



A POLICY AUDIT ON
FERTILITY

Analysis of 9 EU Countries

March 2017

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FOREWORD



It was without a moment's hesitation that I made the decision to support the Policy Audit on Fertility. I urge my fellow members of the European Parliament to join me in advocating for the freedom of citizens; freedom that cannot exist when education and access to treatment remain unequitable. The right to family is protected under Article 12 of the European Convention on Human Rights¹. It is our duty to evolve our understanding of this right in light of today's realities. I invite you to read the main findings of this policy audit so as to better understand infertility in the 21st century, recognising that infertility, while more prevalent, comes with solutions.

More than 25 million EU citizens are affected by infertility. One in six couples worldwide experience some form of infertility. A full range of Medically Assisted Reproduction (MAR) techniques have been developed to help infertile couples. However, due to combining factors, including a lack of awareness, access and availability of treatments and social stigma, many Europeans continue to face insurmountable barriers.

The consequences of not addressing the problem today are not only of a personal nature (potential depressions, emotional and societal effects) but also impact society as a whole by contributing to demographic decline in the EU. It is time to spread information and raise awareness about fertility preservation and protection and that infertility is a medical condition, not a choice. The public has the right to be educated on infertility and its treatment options, in addition to being supported and empowered on their journey to have a child. The time has come for us to recognise the right to have a child as part of an individual's universal human rights. To this end, adequate policy responses to infertility are part of a larger and much needed solution to address the ageing population and demographic decline.

We cannot remain silent in the face of problems when we are privileged to have solutions. In the spirit of the foundations that we find ourselves here, participating in progressive collaboration, we have an obligation to ensure equity in access to infertility services across member states. While many actions will need to be taken in respective countries, much can be done at EU level, including data collection, awareness raising, exchange of best practices and formalised, constructive debates on this topic.

Norica Nicolai

ALDE, Romania

Member of the European Parliament

Sponsored by Merck KGaA, Darmstadt, Germany, as contribution to public policy debate and conducted on behalf of Fertility Europe (FE) and the European Society of Human Reproduction and Embryology (ESHRE) between March 2016 and January 2017. The findings of the audit are the result of targeted desk research, one-to-one interviews, written questionnaire responses and written input from ESHRE and FE national member associations and respective experts.

Apart from local experts who provided country-specific information and perspectives (see Annex I), special acknowledgments go to Monika Bulmańska-Wingett, Isabelle Chandler, Elín Einarsdóttir and Satu Rautakallio-Hokkanen from Fertility Europe as well as Dr Roy Farquharson, Helen Rendrew, Dr Tatjana Motrenko and Bruno Van den Eede from ESHRE, who provided extensive review and coordination to this project.



INTRODUCTION

This report provides an overview of the situation and policies in place to tackle infertility across a sample of nine EU member states, namely: the Czech Republic, France, Germany, Italy, Poland, Romania, Spain, Sweden and the United Kingdom.

Infertility is defined and recognised by the World Health Organisation as a medical condition characterised by the failure to achieve pregnancy after 12 months² and without investigations or treatment, it prevents people from becoming parents³. It is estimated that one out of six people worldwide experience some form of infertility during their reproductive lifespan. In the EU alone, infertility affects approximately 25 million citizens⁴. While Medically Assisted Reproduction (MAR) offers a full range of techniques to assist infertile couples or individuals, vast differences in accessibility exist between the nine countries examined in the report. Treatments range in complexity from: Intrauterine Insemination (IUI) and In Vitro Fertilisation to Preimplantation Genetics Diagnosis and Screening, to gamete and embryo donation and surrogacy.

From a demographic perspective, the EU as a whole is in a phase of population decline, further underscoring the need for supporting policies that address growth and support families. To this aim, figures on the Total Fertility Rate (TFR)⁵ have been provided throughout *Table 1. EU9 Overview on Fertility, Age, Access, Treatments and Funding, Table 2. EU28 Key Facts and Figures* and in each

country chapter to support the reader's understanding. The TFR of the nine EU member states included in this report score between 1.32 (Spain and Poland) and 2.01 (France) TFR, as compared to the EU average of 1.58.

It is through this lens that the audit brings together key facts about important public health issues ranging from: infertility policies, screening and diagnosis, treatment availability and awareness raising activities specific to each country examined. Accordingly, each country chapters includes a brief overview of the situation followed by detailed examination in six areas of interest: 1) Key Facts and Figures; 2) Infertility Policies; 3) Screening and Diagnosis; 4) Treatment and Reimbursement / State Funding; 5) Awareness Raising Activities and 6) Future Outlook.

The report is intended to contribute to a constructive discussion and support a much needed exchange between stakeholders and policy makers with the aim to facilitate meaningful progress for EU citizens.

KEY FINDINGS OF THE REPORT



HIGH PREVALENCE OF INFERTILITY

**25
million**
EU citizens

**1 in 6
couples**
worldwide

HIGH REGULATORY VARIATION WITH RESPECT TO TREATMENT AVAILABILITY

INFERTILITY BY THE NUMBERS

- ▶ One in six couples worldwide experience some form of infertility. Estimates suggest, more than 25 million EU citizens are affected by infertility⁶.
- ▶ There is a lack of updated comparative data on infertility rates in the EU 28 and/or examined nine EU countries. The calculation of data identified and reflected upon in specific country chapters is based on different methodologies and therefore does not allow for proper comparison.
- ▶ Fertility rates differ significantly across the nine EU countries examined, from Spain and Poland with a rate of 1.32 to the UK (1.81), Sweden (1.88) and France (2.01). Across the nine EU countries, the highest fertility rate remains below the stabilising rate (2.1 live births per woman) necessary for maintaining population size, according to Eurostat⁷. Please see Table 2. EU28 Key Facts and Figures for an overview of all EU member states.

HEALTH LITERACY, STIGMA AND TABOOS

- ▶ Limited information and education on infertility are common to all countries examined in this study. Infertility and fertility protection remain underestimated and misunderstood. Awareness raising campaigns are mainly driven by patient groups and healthcare professional organisations, with some government involvement, as seen in Germany, France, Italy and Sweden.
- ▶ Infertility stigma and taboos remains a considerable issue to be addressed. Many experience difficulty discussing infertility with their partner and/or healthcare provider for cultural reasons or due to prevailing perceptions that it is a social, rather than medical, condition. Male infertility stigma was identified in a recent Swedish report⁸ and a focal point in awareness campaigns in the Czech Republic, Poland, Spain and the UK.

INFERTILITY LEGISLATION

- ▶ All nine EU countries examined have legislation governing Medically Assisted Reproduction (MAR), whether independently or part of broader legislative frameworks. Amendments and revisions over the past 30 years have sometimes been surrounded by dividing debates (as with Italy in 2004 or Poland in 2016). Nearly all the countries examined supplement legislation with professional guidelines.
- ▶ Treatment eligibility criteria (e.g. sexual orientation, marital status, age etc.), as outlined by country specific laws, also differ significantly across all nine EU countries surveyed. Access to MAR by single women and same sex couples is currently available in the Czech Republic, Germany, Spain, Sweden, UK (see *Table 1. EU9 Overview on Fertility, Age, Access, Treatments and Funding*).
- ▶ Regulatory variation can be seen with respect to treatment availability, most notably in: embryo selection via Preimplantation Genetic Diagnosis (PGD) and Preimplantation Genetic Screening (PGS), anonymity of donors (e.g. gametes and embryos) and surrogacy. While the UK is the only country where surrogacy is legalised, legal vacuums in the Czech Republic and Romania allow for its practice (see *Table 1. EU9 Overview on Fertility, Age, Access, Treatments and Funding*).
- ▶ Due to flexible legal frameworks and the safe, clinically efficient, patient focused and evidence-based medicine care offered, the Czech Republic and Spain rank among the highest in Europe for infertility treatment to non-nationals.

TREATMENT: ACCESS AND REIMBURSEMENT/ FUNDING

- ▶ Available treatments options vary across the nine EU countries. The Czech Republic and the UK have the largest number of options available, followed by Spain where, with the exception of surrogacy, all treatment options are possible. It is important to note that while treatments are available, there are rules, conditions and structures in place that may make treatment availability more restrictive (e.g. embryo freezing in Germany).
- ▶ In all nine EU countries, psychological counselling is recommended. However, patient groups identify a common need for psychological counselling not only before treatment but also during and after treatment.

REIMBURSEMENT / STATE FUNDING

- ▶ A variety of biological factors determine an individual's eligibility for treatment reimbursement / state funding, with age as a common criterion across all countries surveyed. With the exception of Poland ceasing its state funding for infertility treatment in June 2016, women up to age 40 in most other countries, 43 in France, are eligible for treatment reimbursement / state funding. In Italy and Spain, it is necessary to obtain a medical certificate confirming an infertility diagnosis in order to qualify for state funded IUI and IVF treatment.
- ▶ IVF remains the first line of treatment for providers, however reimbursed at various levels and under differing criteria by each country. Surrogacy, gamete and embryo donation, remain embroiled by public debate.
- ▶ Significant intra-regional variation in state funded MAR can be seen in the UK, Italy, Spain and to some extent, Germany. In Sweden and the UK, intra-regional variation was observed most significantly in wait times and availability of psychological counselling.
- ▶ Political priorities and public attitudes also determine the scope and availability of publically funded treatments in the countries surveyed. Reimbursement / State funding levels and the criteria for inclusion in reimbursement schemes (e.g. marital status or sexual orientation) also vary significantly among the nine EU countries examined.

