readily accessible to the public (e.g., using illustrations if necessary).
- Clinics should provide access to evidence-based sources of data for purposes of verification.
- Information about associated health risks to MAR provided through websites and advertising should match the information provided through informed consent.

ADDITIONAL KEY RECOMMENDATIONS FOR CLINICS:

- Clinics should make documents of informed consent available to the public through their websites.
- Although Kosovo is not a party to the Convention on the Rights of Persons with Disabilities, it is recommended that they be considered as potential users of the techniques and that the necessary adjustments be made to the information provided by clinics.
- Clinic websites should describe the conditions for receiving governmental support (e.g., Public Health System) for fertility treatment (e.g., age of the woman, etc.) and should provide information about alternative methods.
- Strict compliance with principles of authenticity and truthfulness: advertising should be clearly identifiable as such and

should not be incomplete or otherwise misleading (Law 06/L-034 art. 7.9 and 10)..

CONSIDERATIONS FOR THE IMPROVEMENT OF PUBLIC INFORMATION:

- It is recommended that health authorities create a catalogue of informed consent forms and information sheets that comply with current regulations.
- Persons seeking fertility treatment should be informed of available alternatives to MAR, including adoption and the possibility of treating infertility through biomedical intervention.
- A national registry of clinics should be created that provides standardized, up-to-date information about success rates.
- Citizens should be informed of the legal definition and conditions of parenthood and of the rights that are implicated by fertility treatment (rights of parents, rights of donors, rights of offspring).
- Public information campaigns need support from government and health authorities: Kosovo does not have a National Commission for MAR or a National Bioethics Committee.

NORTH MACEDONIAN CONTEXT

The fertility rate in North Macedonia has remained stable over the last 15 years with slight variations, hovering around the European average. In 2019 it was 1.49 children per woman²⁴ and in 2020 the average age of the mother at the first birth was 27.5²⁵.

Medically Assisted Reproduction (MAR) is regulated by the Law for Biomedical Assisted Fertilization (BAF) adopted in 2008 and by amendments adopted in 2014. These laws regulate the process of assisted insemination, in vitro fertilization (IVF), posthumous reproduction, as well as the process of childbirth through a surrogate since 2014. They also detail other issues such as the requirements for access to MAR techniques, types of medical procedures, rights of users, parental rights, gamete donation, cryopreservation of gamete and embryos, health institutions authorized for MAR and a national registry.

The law stipulates that MAR users have to be fully capable adult men and women, able to exercise parental rights, married or living in union²⁶. MAR is also available to single adult women able to work who are not married or do not live in an extramarital union, if previous treatments were unsuccessful, and who, according to their age and general health condition, are capable of parental care. However, surrogacy is restricted to married couples. There are seven clinics in the country performing MAR. One of them is a public university hospital and the other are private²⁷. North Macedonia offers public support for 3 cycles for the first three children²⁸. It is known that some people travel abroad, predominantly to the Czech Republic, to use MAR when they do not meet the legal criteria.

²⁴ Fertility rate, total (births per woman) - North Macedonia | Dating [Internet]. [cited 2022 Jan 20]. Available from: <https://data.worldbank.org/indicator/SP.DYN.TFRT.IN?locations=MK>

²⁵ Државен завод за статистика - соопштение: Наталитет ,2020 [Internet]. [cited 2022 Jan 20]. Available from: <http://www.stat.gov.mk/PrikaziSoopstenie.aspx?rbtxt=8>

²⁶ Selmani-Bakiu A, Zendeli E. The Parenting Responsibility in the Context of the Convention on the Rights of the Child and Protection before the European Court of Human Rights. *Balkan Soc Sci Rev* [Internet]. 2016;8:65. Available from: <https://heinonline.org/HOL/Page?handle=hein.journals/bssr8&id=65&div=&collection=>

²⁷ The European IVF-Monitoring Consortium (EIM) for the European Society of Human Reproduction and Embryology (ESHRE), Wyns C, De Geyter C, Calhaz-Jorge C, Kupka MS, Motrenko T, et al. ART in Europe, 2017: results generated from European registries by ESHRE†. *Human Reproduction Open* [Internet]. 2021 Jun 1 [cited 2021 Oct 25];2021(3). Available from: <https://doi.org/10.1093/hropen/hoab026>

²⁸ Calhaz-Jorge C, De Geyter CH, Kupka MS, et al. Survey on ART and IUI: legislation, regulation, funding and registries in European countries: The European IVF-monitoring Consortium (EIM) for the European Society of Human Reproduction and Embryology (ESHRE). *Hum Play Open* 2020(1): hoz044. doi:10.1093/hropen/hoz044

FIELDWORK DESCRIPTION

INTERVIEWS

Recruitment of interviewees was carried out by the research team of Health Grouper (B2-InF partner) based in North Macedonia through snowballing method and word of mouth. The researchers used also student association networks and their personal networks to find participants. The research team faced some difficulties finding interviewees for some participant profiles, such as married couples or young people from rural areas.

In total, 10 interviews were carried out between June and July 2021, all of them conducted in Macedonian language. Most of the participants were from Skopje, the capital city of North Macedonia.

All the interviews were conducted remotely using Zoom platform because of the COVID-19 pandemic. All participants spoke openly about the topic, but there were barriers for legal themes and MAR information as they were not familiar with these topics and researchers had to provide extra explanation.

CLINICS

Due to the low number of MAR clinics in North Macedonia, a Google tool search was performed using keywords such as "IVF Centres" or "Assisted Reproduction Centres", and the five centres that appeared first were selected. Subsequently, the selection of centres was checked with local experts in health services research. Local language and country were set up as preferred for every search. Other sources such as journals or blog articles that were not from IVF centres were excluded.

Data collection was carried out by Medistella during November and December 2021. Websites from selected MAR clinics were explored in local official language (Macedonian) and then translated into English, but it should be noted that some websites were available in English, Serbian or Albanian. All information was collected by specially designed templates. Once the template was completed, it was reviewed by an English native speaker. Approximately 200 pages were collected from North Macedonian MAR clinics' websites.

In addition, Medistella contacted North Macedonian MAR clinics directly as well as by "mystery shopping" to collect extra information (e.g., leaflets, consent forms) and two clinics offered extra information about prices. Extra materials available online were included in templates and downloaded for further analysis.

5.2 Recommendation guidelines

SOCIOCULTURAL AND GENDER GUIDELINES

Being better informed about infertility treatment requires that the information provided by clinics is aligned with the concerns and expectations of the public, especially young populations. It also requires that citizens are better educated about infertility, including its causes, prevalence, and treatment.

- To educate citizens, infertility should be the focus of a public information and awareness-raising campaign directed by public health authorities. The campaign should de-stigmatize infertility by providing information about the prevalence and causes of infertility in both men and women. It should provide information about the full range of methods available to couples and individuals for becoming parents.
- A public awareness campaign is needed about different family forms (single persons, non-heterosexual couples).
- The topic of infertility should be included in school curricula in accordance with governmental standards and guidelines (e.g., as part of existing curricula on human reproduction or sexuality).
- Clinics websites should be more detailed, with more information (techniques, access, costs, psychological support). Clinics could also streamline their information (e.g. give the same advice about how to behave after a procedure).
- Information on clinics website should be more gender-balanced (by presenting more information about male infertility, for example).
- Clinics should provide information and advertising in a manner that is consistent with ethnic, racial, and cultural diversity of North Macedonian citizens, and should provide information on Medically Assisted Reproduction (MAR) options for all genders and/or sexual orientations.
- Clinics should systematically provide information on MAR options for trans or intersex people.
- Clinics should be more transparent about costs of treatment, providing information about prices of different techniques and add-ons.
- The government should be aware that young people are concerned not only for improved access to fertility treatment but also for universal access to basic services of primary and reproductive healthcare.

LEGAL GUIDELINES

The availability and adequacy of information provided by clinics depends in part on the state of the relevant legal frameworks: laws that regulate fertility treatments and health services in general, laws that regulate informed consent and the use of personal data, laws that regulate advertising, as well as laws that affect marriage and paternity.

STRENGTHS OF THE LEGAL FRAMEWORK IN NORTH MACEDONIA:

- Art. 10, "Advising on Procedure," of Law 37/2008 on Biomedical Assisted Insemination (BAI) establishes duty to provide information about procedures, success rates, consequences and risks.
- Legal obligation to highlight the price in advertising (art. 26 law 2004).

WEAKNESSES OF THE LEGAL FRAMEWORK IN NORTH MACEDONIA:

- Information about MAR is scarce; law directs Ministry of Health to prepare a National Guidebook.
- Regulation of informed consent is insufficient (art. 10 law 37/2008), less than standard established by 1997 Convention on Human Rights and Biomedicine (aka Oviedo Convention) and European Court of Human Rights case law.
- No obligation for clinics to make documents of informed consent public.
- Access for single persons and same-sex couples is unclear (art. 3 Law 37/2008).
- Surrogacy is permitted (Law 37/2008 amended 149/2014) but not clearly regulated (e.g., non-altruistic surrogacy in exchange for payment is prohibited by art. 18, while art. 12-d requires compensation at level of average North Macedonian salary) and national guidelines required by law are not developed; this is out of step with European Court of Human Rights regulation and vulnerable to change.
- Possible inconsistency between child's right to knowledge of biological origins (Child Convention, art. 8; European Council Recommendation 2156/2019) and donor anonymity (established by domestic law).

DEFICIENCIES IN THE INFORMATION PROVIDED BY CLINICS:

All information provided by clinics – through their websites, advertising, and documents of informed consent – is regulated by legal standards for truthful advertising and informed consent. We have found that information provided by clinics about success rates of fertility treatments, add-ons (supplementary procedures offered by clinics for the purpose of improving fertility treatment outcomes), and possible risks associated with MAR does not meet these standards. Accordingly, in the interest of greater transparency, we make the following recommendations for the improvement of this information:

WITH REGARD TO SUCCESS RATES IT IS RECOMMENDED THAT:

- Success rate should be clearly defined as live birth, in alignment with expectations of persons seeking fertility treatment and their main reason for contracting the services of a clinic.
- Information about success rates should be based on best available evidence. Clinics should clarify the strength of this evidence.
- Different success rates should be specified in relation to age, different techniques, and use of egg donation.
- Clinics should provide access to evidence-based sources of data for purposes of verification.
- Information about success rates provided through websites and advertising should match the information provided through informed consent.

WITH REGARD TO ADD-ONS IT IS RECOMMENDED THAT:

- Clinics should provide clear information, based on best available evidence, in support of any claim that add-ons can improve fertility treatment outcomes. If such data is unavailable, clinics should make this clear.
- All risks associated with the use of add-ons should be clearly explained.
- Clinics should provide access to evidence-based sources of data on add-ons for purposes of verification.
- Information about add-ons provided through websites and advertising should match the information provided through informed consent.

WITH REGARD TO POSSIBLE ASSOCIATED RISKS IT IS RECOMMENDED THAT:

- In websites, advertising, and documents of informed consent, clinics should provide complete, clear, and comprehensible information, based on best available evidence, about potential health risks for persons undergoing fertility treatment. Clinics should clarify the strength of this evidence.
- In websites, advertising, and documents of informed consent, clinics should provide complete, clear, and comprehensible information, based on best available evidence, about potential health risks for children conceived through MAR.
- This information should differentiate specific risks associated with different techniques (IUI, IVF, ICSI) and procedures (chemical and physical manipulation of gametes and embryos). Clinics should clarify the strength of this evidence.
- Information about risks should be expressed at two levels: in technical terms that specify the type of risk and its probability, and in nontechnical language that is readily accessible to the public (e.g., using illustrations if necessary).
- Clinics should provide access to evidence-based sources of data for purposes of verification.
- Information about associated health risks to MAR provided through websites and advertising should match the information provided through informed consent.

ADDITIONAL KEY RECOMMENDATIONS FOR CLINICS:

- Clinics should make information sheets and informed consent forms adapted to people with disabilities as required by article 25 of United Nations International Convention on the Rights of Persons with Disabilities.
- Clinic websites should describe the conditions for receiving governmental support (e.g., Public Health System) for fertility treatment (e.g., age of the woman, etc.) and should provide information about alternative methods.
- Strict compliance with principles of authenticity and truthfulness: advertising should be clearly identifiable as such and should not be incomplete or otherwise misleading (No. 38/04 art. 26 and 27).

CONSIDERATIONS FOR THE IMPROVEMENT OF PUBLIC INFORMATION:

- It is recommended that health authorities create a catalogue of informed consent forms and information sheets that comply with current regulations.
- Art. 10 "Advising on BAI Procedure" requires information about procedures, success rates, and associated risks; this should be extended to include costs and alternatives.
- Persons seeking fertility treatment should be informed of available alternatives to MAR, including adoption and the possibility of treating infertility through biomedical intervention.
- A national registry of clinics should be created that provides standardized, up-to-date information about success rates.
- Citizens should be informed of the legal definition and conditions of parenthood and of the rights that are implicated by fertility treatment (rights of parents, rights of donors, rights of offspring).
- Scarcity of information needs to be addressed through public information campaigns directed by authorities in charge of public health.