CONSIDERABLE STIGMA AND TABOOS

- ▶ Perception that it is a social rather than a medical condition
- ▶ Difficulty discussing with the partner and healthcare provider
- ▶ Limited information and education
- ▶ Infertility and fertility protection underestimated and misunderstood

Table 2. EU28 Key Facts and Figures

EU 28	Total Fertility Rate (2014, Eurostat) ¹¹	Mean Age of Woman at Childbirth (2014, Eurostat) ¹²	Fertility Treatment Regulation (2015, ESHRE ¹³ ; 2016, ECPRD ¹⁴ ; ESHRE, FE input)	Public Clinics (2015, ESHRE; 2016, ECPRD; ESHRE, FE input)	Private Clinics (2015, ESHRE; 2016, ECPRD; ESHRE, FE input)	Reimbursement / State Funding Yes/No (2015, ESHRE; 2016, ECPRD; ESHRE, FE input)
Austria	1.47	30.4	Legislation	8	23	Yes
Belgium	1.74	30.3	Legislation	34 in total		Yes
Bulgaria	1.53	27.3	Legislation	3	32	Yes
Croatia	1.46	29.8	Legislation + guidelines ¹⁵	8	8	Yes
Cyprus	1.31	31.0	Legislation + guidelines	0	5	Yes
Czech Republic	1.53	29.9	Legislation ¹⁶ + guidelines	40 in total ¹⁷		Yes
Denmark	1.69	30.9	N/A	8	13	Yes
Estonia	1.54	29.6	Legislation	3	2	Yes
Finland	1.71	30.5	Legislation	10	14	Yes
France	2.01	30.3	Legislation + guidelines	50	50	Yes
Germany	1.47	30.9	Legislation + guidelines	30	100	Yes
Greece	1.30	31.1	Legislation + guidelines	9	43	Yes
Hungary	1.44	29.5	Legislation + guidelines	3	9	Yes
Ireland	1.94	31.6	Legislation	0	7	No
Italy	1.37	31.5	Legislation + guidelines	63	95	Yes
Latvia	1.65	29.2	Legislation ¹⁸			
Lithuania	1.63	29.4	Legislation	0	5	Yes
Luxembourg	1.50	31.4	N/A	N/A	N/A	N/A
Malta	1.42	30.1	N/A	N/A	N/A	N/A
Netherlands	1.71	31.1	Legislation + guidelines	13	0	Yes
Poland	1.32	29.1	Legislation ¹⁹ + guidelines	4	37	No (expired June 2016)
Portugal	1.23	30.7	Legislation	10	16	Yes ²⁰
Romania	1.52	27.5	Legislation + guidelines ²¹	2	20	Yes ²²
Slovakia	1.37	28.8	Legislation	1	8	Yes
Slovenia	1.58	30.2	Legislation + guidelines	3	0	Yes
Spain	1.32	31.8	Legislation + guidelines	41	197	Yes
Sweden	1.88	31.0	Legislation + guidelines	6	10	Yes
UR	1.81	30.2	Legislation + guidelines	78 in total		Yes

ABOUT THE PARTNERS



With member representation from over 20 European countries, Fertility Europe (abbreviated "FE") is the Pan-European organisation representing infertility focused associations. FE national organisations work tirelessly to assist those with difficulties conceiving. Their goal is to improve the rights of individuals affected by infertility by building stronger cross border networks amongst European patients. These synergies foster the sharing of best practices, social change in perception of infertility and increase education in the protection of reproductive health. FE's work aims to promote: patient empowerment, the fight against health inequalities and discrimination, the support of quality care, patient safety and patient centred treatments, as well as the development of ethical guidelines and regulations within each European country.

For more information about FE, visit: <http://www.fertilityeurope.eu/>.



The European Society of Human Reproduction and Embryology (abbreviated "ESHRE") is a scientific society incorporated as an international non-profit organisation. ESHRE's main aim is to promote interest in, and understanding of, reproductive biology and medicine. It does this through facilitating research and the subsequent dissemination of research findings in human reproduction and embryology to the general public, scientists, clinicians and patient associations. It also collaborates with politicians and policy makers throughout Europe. It promotes improvements in clinical practice through organising teaching and training activities, developing and maintaining data registries and providing guidance to improve safety and quality assurance in clinical and laboratory procedures.

For more information about ESHRE, visit: <https://www.eshre.eu/>.



Merck KGaA, Darmstadt, Germany is a leading science and technology company in healthcare, life science and performance materials. As the world market leader in fertility treatments it offers a complete and clinically proven portfolio of fertility treatments at every stage of the reproductive cycle, and combines this drug portfolio with its continuously expanding offering of innovative technologies. Merck KGaA, Darmstadt, Germany has an enduring commitment to improve treatment outcomes for patients, in partnership with their providers', in accessing treatment.

For more information about Merck KGaA, Darmstadt, Germany visit: <http://biopharma.merckgroup.com/en/index.html>.



This project was funded by Merck KGaA, Darmstadt, Germany as contribution to public policy debate. To ensure editorial integrity, in a Memorandum of Understanding with Fertility Europe (FE) and the European Society of Human Reproduction and Embryology (ESHRE), Merck KGaA, Darmstadt, Germany signed complete editorial control over the report to FE and ESHRE.

METHODOLOGY

The Policy Audit on Fertility includes an examination of nine EU member states: the Czech Republic, France, Germany, Italy, Poland, Romania, Spain, Sweden and the United Kingdom. The country selection meant to ensure a meaningful and balanced geographical scope of analysis. The methodology of the report was to carry out research in a structured approach that included: a pre-defined questionnaire, desk research, interviews/written input and upwards of three revision cycles with the lead partners, FE and ESHRE, their respective members and experts.

A pre-defined questionnaire was developed in collaboration with the partners to guide desk research and interviews. Partners agreed to the following headings, as representative of the main areas of interest: Key Facts and Figures; Infertility Policies; Screening and Diagnosis; Treatment and Reimbursement / State Funding; Awareness Raising Activities; and Future Outlook. For each heading, a number of specific questions were developed to facilitate the harmonised collection of comparable information, thus providing a comprehensive assessment of the situation in each country.

Desk research was carried out using a range of internet sites including national ministries, academic institutes, professional and patient associations, media articles and approved reference documents. Information was gathered from each of the nine EU countries based on the pre-defined questionnaire.

Interviews/written input were used to build on desk research. Information gathered from one-to-one interviews and rounds of written input were carried out with patient groups and fertility specialists, representing each of the nine countries surveyed. FE member organisations from the Czech Republic, France, Italy, Poland, Romania, Sweden and the UK participated in the interviews. Due

to lack of a local FE representative in Spain and Germany, feedback into their respective country chapters were provided by the Wunschkind association in Germany and Dr Diana Guerra, Spanish Infertility Association - Genera (dissolved in 2016). ESHRE members from each of the nine EU countries provided feedback via written input or interviews. Interviews were conducted according to the pre-defined questionnaire and written input on specific information was coordinated by members in each country. This process was used to discuss and fact-check information garnered through desk research, as well as to assess and gather opinions on the implementation of a framework that optimally presents the situation of the countries in focus.

Revision by the parties involved – information collected through desk research, complementary one-to-one interviews and written input were analysed and reviewed to create a comprehensive overview, followed by a 4-5 page in-depth assessment of the situation in each of the nine EU countries. The report then underwent upwards of three review cycles by members of FE and ESHRE, with feedback incorporated into the report you read today.

This report was produced by Burson-Marsteller Brussels, a public affairs and communication agency, on behalf of the audit partners.

► Disclaimer

The views and opinions expressed in this audit report are exclusively those of Fertility Europe (FE) and the European Society of Human Reproduction and Embryology (ESHRE) and do not necessarily reflect the official policies or positions of stakeholders involved. This is in keeping with the terms of agreement for full editorial rights and control by FE and ESHRE, as outlined in the memorandum of understanding between FE, ESHRE and its sponsor, Merck KGaA, Darmstadt, Germany. Content presented in this report is not reflective of consultations with government entities. Assertions and statements provided by FE and ESHRE are, as per the methodology, the product of consultations with their respective networks and therefore should not be extended beyond the intent for which this report was originally conceived, a current state assessment of infertility in the nine EU countries surveyed.



COUNTRY CHAPTERS



OVERVIEW

- ▶ The fertility rate in the Czech Republic is 1.53 (vs. 1.58 EU average)²³.
- ▶ Fertility policy is part of family policy, which falls under the portfolio of the Ministry of Labour and Social Affairs. Access to Medically Assisted Reproduction (MAR) is regulated by "Act No. 373/2011, Coll. – the Act on Specific Health Services, Title II – Health Services Provided Under Special Conditions, Part 1 Assisted Reproduction"²⁴.
- ▶ A wide range of treatment options are available in the Czech Republic from, Intrauterine Insemination (IUI) to surrogacy, the latter practiced but surrounded by a legal vacuum. The use of donor eggs, as well as sperm and embryos are explicitly protected under Czech law.
- ▶ Women who undergo IUI or In Vitro Fertilisation (IVF) must first obtain written consent from the husband or male partner, to be registered as the biological father of the child if treatment results in a successful pregnancy. This is a requirement regardless of the origin of the gamete used in the process.
- ▶ In the Czech Republic, three to four IVF attempts are 100% covered by mandatory health insurance, but some related procedures require co-financing by the patient. Mandatory health insurance covers IVF for women between 22-39 years of age. The age limit may be reduced to 18 years, if the patient is found to have a bilateral fallopian tube blockage.
- ▶ Public awareness is raised predominantly by MAR centres, the Adam Česká republika patient association and by endowment funds.
- ▶ A new family policy is under development, with MAR on the agenda, as part of reform discussions. This may lead to legislative changes such as, raising the maximum age a woman is eligible to receive covered MAR treatments, as well as allowing single women to undergo IVF.
- ▶ The Czech Republic is a destination country for infertility treatment. The number of IVF cycles undergone by non-nationals increased from 1795 in 2010 to 3030 in 2014²⁵.

Table 1.

KEY FACTS & FIGURES

TOTAL FERTILITY RATE (TFR) ²⁶	1.53 ²⁷
INFERTILITY RATE	20% of couples ²⁸
MEAN AGE OF WOMAN AT THE FIRST CHILDBIRTH	29.9 years ²⁹
FERTILITY TREATMENT SUCCESS RATE	30.5% (number of pregnancies relative to the number of IVF cycles in women up to 34 years of age) ³⁰
REIMBURSEMENT	100% coverage by mandatory health insurance for up to four cycles IVF and six IUI, for women aged 22-39 years of age. The age limit criteria may be reduced to 18 years, if the patient is found to have a bilateral fallopian tube blockage ³¹
AWARENESS RAISING CAMPAIGNS/ INITIATIVES	<p>Patient association campaign:</p> <ul style="list-style-type: none"> ▶ Adam Česká republika (www.adamcr.cz) is a patient association that offers information to support men during infertility treatment. <p>Two endowment fund campaigns:</p> <ul style="list-style-type: none"> ▶ The endowment fund of Petr Koukal, www.stkprochlapy.cz and the "Rrtek" endowment fund, www.maskoule.cz both focus on testicular cancer. <p>Infertility websites:</p> <ul style="list-style-type: none"> ▶ www.zenska-neploinnost.cz – is a website focused on infertility, operated by the Meditorial+ company; ▶ www.stopneploinnosti.cz – published via an unrestricted educational grant from Merck spol. s r.o.



INFERTILITY POLICIES

- ▶ It is estimated that 20% of couples in the Czech Republic are affected by infertility³². The fertility rate in the Czech Republic is 1.53 (vs. 1.58 EU average)³³.
 - ▶ The Czech Republic's fertility policy is part of the "National Family Policy", which falls under the portfolio of the Ministry of Labour and Social Affairs. Fertility and infertility are part of the "National Program for the Restoration and Promotion of Health" under the section for "Improvement of Reproductive Health"³⁴. The National Program came into effect in 1991 under the Czech Republic Government Resolution. The "Health2020" program was approved by the Government in 2012 and is currently under way³⁵. The state policy also includes the training of medical personnel (e.g. introduction of a certified course in accordance with "Decree No. 185/2009, Coll. on Specialisation Areas in the Education of Physicians and Pharmacists" entitled "Reproductive Medicine Further Education Program")³⁶. Conferences, seminars and courses on assisted reproduction are also held both nationally and regionally.
 - ▶ Access to Medically Assisted Reproduction (MAR) is regulated by "Act No. 373/2011, Coll. – the Act on Specific Health Services, Title II – Health Services Provided Under Special Conditions, Part 1 Assisted Reproduction"³⁷. Other acts and subordinate acts relevant to this Act include: "Act No. 227/2006, Coll., on Research on Human Embryonic Stem Cells and Related Activities"³⁸, "Act No. 296/2008, Coll., on Safeguarding the Quality and Safety of Human Tissues and Cells Intended for Use in Man"³⁹, "Act No. 101/2000, Coll., on the Protection of Personal Data"⁴⁰, and "Decree No. 116/2012, Coll., on the Transfer of Data to the National Health Information System (NHIS)"⁴¹, which outlines the binding instructions of the NHIS.
 - ▶ A National Registry of Assisted Reproduction (NRAR)⁴² was established in 2007 to collect information for the evaluation, management and improvement of care for infertile couples. Data from the NRAR also supports MAR policy development and treatment options. The NRAR is part of the Institute of Health Information and Statistics of the Czech Republic, which is under the purview of the Ministry of Health. Data submissions are prospective and mandatory for all providers of MAR.
- The Institute of Health Information and Statistics publishes an annual report on assisted reproduction in the Czech Republic, which includes the number of IVF procedures performed, prevalence by diagnostic type and success rates⁴³.
- ▶ The law does not require information on sexual orientation or marital status in order to access MAR⁴⁴. For a woman to undergo IUI or IVF, Czech law requires written consent from the husband or male partner who has to agree to be registered as a biological father of the child, if treatment results in successful pregnancy. This is a requirement regardless of the origin of the sperm or embryo used in the process. In the Czech Republic there is a legal vacuum with respect to surrogacy, as the law does not explicitly encourage, or have legal provisions discouraging it. Under this circumstance, surrogacy is practiced in the Czech Republic⁴⁵.



Screening and diagnosis in the Czech Republic is advancing hand in hand with the achievements of science. Gynaecological screening and women's healthcare in the Czech Republic are generally top-quality. Infertility diagnosis is to a great extent covered by mandatory health insurance regardless of age, and is also of a very high quality. ”

Adam Česká republika
patient association,
Czech Republic
August 2016

SCREENING AND DIAGNOSIS

- ▶ There is an assortment of screening and diagnostic options for patients in the Czech Republic⁴⁶.
- ▶ Common female infertility diagnostic techniques include: ultrasound examination of the pelvis, testing of hormone levels, X-ray examination of the uterus and fallopian tubes (hysterosalpingography or HSG for short), hysteroscopy, laparoscopy testing, genetic testing and immunological examination^{47,48}.
- ▶ Common male infertility diagnostic techniques include: sperm cultivation, andrology testing, sperm acrosome integrity testing, DNA fragmentation of sperms, genetic testing, immunological examination and hormonal examination⁴⁹.
- ▶ However, the number of follow-up examinations covered by mandatory health insurance is limited. They include, for example: seven ultrasound examinations per year, four cervical mucus examinations per month, one spermogram examination every three months, etc.⁵⁰.
- ▶ Gynaecologists, urologists or andrologists are usually the first point of contact for couples seeking infertility treatment, but patients may also contact a MAR centre directly.
- ▶ Gynaecologists typically refer patients for specialised examinations and to MAR centres. Once infertility is diagnosed, receiving treatment is generally quick and easily accessible⁵¹.

TREATMENT AND REIMBURSEMENT / STATE FUNDING

- ▶ A wide variety of treatments are available in the Czech Republic. Patients undergo infertility treatments such as: IVF, transcervical embryo transfer and cryopreservation of gametes and embryos⁵² to name a few. Embryos are examined genetically and continuously monitored using an embryoscope in an incubator. Surveillance facilitates early detection of irregularities in embryo development, as well as the selection of the embryos that will undergo gestation⁵³.
- ▶ The law allows for the use of donor eggs, sperm and embryos⁵⁴. While not explicitly defined by law, surrogacy is practiced in the Czech Republic⁵⁵.
- ▶ Mandatory health insurance entitles a patient to three to four cycles of IVF and six cycles of IUI at 100% coverage⁵⁶. However, some treatment related procedures, such as: Intracytoplasmic Sperm Injection (ICSI), Preimplantation Genetic Diagnosis (PGD), Embryo Cryopreservation, thawing and subsequent Frozen Embryo Transfer (FET) are not covered by mandatory health insurance.
- ▶ MAR is available for women of childbearing age, provided their health allows for treatment. Mandatory health insurance covers IVF for women between 22-39 years of age. The age limit may be reduced to 18 years, if the patient is found to have a bilateral fallopian tube blockage⁵⁷. IVF is not currently covered for women of the age of 40 and above⁵⁸.
- ▶ Mandatory health insurance coverage includes procedures related to IVF treatment, as well as certain examinations prior to starting IVF. However, in order to receive 100% IVF coverage, the patient must agree to take complementary drugs. If the patient chooses not to comply, he/she is required to co-finance the drugs used during IVF. Surcharges for these drugs range from approximately CZK 3,000 – CZK 10,000 (approximately EUR 110 – EUR 370)^{59,60}.



- ▶ Women outside of the eligible age range must cover all costs independently. The price of one IVF cycle (including drugs) is around CZK 45,000 (approximately EUR 1,665)⁶¹.
- ▶ Access to certain MAR treatments may be limited by a patient's ability to pay⁶². This is due in part to how the financing was initially established during the 1990's. Since then, science and medicine have evolved to offer innovative, and accordingly, more expensive drugs and techniques, not captured under the current financing model. While these advances are not medically necessary, according to the Human Reproduction Journal, they still present additional costs, that can be limiting for many patients⁶³.
A recipient of donated gametes may be a woman with normally functioning ovaries who has repeatedly undergone IVF without success, has had chemotherapy, is about to start menopause, has just gone through menopause, or has a genetic variation⁶⁴.
- ▶ MAR centers collaborate with psychologists to provide patients with psychological care. The government, in partnership with municipalities, also offers free marriage and pre-marriage counselling with psychologists. NGOs and informal groups also play an important role in the delivery of psychological support through a variety of social and informational networks⁶⁵.
- ▶ Clinical pregnancy occurs in one-third of cycles in women aged 22-35, one-quarter of cycles in women aged 36-39 and one-tenth in women aged 40 and above. Eggs donated by younger women make up the majority of cycles for women aged 40 and above, increasing success rates⁶⁶.
- ▶ Due to the variety and availability of treatments, as well as the high quality of services, relative to price, the Czech Republic is a top destination for infertility treatment⁶⁷. The number of IVF cycles undergone by non-nationals increased from 1795 in 2010 to 3030 in 2014⁶⁸.