SLOVENIAN CONTEXT

Slovenia's fertility rate has been steadily increasing since 2003 after continually decreasing during the 80's and 90's. At present, it is above the European average fertility rate²⁹ with 1.6 children per woman. The average maternal age at first birth is 30 years³⁰.

Since it gained independence in 1991, the country has implemented a number of family policy measures. For instance, the Public Finance Balancing Act, adopted in 2012, reduced the amount of paternity and parental benefits. In general, the law has proved to have a significant impact on families and young people planning a family³¹.

Slovenia has specific laws which address infertility and Medically Assisted Reproduction (MAR), specifying the techniques and requirements for access³². According to these laws, MAR is restricted to infertile heterosexual couples. The techniques allowed in the country are: In Vitro Fertilisation (IVF), Intracytoplasmic Sperm Injection (ICSI), sperm donation, egg donation and Preimplantation Genetic Diagnosis (PGD) (allowed only for serious illness). Sperm donation is anonymous and the donors must be between 18 and 55. Egg donation is anonymous and egg donor

must be between 18 and 35 years old. Embryo donation, surrogacy and the use of cryopreserved gametes are not allowed in Slovenia³³.

There are three clinics in the country performing MAR, all of them public. All the techniques offered are publicly funded, limited to women 18-42 years old and men over 18. Currently there is no MAR registry, but one is in the process of being set up. It is known that some Slovenian people cross borders to use MAR when they do not meet legal criteria or because of the long waiting list for gamete donation.

²⁹ The World Bank. Fertility rate, total (births per woman) - European Union | Data [Internet]. [cited 2021 Jul 15]. Available from: https://data.worldbank.org/indicator/SP.DYN.TFRT.IN?contextual=min&locations=EU&most_recent_value_desc=false

³⁰ Republika Slovenija Statisticni Urad. 2021 [cited 2022 Jan 19]. Available from: <https://www.stat.si>

³¹ Resolucija o družinski politiki 2018–2028 »Vsem družinam prijazna družba« (ReDP18–28) 2018. Uradni list RS 15/2018. [Resolution on the Family Policy 2018–2028: "A Society Friendly to All Families" (ReDP18–28) 2018. Official gazette of the Republic of Slovenia 15/2018].

³² Zakon o zdravljenju neplodnosti in postopkih oploditve z biomedicinsko pomočjo (ZZNPOB) 2000. Uradni list RS 70/2000. [Infertility treatment and procedures of biomedically-assisted procreation act (ZZNPOB) 2000. Official gazette of the Republic of Slovenia 70/2000]

³³ Calhaz-Jorge C, De Geyter CH, Kupka MS, et al. Survey on ART and IUI: legislation, regulation, funding and registries in European countries: The European IVF-monitoring Consortium (EIM) for the European Society of Human Reproduction and Embryology (ESHRE). Hum Reprod Open 2020(1): hoz044. doi: 10.1093/hropen/hoz044

FIELDWORK DESCRIPTION

INTERVIEWS

Recruitment of interviewees was carried out by Health Grouper (B2-INF partner) through snowballing method and word of mouth. There were difficulties in finding participants with non-heterosexual sexual orientations, which means that the Slovenian sample does not include homosexual, bisexual or transgender participants. In an effort to find participants with these profiles, LGBTQ+ organizations and personal networks were contacted, but all efforts remained fruitless.

In total, ten interviews were carried out between June and August 2021, all in Slovenian. With regard to geographical distribution, the research team looked for young people from different parts of the country to represent regional diversity. Some participants were from the central parts of the country (regions of Ljubljana and Notranjska), others from the south-eastern parts (regions of Dolenjska and Bela Krajina) and others from the northern parts (region of Štajerska).

All the interviews were conducted remotely using Zoom platform, because of the COVID-19 pandemic and governmental recommendations to avoid personal contact as much as possible.

All participants spoke openly about the topic, without reporting any other problem related to IT issues or remotely conducted interviews.

CLINICS

There are only three centres that perform MAR in Slovenia, therefore all centres were included in the sample.

Data collection was carried out by Medistella during November and December 2021. Websites from selected MAR clinics were explored in local language (Slovenian) and then translated into English. All the information was collected by specially designed templates. Once the template was completed, it was reviewed by an English native speaker. Nearly 100 pages were collected from Slovenian MAR clinics' websites.

In addition, Medistella contacted Slovenian MAR clinics directly as well as by "mystery shopping" to collect extra information (e.g., leaflets, consent forms) but no clinic provided additional material.

6.2 Recommendation guidelines

SOCIOCULTURAL AND GENDER GUIDELINES

Being better informed about infertility treatment requires that the information provided by clinics is aligned with the concerns and expectations of the public, especially young populations. It also requires that citizens are better educated about infertility, including its causes, prevalence, and treatment.

- To educate citizens, infertility should be the focus of a public information and awareness-raising campaign directed by public health authorities. The campaign should de-stigmatize infertility by providing information about the prevalence and causes of infertility in both men and women. It should provide information about the full range of methods available to couples and individuals for becoming parents.
- Clinics' websites should provide more detailed information in general (about techniques, legal framework, psychological services) and equally detailed information for women and men.
- Clinics should be more transparent about costs of treatment, providing information about prices of different techniques and add-ons.
- Clinics' information should be more gender-inclusive, not focusing only on women.
- Clinics should provide information and advertising in a manner that is consistent with ethnic, racial, and cultural diversity of Slovenian citizens, and should provide information on Medically Assisted Reproduction (MAR) options for all genders and/or sexual orientations.
- General information should be accessible through multiple sources: family doctor, public website, clinics, and social networks.
- The government should be aware that young people are concerned not only for improved access to fertility treatment but also for universal access to basic services of primary and reproductive healthcare.

LEGAL GUIDELINES

The availability and adequacy of information provided by clinics depends in part on the state of the relevant legal frameworks: laws that regulate fertility treatments and health services in general, laws that regulate informed consent and the use of personal data, laws that regulate advertising, as well as laws that affect marriage and paternity.