- ▶ In 2014 there were 42 MAR clinics (both public and private) in the Czech Republic⁶⁹. Reimbursement / State funding remains dependent on contractual agreements between individual clinics (public or private) and their insurer.

Table 2. Treatment Options Available in the Czech Republic

Intrauterine Insemination (IUI)
In Vitro Fertilisation (IVF)
Intracytoplasmic Sperm Injection (ICSI)
Embryo Freezing; Frozen Embryo Transfer (FET)
Preimplantation Genetic Diagnosis (PGD)
Preimplantation Genetic Screening (PGS)
Microsurgical Epididymal Sperm Aspiration (MESA); Testicular Sperm Extraction (TESE)
Gamete Donation
Surrogacy

AWARENESS RAISING ACTIVITIES

- ▶ Public awareness is raised predominantly through civic associations such as www.adamcr.cz, by endowment funds such as www.stkprochlapy.cz and www.maskoule.cz and by MAR centres and pharmaceutical manufacturers via websites, such as www.stopneploдности.cz and www.zenska-neploдность.cz.
- ▶ Articles in lifestyle magazines increasingly discuss infertility and the rise in male infertility^{70,71,72,73}. One article mentioned that 3-4% of children in the Czech Republic are born through MAR treatments and that this proportion will continue to rise⁷⁴. Unbiased information from scientific research can be found in scientific journals, but are not intended for the general public.



The MAR situation, accessibility, quality of screening and treatment is very good in the Czech Republic. However, the social context of MAR is generally underestimated. ”

Adam Česká republika
patient association,
Czech Republic
August 2016

FUTURE OUTLOOK

- ▶ A new “Family Policy” is under development, including the set-up of an Expert Commission on Family Policy⁷⁵, which will operate under the direction of the Ministry of Labour and Social Affairs,⁷⁶ whose responsibility includes the drafting of the “National Family Policy”⁷⁷.
- ▶ Outcomes from the Expert Commission may result in specific proposals for amendments to the current law. With declining demographics, the Expert Commission for Family Policy will discuss several changes to the current legislation, including: raising the maximum age a woman is eligible to receive covered MAR treatments, as well as explicitly allowing single women to undergo IVF with the state guarantee and state responsibility⁷⁸.
The Expert Commission for Family Policy requests that the state increase its financial support of MAR and broader accessibility⁷⁹.

OVERVIEW

- ▶ The fertility rate in France is 2.01 (vs. 1.58 EU average)⁸⁰.
- ▶ Fertility policy is the responsibility of the Ministry of Health. Access to Medically Assisted Reproduction (MAR) is regulated under the 1994 bioethics law, which includes the following three laws: "Law 94-654" from 29 July 1994 on the "Donation and Use of Elements and Products of the Human Body, Medically Assisted Procreation and Prenatal Diagnosis", revised in 2004⁸¹ and again in 2011⁸² and two supporting laws concerning respect for the human body and the use of personal data for medical research⁸³.
- ▶ Treatment options covered under the law range from Intrauterine Insemination (IUI) to Preimplantation Genetic Diagnosis (PGD), gamete and embryo donation. Surrogacy, double gamete donation and Preimplantation Genetic Screening (PGS) are not available. MAR is currently available for women under 43 years of age, in a heterosexual couple, either married or cohabitating. Access to MAR is not available for same sex couples or single women.
- ▶ In France, reimbursement / state funding includes four IVF treatments and up to six IUI's (one IUI per menstruation cycle), for women under 43 years of age.
- ▶ Doctors, scientists and patients believe stigma, insufficient information, support, education and prevention, as well as research, remain key challenges. They advocate for a National Fertility Plan to be put in place⁸⁴.
- ▶ More specifically, patient groups call for a national plan that addresses: diagnosis, medical care, holistic support and increased treatment availability, including specific examinations and techniques (i.e. double gametes donation), as well as more inclusive access to treatment for single women and same sex couples⁸⁵.
- ▶ Despite the 100 MAR centres in France (nearly 1 per department)⁸⁶, patients report that access to clinically efficient, patient focused and evidence-based care is not insured equally throughout France⁸⁷. Regarding access to oocyte donation, lengthy wait lists cause patients to seek treatment abroad⁸⁸.
- ▶ The National Consultative Ethics Committee⁸⁹ is expected to deliver a 'general' opinion on MAR in spring 2017⁹⁰. The outcomes of the 2017 presidential elections and subsequent legislation will determine long-term policies on infertility, including the planned 2018 revision of the bioethics law.

Table 1.

KEY FACTS & FIGURES

TOTAL FERTILITY RATE (TFR) ⁹¹	2.01 ⁹²
INFERTILITY RATE	<p>There are two reference studies on the infertility rate in France:</p> <ul style="list-style-type: none"> ▶ According to a 2003 "Perinatal National Survey" infertility was diagnosed in 18% of couples tested after a 12-month period and 8% in couples tested after a 24-month period⁹³. The study did not specify the ages of women surveyed. ▶ The Epidemiologic Observatory of Fertility in France, found that 24% of couples tested after 12 months and 11% of couples tested after 24 months were infertile⁹⁴. Women surveyed in this study (2007-2010) were between 18-44 years of age.
MEAN AGE OF WOMAN AT THE FIRST CHILDBIRTH	30.3 years ⁹⁵
FERTILITY TREATMENT SUCCESS RATE	<p>Approximately 25.5% live births with In Vitro Fertilisation (IVF/ Intracytoplasmic Sperm Injection (ICSI))⁹⁶</p> <p>Approximately 10% live births with Intrauterine Insemination (IUI)⁹⁷</p>
REIMBURSEMENT	<p>IUI and IVF/ICSI are fully reimbursed for women under 43 years of age:</p> <ul style="list-style-type: none"> ▶ Up to six IUIs (one IUI per menstruation cycle) ▶ Four IVFs⁹⁸ <p>MAR is available to heterosexual couples, of childbearing age, in a stable relationship (either married or cohabitating)⁹⁹. The couple must be in one or both of the following situations:</p> <ul style="list-style-type: none"> ▶ The couple or at least one partner must be diagnosed with medical infertility ▶ A partner has a serious disease that can be transmitted to their partner or the child



AWARENESS RAISING CAMPAIGNS/ INITIATIVES

Governmental campaign:

- ▶ A radio campaign on gamete donation, coordinated by the French Agency for Biomedicine in November 2016¹⁰⁰. The campaign featured healthcare providers (HCPs) providing information on MAR.

Patient associations and NGO campaigns:

- ▶ National Infertility Day, organised annually by the MAIA¹⁰¹ patient association, facilitates infertility discussions between patients, doctors and association members. The latest conference was held on 4 November 2016 in Paris.
- ▶ Manif pour tous (March for all)¹⁰² was a protest movement launched in France during the introduction of the marriage equality bill¹⁰³. It called for access to MAR treatments for same sex couples and surrogacy.
- ▶ Infertility Awareness Week, a campaign organised by the Association of Medically Assisted Reproduction Patients and Infertile People (BAMP)¹⁰⁴, took place between 25 and 30 April 2016.

INFERTILITY POLICIES

- ▶ Between 18-24% of couples report having failed to conceive after 12 months without contraception. After 24 months, the proportion decreases to 8%-11%^{105,106}. The fertility rate in France is 2.01 (vs. 1.58 EU average).
- ▶ Fertility policy in France is under the purview of the Ministry of Health. Over the years, infertility has been discussed in relation to other health policies such as cancer and the effect of endocrine disruptors on fertility¹⁰⁷. These discussions have not led to the adoption of a consistent approach in addressing such risk factors. France's family policies are typically assessed through a post-

birth lens, focusing primarily on financial support for families and day-care service availability¹⁰⁸.

- ▶ Access to MAR is regulated under the 1994 bioethics law, which includes the following three laws: "Law 94-654" from 29 July 1994 on the "Donation and Use of Elements and Products of the Human Body, Medically Assisted Procreation and Prenatal Diagnosis", revised in 2004¹⁰⁹ and again in 2011¹¹⁰ and two supporting laws concerning respect for the human body and the use of personal data for medical research¹¹¹.
- ▶ A 2009 report on women's health in France found that the use of MAR treatments has consistently increased over the last 30 years¹¹².
- ▶ MAR is currently available to heterosexual couples, either married or cohabiting, where the woman is under 43 years of age¹¹³. Access to MAR is not available for same sex couples or single women¹¹⁴. Patient groups feel there has been reluctance to re-open the debate on access to MAR for all couples, since the debates on access to MAR for same sex couples in 2013-2014¹¹⁵. Recent debates on marriage equality have further solidified the French government's opposition to surrogacy¹¹⁶.
- ▶ In March 2016, doctors published the "130 doctors manifesto" calling for changes to the French MAR legislative framework to include wider and improved access to some treatments¹¹⁷ in addition to a National Fertility Plan.



In terms of infertility, the approach in France is geared towards symptoms treatment instead of education and prevention. Patients in big cities have better access to treatment than patients in rural areas, who are faced with a so-called 'medical desert'.

Maia patient association,
France
July 2016

SCREENING AND DIAGNOSIS

- ▶ France's existing infertility screening professional guidelines have been developed by the Biomedicine Agency and are mandatory¹¹⁸. Guidelines were also developed by the National College of French Gynaecologists and Obstetricians but are not mandatory¹¹⁹.
- ▶ The following screening and diagnostic tests are available for women: examination to assess vaginal abnormalities, blood analysis and examination of reproductive organs via echography or X-rays.
The following screening and diagnostic tests are available for men: spermogram, hormonal screening through blood sample analysis, echography of the reproductive system and immunological testing¹²⁰.
- ▶ Gynaecologists are the main contact for couples struggling to conceive. If the causes of infertility are not discovered after an initial screening, gynaecologists can refer patients to other specialists such as: andrologists, endocrinologists, urologists, geneticists, psychologists or to a MAR centre. Clinical embryologists are available in every MAR centre.

TREATMENT AND REIMBURSEMENT / STATE FUNDING

- ▶ Many treatment options are available under French law, such as: IUI, IVF, ICSI, Preimplantation Genetic Diagnosis (PGD), gamete and embryo donation, Embryo Freezing and vitrification (as of 2011). While gamete donation is anonymous¹²¹, surrogacy, double donation¹²² and PGS are not available¹²³. In cases where both patients are infertile, couples are reliant on donated embryos, which can take between 12 to 18 months to receive¹²⁴. Every MAR centre in France must follow-up with couples that have frozen embryos and report annually to French authorities¹²⁵.
- ▶ The following MAR treatments are fully reimbursed for women under 43 years of age:
 - Up to six IUIs (one IUI per menstruation cycle)
 - Four IVFs¹²⁶
- ▶ Health insurance will reimburse treatment received abroad under the following conditions: that the patient meets eligibility criteria in France, that treatment is not delivered in France with the same level of success and that the treatment is appropriate to the patient's condition¹²⁷.
- ▶ While each MAR centre has its own assessment criteria, patient representatives believe there is an acceptance bias on the basis of: age, weight and simplicity of infertility condition¹²⁸. Couples may go to a gynaecologist to perform their inseminations or to an MAR centre. Gynaecologists are subjected to the same legal framework as MAR centres and reproductive biology labs. Laboratory costs are fixed by the healthcare system¹²⁹.



- ▶ A consult with a psychologist is mandatory for couples receiving gamete and embryo donations. The couple needs to confirm their MAR request in writing within a month following the consult. The letter is then sent to an MAR centre that will decide if access to treatment is granted.¹³⁰
- ▶ French legislation and the Agency for Biomedicine's website¹³¹ are one source of information on infertility treatment. Information is also available on patient associations' websites¹³² and other health websites¹³³. In an article by the French National Institute for Health Research, better gamete selection can lead to improved success rates¹³⁴.
- ▶ Patient groups believe that access to fertility experts and MAR centres are not equally insured throughout France and that lengthy wait times for oocyte donations (estimated between 2-5 years) causes patients to seek treatment abroad¹³⁵.
- ▶ Patient groups also call for improved treatment standards, in keeping with scientific developments and increased success rates^{136,137}.
- ▶ MAR success rates are approximately 25% with IVF and 10% with IUI¹³⁸.
- ▶ There are 50 private and 50 public MAR clinics in France¹³⁹.
- ▶ It is estimated that 25,208 children were born through MAR, representing 3.1% of new births in 2014¹⁴⁰.

Table 2. Treatment Options Available in France

Intrauterine Insemination (IUI)
In Vitro Fertilisation (IVF)
Intracytoplasmic Sperm Injection (ICSI)
Embryo Freezing; Frozen Embryo Transfer (FET)
Preimplantation Genetic Diagnosis (PGD)
Gamete and Embryo Donation

AWARENESS RAISING ACTIVITIES

- ▶ Patient groups consider stigma to be a significant problem that remains unaddressed¹⁴¹.
- ▶ Currently, there are no state funded awareness campaigns, apart from information on MAR on the French Agency for Biomedicine's website^{142,143}. The agency did organise a radio campaign on gamete donation in June 2015¹⁴⁴, with a second radio campaign in November 2016¹⁴⁵.
- ▶ On 4 November 2016, MAIA in partnership with Magic Maman Famili magazine organised the 3rd annual Infertility Awareness Day. The Awareness Day provided an open forum for infertile individuals to receive information on infertility issues¹⁴⁶.

FUTURE OUTLOOK

- ▶ The scientific community shows increasing interest in the causes of male infertility. The national institute for health monitoring published a study in 2012 on the environmental causes of male infertility¹⁴⁷ but this has yet to lead to a shift in infertility policies.
- ▶ The Biomedicine Agency regularly assesses success rate data from MAR centres and is currently working to address disparities among MAR centres¹⁴⁸.
- ▶ Recent debates around access to MAR for same sex couples called into question the need to increase access in general.
- ▶ Doctors, scientists and patients believe stigma, insufficient information, support, education and prevention, as well as research, remain key challenges. They advocate for a National Fertility Plan to be put in place¹⁴⁹.



Reimbursement has helped many couples have access to treatment, but now France is lagging behind in Europe in terms of public debates and policies on infertility.

Maia patient association,
France
July 2016

- ▶ More specifically, patient groups call for a national plan that addresses: information campaigns, research, equitable access across MAR centres, improved diagnosis and medical care, holistic support and increased treatment availability, including specific examinations and medical techniques (i.e. double gamete donation and double donor status regarding gamete donation, embryo screening, compensation for women donating oocytes and self-preservation of oocytes), as well as more inclusive access to treatment for single women and same sex couples¹⁵⁰. Further, stakeholders call for a regulated framework that allows for ethical and non-commercial surrogacy and the registration of children born through surrogacy abroad in the civil register¹⁵¹.
- ▶ The National Consultative Ethics Committee¹⁵² is expected to deliver a 'general' opinion on MAR in spring 2017¹⁵³. Long-term changes (including the revision of the bioethics law) will depend on the outcome of presidential and legislative elections in 2017. Both patient and healthcare professional groups are keen to be a part of these discussions¹⁵⁴.

OVERVIEW

- ▶ The fertility rate in Germany is 1.47 (vs. 1.58 EU average)¹⁵⁵.
- ▶ The 1990 "Embryo Protection Act"¹⁵⁶ and the regional guidelines for reproductive treatment by the States' Medical Associations, regulates access to Medically Assisted Reproduction (MAR) techniques.
- ▶ The 2012 Directive on the "Granting of Aid to Promote Activities of Assisted Reproduction"¹⁵⁷, known as the MAR funding Directive, offers reimbursement in addition to the regular statutory health insurance reimbursement.
- ▶ As of 2015, sperm donation is no longer anonymous. Egg donation and surrogacy are not available.
- ▶ If the age criterion is met by married couples, statutory health insurance reimburses 50% of MAR treatments for the first 3-4 attempts, while the remaining 50% is paid by the couple. In some federal states 25% of the private cost is reimbursed by federal and state governments. As of 2016, non-married couples who meet the age criteria, are eligible to be reimbursed up to 12.5% of their private costs in 6 out of 16 federal states.
- ▶ The Ministry of Family Affairs (BMFSFJ) offers an online portal with information on infertility issues and treatment options¹⁵⁸. Patient organisations offer similar information portals, in addition to organising awareness campaigns¹⁵⁹.
- ▶ According to patient organisations, couples discussing infertility and treatment options with their gynaecologist do not encounter many issues. However, infertility is surrounded by many taboos and is largely perceived as a social, rather than biological, condition¹⁶⁰.
- ▶ Although ethical discussions remain ongoing, patients call for an amendment to the 1990 "Embryo Protection Act" to allow for greater access to treatments such as, egg donation and surrogacy and to improve access to existing treatments like: Embryo Freezing, Preimplantation Genetic Diagnosis (PGD) and Preimplantation Genetic Screening (PGS)¹⁶¹.

Table 1.

KEY FACTS & FIGURES

TOTAL FERTILITY RATE (TFR)¹⁶²

1.47¹⁶³

INFERTILITY RATE

Primary infertility: 2%
Secondary infertility: 8%¹⁶⁴

MEAN AGE OF WOMAN AT THE FIRST CHILDBIRTH

30.9 years¹⁶⁵

FERTILITY TREATMENT SUCCESS RATE

20.5% live birth rate per treatment cycle for In Vitro Fertilisation (IVF) and Intracytoplasmic Sperm Injection (ICSI)¹⁶⁶

REIMBURSEMENT / STATE FUNDING

- ▶ Regarding available treatment options, health insurance reimburses 50% of the costs, while federal and state governments provide 25% respectively to cover the remaining private contributions - available only to married couples (women aged 25-40 and men aged 25-50)
- ▶ As of 2016, non-married couples within the age criteria detailed above, are eligible to receive up to 12.5% reimbursement of their private costs, depending on available supplementary support at the federal level – currently only available in 6 out of 16 federal states¹⁶⁷

AWARENESS RAISING CAMPAIGNS/ INITIATIVES

- ▶ Ministry of Family Affairs (BMFSFJ) information portal "Hinderwunsch"¹⁶⁸
- ▶ Patient organisation information campaign "Wunschkind"¹⁶⁹



INFERTILITY POLICIES

- ▶ The fertility rate in Germany is 1.47 (vs. 1.58 EU average)¹⁷⁰.
- ▶ The 1990 "Embryo Protection Act (Embryonenschutzgesetz)"¹⁷¹ and the regional guidelines for reproductive treatment by the States' Medical Associations regulates access to Medically Assisted Reproduction (MAR) techniques.
- ▶ Egg donation and surrogacy is not available under the "Embryo Protection Act"¹⁷². Preimplantation Genetic Diagnosis (PGD) is allowed under specific conditions and requires approval from a specialised ethics committees. Preimplantation Genetic Screening (PGS) is allowed under limited circumstances. Embryo freezing is possible under certain circumstances as an emergency measure¹⁷³. As of 2015, sperm donation is no longer anonymous, after the German Federal Court of Justice ruled in favour of children's rights to know the identity of their biological father¹⁷⁴.