STRENGTHS OF THE LEGAL FRAMEWORK IN SLOVENIA:

- Informed consent forms are made public; this is a model of good practice for other countries.
- Clinics distinguish less invasive techniques like IUI and recommend that patients start with these when indicated by medical professionals.
- Art. 12 (Law on the treatment of infertility and biomedical assisted procedures (LTIBAP). Law n. 542-10/99-2/5, of 20 July 2000) establishes obligation for couples to be instructed by a jurist on legal consequences of resorting to gamete donation, as well as obligation for clinics to provide psycho-social counselling.
- Detailed regulation of misleading advertising by Consumer Protection Law (ZVPot-1 of 11 October 2022) and Slovenian Advertising Code.

WEAKNESSES OF THE LEGAL FRAMEWORK IN SLOVENIA:

- Possible instability, due to fact that Advocate of Principle of Equality has challenged the constitutionality of restricting MAR to heterosexual couples who are married or civil partnership.
- Possible inconsistency between child's right to knowledge of biological origins (Child Convention, art. 8; European Council Recommendation 2156/2019), and donor anonymity (established by domestic law).

DEFICIENCIES IN THE INFORMATION PROVIDED BY CLINICS:

All information provided by clinics – through their websites, advertising, and documents of informed consent – is regulated by legal standards for truthful advertising and informed consent. We have found that information provided by clinics

about success rates of fertility treatments, add-ons (supplementary procedures offered by clinics for the purpose of improving fertility treatment outcomes), and possible risks associated with MAR does not meet these standards. Accordingly, in the interest of greater transparency, we make the following recommendations for the improvement of this information:

WITH REGARD TO SUCCESS RATES IT IS RECOMMENDED THAT:

- Success rate should be clearly defined as live birth, in alignment with expectations of persons seeking fertility treatment and their main reason for contracting the services of a clinic.
- Information about success rates should be based on best available evidence. Clinics should clarify the strength of this evidence.
- Different success rates should be specified in relation to age, different techniques, and use of egg donation.
- Clinics should provide access to evidence-based sources of data for purposes of verification.
- Information about success rates provided through websites and advertising should match the information provided through informed consent.

WITH REGARD TO ADD-ONS IT IS RECOMMENDED THAT:

- Clinics should provide clear information, based on best available evidence, in support of any claim that add-ons can improve fertility treatment outcomes. If such data is unavailable, clinics should make this clear.
- All risks associated with the use of add-ons should be clearly explained.
- Clinics should provide access to evidence-based sources of data on add-ons for purposes of verification.

- Information about add-ons provided through websites and advertising should match the information provided through informed consent.

WITH REGARD TO POSSIBLE ASSOCIATED RISKS IT IS RECOMMENDED THAT:

- In websites, advertising, and documents of informed consent, clinics should provide complete, clear, and comprehensible information, based on best available evidence, about potential health risks for persons undergoing fertility treatment. Clinics should clarify the strength of this evidence.
- In websites, advertising, and documents of informed consent, clinics should provide complete, clear, and comprehensible information, based on best available evidence, about potential health risks for children conceived through MAR.
- This information should differentiate specific risks associated with different techniques (IUI, IVF, ICSI) and procedures (chemical and physical manipulation of gametes and embryos). Clinics should clarify the strength of this evidence.
- Information about risks should be expressed at two levels: in technical terms that specify the type of risk and its probability, and in nontechnical language that is readily accessible to the public (e.g., using illustrations if necessary).
- Clinics should provide access to evidence-based sources of data for purposes of verification.
- Information about associated health risks to MAR provided through websites and advertising should match the information provided through informed consent.

ADDITIONAL KEY RECOMMENDATIONS FOR CLINICS:

- Clinics should make documents of informed consent available to the public through their websites.
- Clinics should make information sheets and informed consent forms adapted to people with disabilities as required by article 25 of United Nations International Convention on the Rights of Persons with Disabilities.
- Clinic websites should describe the conditions for receiving governmental support (e.g., through social security) for fertility treatment (e.g., age of the woman, etc.) and should provide information about alternative methods.
- If clinic websites mention surrogacy, they should clarify that surrogate contracts are not legally supported within Slovenian

legal framework.

- Strict compliance with Principle of Advertising Authenticity, as described in art. 6 of Slovenian Advertising Code: all advertising should be clearly recognizable as such.
- Testimonials should comply with art. 5 of Slovenian code: they should not be claim to be factual (should be clearly identifiable as advertising) and should be obtained with written authorization of witness.

CONSIDERATIONS FOR THE IMPROVEMENT OF PUBLIC INFORMATION:

- It is recommended that health authorities create a catalogue of informed consent forms and information sheets that comply with current regulations.
- It is recommended to extend Art. 12 (obligation to be instructed by jurist) to all procedures regulated by Art. 22 (information included in informed consent) in Law on the Treatment of Infertility and Biomedical Assisted Procedures (LTIBAP July 20 2000).
- Persons seeking fertility treatment should be informed of possible alternatives to MAR, including adoption and the possibility of treating infertility through biomedical intervention.
- A national registry of clinics should be created that provides standardized, up-to-date information about success rates.
- Citizens should be informed of the legal definition and conditions of parenthood and of the rights that are implicated by fertility treatment (rights of parents, rights of donors, rights of offspring).
- Information campaigns should include the legal regulation of techniques, and this information must cover biological, legal, ethical and economic aspects of the use of techniques.

SPANISH CONTEXT

In Spain, the average number of children per woman was 1.18 and the average maternal age reached 31 years in 2020³⁴. That makes Spain the country with the second lowest fertility rate in Europe³⁵. Moreover, together with Italy, Spain is one of the European Union countries with the highest maternal age at first birth³⁶. The first Spanish legislation on Medically Assisted Reproduction (MAR) was passed in 1988. It was revised in 2006³⁷. This legislation is one of the most liberal in Europe, with no official age limit and no restrictions regarding the family situation. In 2023, two laws were approved that affect the legal context of surrogate maternity and access for trans persons in Spain. The LO 1/2023 of February 28 describes surrogacy as a form of violence against women, emphasizes the nullity of surrogacy contracts, and requires public authorities to conduct information campaigns about the illegality of surrogacy. It also prohibits all commercial publicity and information about surrogacy.

The second law, LO 4/2023 of February 28, in support of real and effective equality for trans persons and to secure the rights of LGBTI persons, guarantees access to MAR techniques for lesbian, bisexual, and single women, and for trans persons without gestational capacity.

Spain is the largest European MAR provider (especially for egg donation) and the European country with the largest treatment numbers and the highest rate of MAR birth per national births. In 2018, nearly 10% of children born in Spain were the result of MAR³⁸.

There are about 500 MAR clinics in Spain, most of them private. Spanish National Health System covers treatments for women up to 40 and for men up to 55 years old. However, some techniques are excluded from the Spanish National Health System, such as oocyte donation and preimplantation genetic diagnosis (PGD)³⁹, and waiting lists at public centres may be long. Therefore, most treatments are carried out in private clinics. People from other countries come to Spain to use MAR, due to the restrictions in their home countries^{40,41}.

³⁴ Instituto Nacional de Estadística. Edad Media a la Maternidad por orden del nacimiento según nacionalidad (española/extranjera) de la madre [Internet]. 2020 [cited 2021 Jul 15]. Available from: <https://www.ine.es/jaxiT3/Datos.htm?t=1579>

³⁵ The World Bank. Fertility rate, total (births per woman) - European Union | Data [Internet]. [cited 2021 Jul 15]. Available from: https://data.worldbank.org/indicator/SP.DYN.TFRT.IN?contextual=min&locations=EU&most_recent_value_desc=false

³⁶ Eurostat. Women are having their first child at an older age - Products Eurostat News [Internet]. 2020 [cited 2021 Jul 15]. Available from: <https://ec.europa.eu/eurostat/web/products-eurostat-news/-/ddn-20200515-2>

³⁷ Melo-Martín I. Assisted Reproductive Technology in Spain: Considering Women's Interests. *Cambridge Q Healthc Ethics* [Internet]. 2009 Jul [cited 2021 Jul 15];18(3):228–35. Available from: <https://www.cambridge.org/core/journals/cambridge-quarterly-of-healthcare-ethics/article/abs/assisted-reproductive-technology-in-spain-considering-womens-interests/790F665819304AFD3693E9A4A0C3D75C>

³⁸ Geyter C De, Calhaz-Jorge C, Kupka MS, Wyns C, Mocanu E, Motrenko T, et al. ART in Europe, 2015: results generated from European registries by ESHRE. *Hum Reprod Open* [Internet]. 2020 Jan 1 [cited 2021 Jul 15];2020(1). Available from: <https://pmc/articles/PMC7038942/>

³⁹ Castilla JA, Hernandez E, Cabello Y, Navarro JL, Hernandez J, Gomez JL, et al. Assisted reproductive technologies in public and private clinics. *Reprod Biomed Online*. 2009 Dec 1;19(6):872–8.

⁴⁰ Präg P, Mills MC. Assisted Reproductive Technology in Europe: Usage and Regulation in the Context of Cross-Border Reproductive Care. *Demogr Res Monogr* [Internet]. 2017 [cited 2021 Jul 16];289–309. Available from: https://link.springer.com/chapter/10.1007/978-3-319-44667-7_14

⁴¹ Ikemoto LC. Reproductive Tourism: Equality Concerns in the Global Market for Fertility Services. *Minnesota J Law Inequal*. 2009;27(2)

FIELDWORK DESCRIPTION

INTERVIEWS

The recruitment process was carried out by the research team of APLICIA through its own panel and networks, contacting potential participants by email or telephone to be included in the sample according to inclusion/exclusion criteria.

15 interviews were carried out from March to July 2021, all of them in Spanish. Eight interviews were done face-to-face in Madrid and seven were conducted by Zoom because of the COVID-19 pandemic situation or because the participant was based in a different city (Bilbao, Barcelona, Huesca). Although in general the interviews conducted online did not face problems with the connection, in some of them, minor problems occurred without jeopardizing the engagement and responses of participants.

Interviews were conducted by male or female researchers, in concordance with the interviewee's gender. Participants were willing to cooperate and spoke openly.

CLINICS

A thematic search was performed with the tool Google TRENDS to select the most commonly used keywords when searching for MAR clinics.

The top 5 key words (1. Fertilización; 2. Inseminación; 3. Infertilidad; 4. Embarazo FIV; 5. ICSI) were selected and searched in Google one by one, for each key word search the top clinic was selected. Local language and country were set up as preferred for every search. Other sources, such as journals or blog articles that were not from IVF centres were excluded.

Data collection was carried out by Medistella during July and August 2021. Websites from selected MAR clinics were explored in local language (Spanish) and then translated into English. All the information was collected by specially designed templates. Once the template was completed, it was reviewed by an English native speaker. Spanish MAR clinics provide very extensive information in their websites. In total, almost 500 pages were collected.

In addition, Medistella contacted Spanish MAR clinics directly as well as by "mystery shopping" to collect extra information. Some brochures were received, but clinics did not send their consent forms freely.

7.2 Recommendation guidelines

SOCIOCULTURAL AND GENDER GUIDELINES

Being better informed about infertility treatment requires that the information provided by clinics is aligned with the concerns and expectations of the public, especially young populations. It also requires that citizens are better educated about infertility, including its causes, prevalence, and treatment.

- To educate citizens, infertility should be the focus of a public information and awareness-raising campaign directed by public health authorities. The campaign should de-stigmatize infertility by providing information about the prevalence and causes of infertility in both men and women. It should provide information about the full range of methods available to couples and individuals for becoming parents.
- Clinic websites should be simpler, with more well-synthesized information (to avoid confusion) and fewer medical terms and details.
- Clinics should be more transparent about costs of treatment, providing information about prices of different techniques and add-ons.
- Information on clinic websites should be more gender-inclusive, not focusing only on women (e.g., avoiding systematic references to motherhood), and should provide information on MAR options for trans or intersex people.
- Clinics should make sure they approach possible donors respectfully.
- Clinics need to think thoroughly about their discourse on embryos. Clinics should try to avoid ambivalence in the discourse on embryo donation/adoption.
- Clinics should provide information and advertising in a manner that is consistent with ethnic, racial, and cultural diversity of Spanish citizens, and should provide information on Medically Assisted Reproduction (MAR) options for all genders and/or sexual orientations.
- The government should be aware that young people are concerned not only for improved access to fertility treatment but also for universal access to basic services of primary and reproductive healthcare.

LEGAL GUIDELINES

The availability and adequacy of information provided by clinics depends in part on the state of the relevant legal frameworks: laws that regulate fertility treatments and health services in general, laws that regulate informed consent and the use of personal data, laws that regulate advertising, as well as laws that affect marriage and filiation.