Sperm donation is not anonymous. In 2015 the German Federal Court of Justice ruled in favour of children's rights to know the identity of their biological father. ”

**Fertility Centre Berlin,
Germany
July 2016**

- ▶ In 2016, the Ministry of Family Affairs (BMFSFJ) advocated for reimbursement of treatment costs for non-married couples, resulting in an amendment to the 2012 Directive on the "Granting of Aid to Promote Activities of Assisted Reproduction"¹⁷⁵.
- ▶ There is a legal vacuum with regard to access to MAR by same-sex couples, as there is no general legal provision limiting the right to MAR based on marital status. However, sexual orientation and marital status influence eligibility and the level of reimbursement available.

SCREENING AND DIAGNOSIS

- ▶ Screening and diagnosis include all standard techniques (non-invasive tests as well as invasive procedures like laparoscopy). As of December 2011, PGD and PGS became legalised forms of screening, but are subject to limitations. Doctors can perform PGD screening only when there is a strong likelihood of passing on a genetic defect by either parent, or when the chances of miscarriage or stillbirth are (genetically) high. PGD tests occur rarely and are only feasible among patients who have already opted for IVF.
- ▶ The Ministry of Family Affairs (BMFSFJ) offers an online portal to provide information on screening¹⁷⁶.
Gynaecologists are the first point of contact. If the causes of infertility are not discovered after the initial screening, the couple is then directed to other specialists such as: andrologists, endocrinologists, urologists, geneticists, psychologists or towards an MAR centre¹⁷⁷.



TREATMENT AND REIMBURSEMENT / STATE FUNDING

- ▶ The following treatments are available: Intrauterine Insemination (IUI)¹⁷⁸, IVF, ICSI and under certain circumstances Embryo Freezing, Polar Body Biopsy (PB), PGD, PGS, Microsurgical Epididymal Sperm Aspiration (MESA), Testicular Sperm Extraction (TESE) and sperm donation.
- ▶ IVF and ICSI can be performed with the sperm of the male partner or donor. 78,000 IVF/ICSI cycles are performed annually, with a delivery rate of 20% per embryo transfer¹⁷⁹, and a cumulative delivery rate of more than 50% after three trials¹⁸⁰.
- ▶ The freezing of fertilised and unfertilised eggs is allowed without time limit, while the freezing of embryos is allowed only under exceptional circumstances (e.g. if the embryo cannot be implanted within the same cycle)¹⁸¹. Reimbursement is only granted to married women¹⁸².
- ▶ Ovum donations, gender selection among generated embryos and surrogacy are not possible.
- ▶ Sperm donation is not anonymous and neither state, nor private health insurers cover the costs of donor insemination, regardless if the couple is married or not¹⁸³.
- ▶ However, the costs of general diagnostic testing prior to treatment and the cost of maternity care are usually covered by statutory insurance¹⁸⁴.
- ▶ As of 1 April 2012, treatments are state funded under the Directive on the "Granting of Aid to Promote Activities of Assisted Reproduction"¹⁸⁵ with the following conditions:
 - Statutory health insurances reimburse 50% of the first 3-4 attempts (depending on the federal state), and some federal states provide 25% respectively of the remaining 50% of private contributions.
 - These conditions are applicable to married couples (women aged 25-40 and men aged 25-50)¹⁸⁶.
- ▶ On 7 January 2016, an amended MAR Funding Directive was entered into force addressing non-married couples:
 - Non-married couples (same age groups as detailed above) can receive up to 12.5% reimbursement from federal and state governments for their private contributions for their first 3 attempts and up to 25% for their 4th attempt – depending on co-participation at federal level. Currently this is only possible in 6 out of 16 federal states¹⁸⁷.
 - Health insurance companies may not reimburse non-married couples, according to a judgment by the Federal Social Court in November 2014¹⁸⁸.
- ▶ Same sex couples and single women are not eligible for reimbursement;
 - The guidelines for the MAR Funding Directive do not explicitly prohibit the insemination of women in a same-sex relationship or single women by a donor, but there are few doctors in Germany who perform this treatment¹⁸⁹.

- ▶ According to patient and healthcare provider (HCP) organisations, the quality of care across the country is perceived as “very good”¹⁹⁰. Data on IVF treatments is collected systematically¹⁹¹.
- ▶ The success rate for IVF and ICSI is 20.5% live birth rate per treatment cycle¹⁹².
- ▶ Germany has 24 private and 106 public MAR clinics¹⁹³.
- ▶ Interest in MAR is estimated to be significantly larger than reflected by documented treatment rates¹⁹⁴.
- ▶ Patient organisations focus on providing access to qualitative information on treatment centres across Germany and Europe. The campaign “Wunschkind” is one example of the many information portals offered by patient organisations¹⁹⁷.
- ▶ The awareness campaign “Ilse” focuses on reproductive rights for same-sex couples¹⁹⁸.



Our infertility campaign, Wunschkind reached out to millions of people helping to inform about options as well as increase social acceptance for married, non-married couples as well as single women seeking infertility treatment. ”

Wunschkind e.V. patient association, Germany
July 2016

Table 2. Treatment Options Available in Germany

Intrauterine Insemination (IUI)
In Vitro Fertilisation (IVF)
Intracytoplasmic Sperm Injection (ICSI)
Embryo Freezing (only allowed in emergency)
Preimplantation Genetic Diagnosis (PGD)
Preimplantation Genetic Screening (PGS)
Polar Body Biopsy (PB)
Microsurgical Epididymal Sperm Aspiration (MESA); Testicular Sperm Extraction (TESE)
Sperm Donation (non-anonymous)

AWARENESS RAISING ACTIVITIES

- ▶ In 2013 the Ministry of Family Affairs (BMFSFJ) launched an online portal “Hilfe und Unterstützung bei ungewollter Kinderlosigkeit” to provide comprehensive information on infertility issues and treatment options. The initiative receives €10 million annually¹⁹⁵.
- ▶ The National Agency for Health Education (BZgA) is responsible for preventing health risks and encouraging healthy lifestyles. They provide general information on reproduction but not on infertility¹⁹⁶.

FUTURE OUTLOOK

- ▶ Although ethical discussions are still ongoing, patient organisations petition for an amendment to the 1990 “Embryo Protection Act” to allow for greater access to treatment options such as egg donation and surrogacy¹⁹⁹. They also call for improved access to embryo freezing, PGD and PGS²⁰⁰.
- ▶ The recent amendment of the MAR Funding Directive to provide partial reimbursement by federal and state governments for non-married couples seeking infertility treatment, might reignite the debate for a revision of the Federal Social Court judgement ruling against reimbursement for non-married couples by health insurance companies.

OVERVIEW

- ▶ The fertility rate in Italy is 1.37 (vs. 1.58 EU average)²⁰¹. Approximately 15% of couples are infertile²⁰².
- ▶ Access to Medically Assisted Reproduction (MAR) is regulated by a 2004 law²⁰³, initially limiting in treatment access, but has since been amended by the Italian Constitutional Court to be less restrictive.
- ▶ In 2015 the Ministry of Health announced an ambitious 'National Plan for Fertility'²⁰⁴ which was activated in September 2016 and focused on education and awareness raising activities to inform citizens about MAR treatment availability, success rates and associated risks.
- ▶ The following treatments are available in Italy: Intrauterine Insemination (IUI), In Vitro Fertilisation (IVF), Intracytoplasmic Sperm Injection (ICSI), Embryo Freezing, Frozen Embryo Transfer (FET), Preimplantation Genetic Diagnosis (PGD), Preimplantation Genetic Screening (PGS), Testicular Sperm Extraction (TESE), and gamete and double gamete and embryo donation²⁰⁵. Single women and same sex couples do not have access to MAR treatments and surrogacy is not available.
- ▶ The majority of MAR treatments for homologous and heterologous fertilisation are covered under the national health system, but the amount of treatment funding varies between regions. This has fostered a practice of "inter-regional health tourism"²⁰⁶.
- ▶ In the last five years, the main awareness campaigns have been organised by fertility clinics, pharmaceutical manufacturers in partnership with policymakers, scientific societies and patient associations. Government initiatives include: an online registry of all authorised MAR centres, creation of 'Fertility Day' and the launch of a regional network of 'family advice bureaux' that act as the first point of contact for individuals seeking information on reproductive health promotion, prevention and psychosocial support.
- ▶ Key issues around infertility are: regional variations in state funded MAR treatments and the need to increase awareness and health literacy on infertility at societal level²⁰⁷. A revised list of health services covered under the public health system, "Livelli essenziali di assistenza" / "Essential levels of care" (LEA), was published on 12 January 2017 and is expected to, over time, equalise regional differences in treatment access²⁰⁸.

Table 1.