STRENGTHS OF THE LEGAL FRAMEWORK IN SPAIN:

- Legal obligation for information accessible to people with disabilities (arts. 4.2, 5.4, 6.4 and 11.7 of Law 14/2006 and art. 29 bis of General Law on the Rights of Persons with Disabilities and their social inclusion, 2022).
- Testimonial advertising requires written authorization (Deontological Rule 19 Advertising Code of Conduct).
- Gamete donation regulated by Donor Study Protocol of the 2021 National Commission for Assisted Human Reproduction (NCAHR)
- Informed consent regulated by art. 8 Patient Autonomy Law.

WEAKNESSES OF THE LEGAL FRAMEWORK IN SPAIN:

- A loophole exists in the Spanish legal system with regard to the practice of receiving oocytes from the partner (ROPA method), as it is not specifically regulated.
- Possible inconsistency between child's right to knowledge of biological origins (Child Convention, art. 8; European Council Recommendation 2156/2019, Opinion of National Bioethics Committee, 2020) and donor anonymity (established by Spanish law).

DEFICIENCIES IN THE INFORMATION PROVIDED BY CLINICS AND RECOMMENDATIONS:

All information provided by clinics – through their websites, advertising, and documents of informed consent – is regulated by legal standards for truthful advertising and informed consent. We have found that information provided by clinics about success rates of fertility treatments, add-ons (supplementary procedures offered by clinics for the purpose of improving fertility treatment outcomes), and possible risks associated with MAR does not meet these standards. Accordingly, in the interest of greater transparency, we make the following recommendations for the improvement of this information:

WITH REGARD TO SUCCESS RATES IT IS RECOMMENDED THAT:

- Success rate should be clearly defined as live birth, in alignment with expectations of persons seeking fertility treatment and their main reason for contracting the services of a clinic.
- Information about success rates should be based on best available evidence. Clinics should clarify the strength of this evidence.
- Different success rates should be specified in relation to age, different techniques, and use of egg donation.
- Clinics should provide access to evidence-based sources of data for purposes of verification.
- Information about success rates provided through websites and advertising should match the information provided through informed consent.

WITH REGARD TO ADD-ONS IT IS RECOMMENDED THAT:

- Clinics should provide clear information, based on best available evidence, in support of any claim that add-ons can improve fertility treatment outcomes. If such data is unavailable, clinics should make this clear.
- All risks associated with the use of add-ons should be clearly explained.
- Clinics should provide access to evidence-based sources of data on add-ons for purposes of verification.
- Information about add-ons provided through websites and advertising should match the information provided through informed consent.

WITH REGARD TO POSSIBLE ASSOCIATED RISKS IT IS RECOMMENDED THAT:

- In websites, advertising, and documents of informed consent, clinics should provide complete, clear, and comprehensible information, based on best available evidence, about potential health risks for persons undergoing fertility treatment.

Clinics should clarify the strength of this evidence.

- In websites, advertising, and documents of informed consent, clinics should provide complete, clear, and comprehensible information, based on best available evidence, about potential health risks for children conceived through MAR.
- This information should differentiate specific risks associated with different techniques (IUI, IVF, ICSI) and procedures (chemical and physical manipulation of gametes and embryos). Clinics should clarify the strength of this evidence.
- Information about risks should be expressed at two levels: in technical terms that specify the type of risk and its probability, and in nontechnical language that is readily accessible to the public (e.g., using illustrations if necessary).
- Clinics should provide access to evidence-based sources of data for purposes of verification.
- Information about associated health risks to MAR provided through websites and advertising should match the information provided through informed consent.

ADDITIONAL KEY RECOMMENDATIONS FOR CLINICS:

- Clinics should make documents of informed consent available to the public through their websites.
- Clinics should provide information that is accessible to persons with disabilities (General Law on the Rights of Persons with Disabilities and their social inclusion, 2022) and should make information sheets and informed consent forms public and adapted to people with disabilities (arts. 4.2, 5.4., 6.4 and 11.7 of Law 14/2006).
- Clinic websites should describe the conditions for receiving governmental support (e.g., social security) for fertility treatment (e.g., age of the woman, etc.) and should provide information about alternatives.
- Clinics should clearly explain that ROPA method (the use of receiving oocytes from the partner) is not a condition for legal co-maternity (art. 7.3 ley 14/2006), which depends on civil marriage between women and not on the origin of the gametes.
- Clinic websites should provide information about the legal requirements that apply to the use of Preimplantation Genetic Diagnosis (PGD) (art. 12 law 14/2006), avoiding information that gives the impression that this technique is generally available.
- According to national law (LO 1/2023, of 28 February, amending Organic Law 2/2010,

of 3 March, on sexual and reproductive health and the voluntary interruption of pregnancy) clinics should clarify that access to MAR for single men and male couples is only possible through surrogacy, which is illegal in Spain and considered a form of violence against women.

- According to national law (LO 1/2023, of 28 February, amending Organic Law 2/2010, of 3 March, on sexual and reproductive health and the voluntary interruption of pregnancy) clinics should not provide any information about intermediaries involved in services related to surrogacy (whether commercial or altruistic) inside or outside the country.
- Testimonial advertising requires the written authorization of the witness (5 of the Unfair Competition Law and art. 19 Advertising Code of Conduct).
- Use of influencers in social media should be clearly recognizable as advertising (Code of Conduct on the use of influencers in advertising 2021).

CONSIDERATIONS FOR THE IMPROVEMENT OF PUBLIC INFORMATION:

- It is recommended that health authorities create a catalogue of informed consent forms and information sheets that comply with current regulations.
- Persons seeking fertility treatment should be informed of available alternatives to MAR, including adoption and the possibility of treating infertility through biomedical intervention.
- A national registry of clinics should be created that provides standardized, up-to-date information about success rates.
- Citizens should be informed of the legal definition and conditions of parenthood and of the rights that are implicated by fertility treatment (rights of parents, rights of donors, rights of offspring).
- Information campaigns should include the legal regulation of techniques, and this information should cover biological, legal, ethical and economic aspects of the use of techniques (art. 3.3 of Law 14/2006).

SWISS CONTEXT

In Switzerland, the average number of children per woman was 1.5 in 2019⁴², which aligns with the average fertility rate for Europe countries (1.53 child per woman)⁴³. This rate has remained relatively stable during the last 30 years. The average maternal age at first birth is 32 years⁴⁴, one of the highest in the EU (mean of 31 years)⁴⁵. The fertility rate of the population over 35 has doubled in recent years. The status of not having children is relatively widespread in Switzerland, applying to around a quarter of women and men aged 50 to 80 years⁴⁶.

The Swiss law on Medically Assisted Reproduction (MAR) has been particularly restrictive compared to other European countries⁴⁷. However, starting in the 1990s, the legislation has become gradually more permissive regarding, for instance, gamete donation and In vitro fertilization (IVF). The current legal framework is determined by the Reproductive Medicine Law (FmedG)⁴⁸, approved in 2016 after a referendum. It states that MAR is intended only for heterosexual couples. The public sector only funds assisted insemination. In vitro fertilization (IVF) is allowed only with

gametes from the couple or with donor sperm (only if the couple is married). Preimplantation Genetic Diagnosis (PGD) is allowed. Sperm donation is non-anonymous and couples may select their own donor. The law prohibits several techniques such as egg donation⁴⁹, embryo donation, surrogacy and sperm donation to unmarried couples. It also prohibits MAR access to single women and same-sex couples. Because of these restrictions, some Swiss residents cross borders to use MAR.

On 1 July 2022, the “marriage for all” law (Federal Act on the Registered Partnership between same sex couples) came into force, decisively changing access to technology by making same-sex couples de facto equal to married couples. Thus, same-sex married couples of women will be eligible for sperm donation and will be able to undergo MAR. The update of the law on MAR entered into force on 1 December 2022.

There are a total of 31 MAR centres in the country⁵⁰, most of them private. In 2019, 11,163 cycles were performed, resulting in a total of 2,204 live births⁵¹.

- ⁴² The World Bank. Fertility rate, total (births per woman) - Switzerland | Data [Internet]. [cited 2022 Jan 10]. Available from: https://data.worldbank.org/indicator/SP.DYN.TFRT.IN?locations=CH&most_recent_value_desc=false
- ⁴³ Sobotka T. Fertility in Austria, Germany and Switzerland: Is there a Common Pattern? *Comparative Population Studies* [Internet]. 2011 [cited 2022 Jan 10];36(2-3). Available from: <https://comparativepopulationstudies.de/index.php/CPoS/article/view/81>
- ⁴⁴ Federal Statistical Office. Reproductive health indicators for Switzerland (2020) [Internet]. [cited 2022 Jan 10]. Available from: <https://www.bfs.admin.ch/bfs/en/home/statistiken/gesundheit/gesundheitszustand/reproduktive.html>
- ⁴⁵ Eurostat. Mean age of women at childbirth and at birth of first child [Internet]. [cited 2022 Jan 10]. Available from: <https://ec.europa.eu/eurostat/databrowser/view/tps00017/default/table?lang=en>
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- ⁴⁷ Rothmayr C. Explaining restrictive ART policies in Switzerland and Germany: similar processes - similar results? *German Policy Studies* [Internet]. 2006 Dec 22 [cited 2022 Jan 10]; 3 (4): 595-648. Available from: <https://go.gale.com/ps/i.do?p=AONE&sw=w&issn=15239764&v=2.1&it=r&id=GALE%7CA170373638&sid=googleScholar&linkaccess=abs>
- ⁴⁸ AS 2017 3641 - Bundesgesetz über die medizinisch unterstützte Fortpflanzung (Fortpflanzungsmedizingesetz, FMedG) [Internet]. [cited 2022 Jan 10]. Available from: <https://www.fedlex.admin.ch/eli/oc/2017/410/de>
- ⁴⁹ Calhaz-Jorge C, De Geyter C h, Kupka MS, Wyns C, Mocanu E, Motrenko T, et al. Survey on ART and IUI: legislation, regulation, funding and registries in European countries. *Human Reproduction Open* [Internet]. 2020 Jan 1 [cited 2022 Jan 11];2020(1):hoz044. Available from: <https://academic.oup.com/hropen/article/doi/10.1093/hropen/hoz044/5715201>
- ⁵⁰ FIVNAT. List of IVF Zentren [Internet]. [cited 2022 Jan 10]. Available from: https://www.sgrm.org/de/kommissionen/fivnat-main_de/fivnat-zentren
- ⁵¹ Federal Statistical Office. Assisted reproductive technology in 2019 - Reproductive health | Publication [Internet]. Federal Statistical Office. 2021 [cited 2022 Jan 10]. Available from: <https://www.bfs.admin.ch/bfs/en/home/statistics/catalogues-databases/publications.assetdetail.17124164.html>

FIELDWORK DESCRIPTION

INTERVIEWS

The recruitment of interviewees was organized by a contracted company based in Switzerland. The company emailed a selection of the relevant age group in its panel and telephoned potential participants to ensure respondents met the inclusion/exclusion criteria. Additionally, an advertisement on Facebook and Instagram was published to recruit LGBTQ profiles.

In total, ten interviews were carried out between November 2 and 8, 2021. Regarding language, four interviews were conducted in French and six in German. Interviewees were from Canton Zurich, Aargau, Valais and Vaude. Because of the COVID-19 pandemic, all interviews took place online using Zoom. This facilitated coverage of several regions of Switzerland, and no major issues regarding connection or engagement were reported.

One interview with a female participant was conducted by a male interviewer as no female French-speaking interviewers were available at that time.

CLINICS

A thematic search was performed with the tool Google TRENDS in order to select the most commonly used keywords when searching for MAR clinics.

The top 5 keywords (1. IVF; 2. Kinderwunsch; 3. Befruchtung; 4. Fruchtbarkeit; 5. Besamung in German, and 1. PMA; 2.FIV; 3. Fertilité; 4. ICSI; 5. IVF in French) were selected each was searched in Google. For each key word search, the first clinic that appeared was selected. Local language and country were set up as preferred for each search. Other sources, such as journals or blog articles that were not from IVF centres were excluded.

Data collection was carried out by Medistella during November 2021. Websites from selected MAR clinics were explored in local language (4 in German, 1 in French) and then translated into English. All information was collected by specially designed templates. Once the template was completed, it was reviewed by an English native speaker. Almost 200 pages were collected from Swiss MAR clinics' websites.

In addition, Medistella contacted Swiss MAR clinics directly as well as by "mystery shopping", in order to collect extra information (e.g., leaflets, consent forms...). Only one clinic provided information about prices.

8.2 Recommendation guidelines

SOCIOCULTURAL AND GENDER GUIDELINES

Being better informed about infertility treatment requires that the information provided by clinics is aligned with the concerns and expectations of the public, especially young populations. It also requires that citizens are better educated about infertility, including its causes, prevalence, and treatment.