KEY FACTS & FIGURES

TOTAL FERTILITY RATE (TFR) ²⁰⁹	1.37 ²¹⁰
INFERTILITY RATE	Approximately 15% of couples ²¹¹
MEAN AGE OF WOMAN AT THE FIRST CHILDBIRTH	31.8 years ²¹²
FERTILITY TREATMENT SUCCESS RATE	10% with Intrauterine Insemination (IUI) 19.4% with In Vitro Fertilisation (IVF) procedures ²¹³
REIMBURSEMENT / STATE FUNDING	Funding varies between regions, however, IVF is generally covered at 65%, depending on a woman's age and the number of previous attempts ²¹⁴
AWARENESS RAISING CAMPAIGNS/ INITIATIVES	<p>Government-sponsored initiatives:</p> <ul style="list-style-type: none"> ▶ National Assisted Reproductive Technologies Registry²¹⁵ - provides information on female and male infertility ▶ Fertile Future Campaign²¹⁶ - provides information on infertility awareness events in different regions and more broadly on fertility ▶ Fertility Day (22nd September)²¹⁷ – focus on infertility



INFERTILITY POLICIES

- ▶ The Italian Health Ministry estimates approximately 15% of all couples suffer from infertility^{218,219}. The fertility rate in Italy is 1.37 (vs. 1.58 EU average)²²⁰.
- ▶ Medically Assisted Reproduction (MAR) treatments in Italy are regulated by "Law n. 40 (Legge 40)" of 19 February 2004²²¹ and MAR guidelines²²² issued in 2015. "Law n. 40" initially set out a series of parameters²²³ limiting access to MAR and the use of embryos for clinical research purposes²²⁴.
- ▶ In 2009 the law was subject to judicial review by the Italian Constitutional Court, which abolished provisions limiting the number and time frame for implantation of fertilised eggs²²⁵. In 2014, the Italian Constitutional Court allowed the use of donor sperm and female gametes in fertility treatments²²⁶.
- ▶ In May 2015, the Italian Ministry of Health presented a comprehensive "National Fertility Plan" (Piano Nazionale per la fertilità)²²⁷, which included education and awareness raising activities to inform citizens about MAR treatment availability, success rates and associated risks. Initial activities began in September 2016.
- ▶ Under "Law n. 40", single women and same sex couples²²⁸ do not have access to MAR treatments and surrogacy is not available²²⁹.



Italy has had low or zero birth rate for years, and if it goes on like this, our economy will be at risk. ”

Beatrice Lorenzin,
Health Minister of Italy,
quoted in September 2014
by ANSA magazine²³⁰

SCREENING AND DIAGNOSIS

- ▶ Under "Law n. 40/2004, couples that are in their "potentially fertile" age"²³¹ have access to diagnosis and treatment.
- ▶ The current "National Fertility Plan" provides the following list²³² of recommended screening techniques:
 - For women: screening for hypogonadotropic hypogonadism, endometriosis, gynecological tumors, HPV, Chlamydia Trachomatis and HIV.
 - For men: screening for prostate cancer, cryopreservation and infectious diseases (e.g. HBsAg, Ab anti-HCV, Ab anti-HIV, CMV Ab anti IgG, Ab anti IgM).
- ▶ Screening and diagnostic testing for infertility are initiated by the patient's general practitioner (GP). The majority of specialised diagnostic tests are provided upon receipt of a co-payment fee, except in certain cases (e.g. economic reasons). Exam costs and the proportion of patient co-payment varies by region, with health federalism differentiating regional health care performance²³³.
- ▶ Access to MAR treatments are only available upon presentation of a "Certificate of Infertility", which can only be obtained after a specialist has assessed the patient's physiological and psychological health status. The certificate is a prerequisite for accessing reimbursed treatment. Further, the specialist must confirm that the nature of the infertility cannot be remedied by other therapeutic means²³⁴. Procedural guidelines from the Ministry of Health require physicians follow a principle of "gradualness" when putting patients forward for MAR treatment. This is done as a means to temper unnecessarily invasive and costly MAR treatments.



In Italy, obstacles of a political nature make it difficult to access MAR treatments. There is a clear orientation of the stark prohibitions that were initially present in the Law 40/2004 and that the Constitutional Court has progressively removed. To date there is not yet adequate financial allocations to ensure the possibility of carrying out treatment cycles through public services and the trend is to limit access to these techniques.

Amica Cicogna patient association,
Italy
July 2016

TREATMENT AND REIMBURSEMENT / STATE FUNDING

- ▶ The following treatments are available in Italy: IUI, IVF, Intracytoplasmic Sperm Injection (ICSI), Embryo Freezing, Frozen Embryo Transfer FET, Preimplantation Genetic Diagnosis (PGD), Preimplantation Genetic Screening (PGS), Testicular Sperm Extraction (TESE) and anonymous gamete and double gamete and embryo donation^{235,236,237}. Regarding embryo donation, there are no rules in place with respect to selection criteria for suitability of embryos used for donation²³⁸.
 - ▶ "Article 7" of "Law n. 40/2004" requires the Ministry of Health to define and regularly update guidelines²³⁹ to ensure MAR procedures and techniques are of high quality (safety) and legal compliance. These guidelines are mandatory for all authorised MAR centres listed in the Ministry of Health's National Registry²⁴⁰.
 - ▶ The majority of MAR treatments (IVF and IUI) for homologous and heterologous fertilisation are covered under the national health system with costs varying by region²⁴¹.
- Over the last twelve years, most regions guarantee the public provision of MARs upon receipt of a co-payment fee, while a few regions, such as Lombardia, provide public treatments without a co-payment fee²⁴². Costs range from approximately 500-1500 EUR per cycle of treatment²⁴³, depending on the region.
 - As of 2016, a number of regions such as: Puglia, Sicily, Basilicata and Campania have exhausted their funds for MAR treatments, resulting in a discontinuation of services, leaving many to pay 100% of treatment costs out-of-pocket. Some couples have resorted to private providers, whose tariffs range from 3500-5500 EUR²⁴⁴. A recent national survey estimates that approximately one third²⁴⁵ of couples choose private MAR centres.
 - On 12 January 2017, the Ministry of Health revised its list of healthcare services covered under the public health system, (the so called "LEA" - "Livelli essenziali di assistenza" - "Essential levels of care"), to include all treatments related to MAR²⁴⁶.

- ▶ State funded MAR treatments (IVF and IUI) are only available to couples upon presentation of a "Certificate of Infertility"²⁴⁷.
- ▶ The "National Fertility Plan" launched a regional network of 'family advice bureaus' to act as the first point of contact for individuals seeking information on reproductive health promotion, prevention and psychosocial support²⁴⁸.
- ▶ With regional variation in MAR treatments, lengthy wait lists (e.g. 29% of couples reported waiting over a year to access treatment from a publicly funded MAR centre in their region)²⁴⁹, have led to the practice of "inter-regional health tourism", with some regions gaining a national reputation amongst infertile patients. The phenomenon ended when public funding from (typically southern) regions for these national centres stopped²⁵⁰.
- ▶ The success rate of IUI and IVF in 2014 remained relatively unchanged and in line with EU data, with an average success rate of 10% for IUI and 19.4% for IVF using fresh gametes²⁵¹. The data represents an average across all age groups.
- ▶ As of 2015, Italy has 63 public and 95 private MAR clinics²⁵².

Table 2. Treatment Options Available in Italy

Intrauterine Insemination (IUI)
In Vitro Fertilisation (IVF)
Intracytoplasmic Sperm Injection (ICSI)
Embryo Freezing; Frozen Embryo Transfer (FET)
Preimplantation Genetic Diagnosis (PGD)
Preimplantation Genetic Screening (PGS)
Testicular Sperm Extraction (TESE)
Gamete Donation

AWARENESS RAISING ACTIVITIES

- ▶ In the last five years, the main awareness campaigns on infertility focused on informing individuals about the role fertility plays in their lives and biological duration /protection through avoidance of unhealthy lifestyle choices.
- ▶ The majority of stakeholders involved are fertility clinics²⁵³ and pharmaceutical manufacturers in partnership with policymakers²⁵⁴, scientific societies²⁵⁵ and patient associations²⁵⁶.
- ▶ State funded campaigns aim to educate individuals on the issue of infertility and the importance of protection as per "Article 2" of "Law n. 40". Every year, the Ministry of Health allocates funding for initiatives such as: print and digital communication campaigns, in partnership with scientific societies (e.g. the Italian Society of Gynecology and Obstetrics)²⁵⁷ and Universities²⁵⁸, with the aim of facilitating specialist led public seminars on fertility protection. The Ministry of Health also manages the online registry (Registro Nazionale Procreazione Medicalmente Assistita) that contains information on all authorised MAR centres (public and private). This allows for the monitoring of activity, the provision of practical answers to frequently asked questions and guidance on how to consult fertility specialists.
- ▶ The Ministry of Health launched an ad-hoc public network of 'family advice bureaus' (consultori familiari)²⁵⁹, to acts as a first point of contact for families seeking information on: reproductive health promotion, protection and psychosocial support.
- ▶ On 22 September 2016, as part of the "National Fertility Plan" the Ministry of Health organised a National Fertility Day²⁶⁰, during which a series of awareness raising initiatives in collaboration with 'local health

corporations' (aziende sanitarie locali [ASLs]), scientific societies and patient organisations took place across all major cities. Promotional leaflets from the campaign sparked public criticism on social media, as they seemed to blame women for putting off child-bearing, appearing uninformed as to the real causes of Italy's low birth rate²⁶¹.

FUTURE OUTLOOK

- ▶ Sources from national patient associations²⁶² have reported that the issue of sexual health and infertility has remained highly politicised and controversial for years. This has influenced policy decisions on the implementation of government programmes around raising awareness about infertility, resulting in campaigns that did not reflect scientific evidence on infertility²⁶³.
- ▶ As announced in July 2016²⁶⁴ and in response to the calls from major national patient associations and scientific communities²⁶⁵, the Ministry of Health reformed the basket of publically funded healthcare services to include all fertility treatments (the so called "LEA" - "Livelli essenziali di assistenza" - 'Essential levels of care') to ensure consistency across the country²⁶⁶. As the reform has just been approved, implementation is expected to begin.
- ▶ The inclusion of "free at the point of delivery" MAR treatments, along with other expected initiatives, are an achievement on the ambitious objectives set forth by the National Plan for Fertility²⁶⁷, and give an optimistic outlook for future development in standards of care and accessibility to MAR. While national patient associations welcome these measures, they highlight the need to amend the new law in alignment with the previous provisions of "Law n. 40/2004", so as to guarantee consistent application of the law as interpreted by the Constitutional Court.