- To educate citizens, infertility should be the focus of a public information and awareness-raising campaign directed by public health authorities. The campaign should de-stigmatize infertility by providing information about the prevalence and causes of infertility in both men and women. It should provide information about the full range of methods available to couples and individuals for becoming parents.
- The topic of infertility should be included in school curricula in accordance with governmental standards and guidelines (e.g., as part of existing curricula on human reproduction or sexuality).
- Information on clinics' websites should be more gender-balanced and more gender-inclusive, considering trans and intersex people.
- Clinics should provide information in a manner that is consistent with ethnic, racial, and cultural diversity of Swiss citizens, and should provide information on Medically Assisted Reproduction (MAR) options for all genders and/or sexual orientations.
- Different sources of information could be developed: a global website for general information on infertility and MAR could be created, family doctors could be prepared to provide more personalized information.
- The government should be aware that young people are concerned not only for improved access to fertility treatment but also for universal access to basic services of primary and reproductive healthcare.

LEGAL GUIDELINES

The availability and adequacy of information provided by clinics depends in part on the state of the relevant legal frameworks: laws that regulate fertility treatments and health services in general, laws that regulate informed consent and the use of personal data, laws that regulate advertising, as well as laws that affect marriage and paternity.

STRENGTHS OF THE LEGAL FRAMEWORK IN SWITZERLAND:

- Article 3 (Federal Act on MAR, 1998) prescribes that techniques will be used only when the wellbeing of the child is ensured.
- Clinics provide detailed information about prices and costs, which are well regulated (art. 17 and 18 of Bundesgesetz gegen den unlauteren Wettbewerb (UWG), updated Jan 1, 2022).
- Clinics commonly report data on success rates to National Registry of In-Vitro Fertilization.
- The Federal Law of Unfair Competition imposes on the advertiser the burden of proof on the veracity of the data contained in their advertisements. In this regard, see art. 13..

WEAKNESSES OF THE LEGAL FRAMEWORK IN SWITZERLAND:

- Possible inconsistency between child's right to knowledge of biological origins (Child Convention, art. 8; European Council Recommendation 2156/2019, NECK Opinion on Samenspende, December 2019) and donor anonymity (established by national law).
- No detailed regulation of informed consent, clinics do not make documents of informed consent public.
- Youth are concerned that access to MAR is guaranteed for all, including transgender and non-binary persons, but law does not clearly allow access to single persons.

DEFICIENCIES IN THE INFORMATION PROVIDED BY CLINICS:

All information provided by clinics – through their websites, advertising, and documents of informed consent – is regulated by legal standards for truthful advertising and informed consent. We have found that information provided by clinics about success rates of fertility treatments,

add-ons (supplementary procedures offered by clinics for the purpose of improving fertility treatment outcomes), and possible risks associated with MAR does not meet these standards. Accordingly, in the interest of greater transparency, we make the following recommendations for the improvement of this information:

WITH REGARD TO SUCCESS RATES IT IS RECOMMENDED THAT:

- Success rate should be clearly defined as live birth, in alignment with expectations of persons seeking fertility treatment and their main reason for contracting the services of a clinic.
- Information about success rates should be based on best available evidence. Clinics should clarify the strength of this evidence.
- Different success rates should be specified in relation to age, different techniques, and use of egg donation.
- Clinics should provide access to evidence-based sources of data for purposes of verification.
- Information about success rates provided through websites and advertising should match the information provided through informed consent.

WITH REGARD TO ADD-ONS IT IS RECOMMENDED THAT:

- Clinics should provide clear information, based on best available evidence, in support of any claim that add-ons can improve fertility treatment outcomes. If such data is unavailable, clinics should make this clear.
- All risks associated with the use of add-ons should be clearly explained.
- Clinics should provide access to evidence-based sources of data on add-ons for purposes of verification.
- Information about add-ons provided through websites and advertising should match the information provided through informed consent.

WITH REGARD TO POSSIBLE ASSOCIATED RISKS IT IS RECOMMENDED THAT:

- In websites, advertising, and documents of informed consent, clinics should provide complete, clear, and comprehensible information, based on best available evidence, about potential health risks for persons undergoing fertility treatment. Clinics should clarify the strength of this evidence.
- In websites, advertising, and documents of informed consent, clinics should provide complete, clear, and comprehensible information, based on best available evidence, about potential health risks for children conceived through MAR.
- This information should differentiate specific risks associated with different techniques (IUI, IVF, ICSI) and procedures (chemical and physical manipulation of gametes and embryos). Clinics should clarify the strength of this evidence.
- Information about risks should be expressed at two levels: in technical terms that specify the type of risk and its probability, and in nontechnical language that is readily accessible to the public (e.g., using illustrations if necessary).
- Clinics should provide access to evidence-based sources of data for purposes of verification.
- Information about associated health risks to MAR provided through websites and advertising should match the information provided through informed consent.

ADDITIONAL KEY RECOMMENDATIONS FOR CLINICS:

- Clinics should make documents of informed consent available to the public through their websites.
- Clinics should make information sheets and informed consent forms adapted to people with disabilities as required by article 25 of United Nations International Convention on the Rights of Persons with Disabilities.
- Clinic websites should describe the conditions for receiving governmental support (e.g., through the public health system) for fertility treatment (e.g., age of the woman, etc.) and should provide information about alternative methods.
- Clinic websites should clarify that egg and embryo donation and surrogacy are prohibited by art. 4 of 1998 MAP law.
- Strict compliance with principles of authenticity and truthfulness: advertising

should be clearly identifiable as such (SLK Grundsatz Principle B.15.a) and should not be incomplete or otherwise misleading (UWG art. 2, art. 3; SLK Grundsatz Principle B.2).

- Testimonials should comply with regulation of SLK Grundsatz B.7.2, and for this it is recommended that they are clearly recognizable as advertising and that written authorization is obtained from witnesses..

CONSIDERATIONS FOR THE IMPROVEMENT OF PUBLIC INFORMATION:

- It is recommended that health authorities create a catalogue of informed consent forms and information sheets that comply with current regulations.
- Persons seeking fertility treatment should be informed of possible alternatives to MAR, including adoption and the possibility of treating infertility through biomedical intervention.
- Information campaigns should help public understand current legal regulation of techniques—what has changed as a result of the Marriage for All Act, and what has not—and this information should cover biological, legal, ethical and economic aspects of the use of techniques.
- Recommended that public information website is hosted by public administration and supervised by health authorities such as the National Ethics Committee.
- Citizens should be informed of the legal definition and conditions of parenthood and of the rights that are implicated by fertility treatment (rights of parents, rights of donors, rights of offspring).

DISCLAIMER

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