OVERVIEW

- ▶ The fertility rate in Poland is 1.32 (vs. 1.58 EU average)²⁶⁸.
- ▶ Access to Medically Assisted Reproduction (MAR) is regulated under the national "Infertility Treatment" legislation²⁶⁹.
- ▶ Treatment options available in Poland range from: Intrauterine Insemination (IUI), In Vitro Fertilisation (IVF), to Preimplantation Genetic Diagnosis (PGD), Preimplantation Genetic Screening (PGS), anonymous gamete (including double gamete) and embryo donation. While there is no explicit legal provision on surrogacy, the wider framework set by the "Family and Guardianship Code"²⁷⁰ excludes surrogacy in practice.
- ▶ Currently MAR treatments are not covered by the public healthcare system, however, some regional programmes exist.
- ▶ The first "National Programme for Treatment of Infertility with the In Vitro Method (2013-2016)"²⁷¹ expired in July 2016. A new "National Procreation Programme for 2016-2020"²⁷² was adopted in September 2016. The new Programme focuses on optimisation of non-assisted fertility, fertility preservation, diagnosis and healthcare professional training, targeting undiagnosed couples (with projected participation of around 8000 couples within five years of its release). The program does not address couples with an existing infertility diagnosis and does not address MAR treatments.
- ▶ Awareness campaigns are mostly sponsored by multi-stakeholder coalitions including: fertility clinics, scientific and patient representatives, with the focus of increased screening uptake, raising awareness of infertility more generally, infertility in men, its psychological aspects, as well as gamete and embryo donation.
- ▶ Infertility treatment is surrounded by social and bioethical debates in Poland. Stigma, family pressure and competing approaches around the topic of infertility characterise these public debates.

Table 1.

KEY FACTS & FIGURES

TOTAL FERTILITY RATE (TFR) ²⁷³	1.32 ²⁷⁴
INFERTILITY RATE	1.5 million couples per year (around 20% of population of reproductive age) ²⁷⁵
MEAN AGE OF WOMAN AT THE FIRST CHILDBIRTH	29.1 years ²⁷⁶
FERTILITY TREATMENT SUCCESS RATE	31% for In Vitro Fertilisation (IVF) per one embryo transfer ²⁷⁷
REIMBURSEMENT / STATE FUNDING	No reimbursement / state funding for MAR treatments; however, some basic screening examinations are covered ²⁷⁸
AWARENESS RAISING CAMPAIGNS/ INITIATIVES	<p>Patient association awareness campaigns and activities:</p> <ul style="list-style-type: none"> ▶ The Nasz Bocian awareness campaigns focus on the extent of the infertility problem in Poland²⁷⁹, male infertility²⁸⁰, gamete and embryo donation²⁸¹ and awareness activities through the framework of the European Fertility Week, as organised by Fertility Europe in autumn 2016²⁸² <p>MAR centre campaigns:</p> <ul style="list-style-type: none"> ▶ Fertility protection campaign led by the Bocian Infertility Clinic^{283,284} ▶ Infertility education campaign led by the Healthcare Professionals (HCPs) from organisations like the Maternity Institute²⁸⁵ ▶ Information portals on infertility^{286,287}



INFERTILITY POLICIES

- ▶ According to the Polish Gynaecologist Society, there are approximately 1.5 million couples per year diagnosed with infertility (around 20% of the population of reproductive age)²⁸⁸. The fertility rate in Poland is 1.32 (vs. 1.58 EU average)²⁸⁹.
- ▶ Infertility has been identified as one of the reasons for demographic decline by the Government Population Council²⁹⁰. In its 2013 report on the demographic situation in Poland, the Council called for increased family friendly policies, as well as the development and monitoring of fertility protection, screening and treatment programmes²⁹¹.
- ▶ In 2013, the “National Programme for Treatment of Infertility with the In Vitro Method (2013-2016)” was adopted. The Programme outlined the rules for reimbursement / state funding of In Vitro Fertilisation (IVF)²⁹² and granted approximately seventeen thousand couples three full IVF attempts²⁹³. The Programme expired in June 2016 and has not been renewed.
- ▶ In 2015, “Infertility Treatment” legislation²⁹⁴ entered into force, regulating access to MAR treatments, quality standards and management systems for fertility clinics (including an embryo register), as well as gamete and embryo donation. According to art. 21.3 of this legislation embryo donation is compulsory in some cases²⁹⁵. This raised controversy and was viewed by the Nasz Bocian patient group as a violation of the main principles of donation, which is to be conducted voluntarily and not as a form of patient ‘extortion’²⁹⁶.
- ▶ A new “National Procreation Programme for 2016-2020”²⁹⁷ entered into force on 1 September 2016. The programme is targeted at couples who have yet to be diagnosed as infertile (with projected participation of around 8000 couples within five years of its release). The programme focuses on optimisation of non-assisted fertility methods and fertility protection. The programme aims to improve: access to high quality infertility diagnostics and treatment through the creation of reference centres, healthcare professional training programs, increased access to advanced diagnostic examinations and physiological supports, as well as referral to specialised fertility centres²⁹⁸. The new programme does not cover couples with a pre-existing infertility diagnosis and does not address MAR treatments.
- ▶ While the current legal framework does not specifically limit access to MAR treatments based on sexual orientation or marital status, eligibility conditions outlined in the current legislation, in practice, exclude same sex couples and single women from treatment. The Nasz Bocian patient group and the Polish Ombudsman have pointed out that this situation specifically impacts single women, who are deprived of the right to the embryo created from their oocytes before the current legislation came into force²⁹⁹. The “National Procreation Programme” specifically refers to married couples or couples cohabiting in partnership³⁰⁰.

SCREENING AND DIAGNOSIS

- ▶ The 2014, the Polish Society of Reproductive Medicine and Embryology (PTMRIE)³⁰¹ published "Guidelines for Diagnostics and Treatment of Infertility", which covered procedural standards of diagnosis (for both women and men) and analysed potential medical causes. In general, it recommends that diagnostic testing begins after one year of attempted conception without success. In exceptional situations, such as age or pre-existing medical conditions, the waiting period may be lessened.
 - For women: it is recommended to conduct basic gynaecological assessments and physical examinations, including: hormonal exams, imagery examination (including ultrasound (USG), hysterosalpingography (HSG) or hysterosalpingo contrast sonography (HyCoSy), examination of ovaries, laparoscopy and endometriosis examination. HSG, HyCoSy, laparoscopy, and hysteroscopy are state funded.
 - For men: sperm mobility tests³⁰²
- ▶ There is a low uptake of the screening and diagnostic testing in Poland as only basic gynaecological check-ups and ultrasound examination are state funded. Semen analysis and sperm tests are excluded from state funding³⁰³. The new "National Procreation Programme" foresees coverage of basic and advanced diagnostic examinations for couples in the programme (the scope of the necessary examinations is to be decided by the coordinating doctor for the couple)³⁰⁴.
- ▶ Usually gynaecologists are the first point of contact for infertile couples³⁰⁵. According to the Nasz Bocian patient group, the level of knowledge among gynaecologists varies and there is no universally adopted procedures for treating and referring patients experiencing problems with conceiving³⁰⁶.

TREATMENT AND REIMBURSEMENT / STATE FUNDING

- ▶ The following treatments are available in Poland: Intrauterine Insemination (IUI), IVF, Intracytoplasmic Sperm Injection (ICSI), embryo and gamete freezing, Frozen Embryo Transfer (FET), Preimplantation Genetic Diagnosis (PGD), Preimplantation Genetic Screening (PGS), Microsurgical Epididymal Sperm Aspiration (MESA), Testicular Sperm Extraction (TESE), anonymous gamete (including double gamete) and embryo donation³⁰⁷. Current legislation provides for compulsory embryo donation in some cases³⁰⁸. While there is no explicit provision preventing surrogacy, the wider framework set by the "Family and Guardianship Code's" definition of a "mother" excludes surrogacy in practice³⁰⁹. Currently, MAR treatments are not state funded³¹⁰. The new "National Procreation Programme" explicitly states that MAR treatments are excluded from the scheme³¹¹.
- ▶ The "National Programme for Treatment of Infertility with the In Vitro Method (2013-2016)" set the conditions for reimbursement / state funding of infertility treatment to three cycles, where the female patient is under 40 years of age and in a heterosexual partnership³¹². However, as the scheme was not extended, currently all treatments remain uncovered by the public healthcare system. There are some regional programmes in place in Czeszochowa, Lodz, Poznan and Sosnowiec³¹³.
- ▶ The new "2016 National Procreation Programme" foresees state funding of psychological support for couples undergoing screening procedures³¹⁴.
- ▶ Fertility treatment clinics are the main source of information about available treatment options for couples trying to conceive³¹⁵.
- ▶ The quality of infertility treatment in Poland is of the highest European standards, with a success rate of 32% with In Vitro per one embryo transfer³¹⁶.

- ▶ According to the Nasz Bocian patient group, several barriers exist for couples trying to access infertility treatments, such as: lack of state-funding, limited personal financial means, socio-political beliefs, a strong Catholic tradition and stigma³¹⁷.
- ▶ Of the 1.5 million couples facing infertility annually in Poland, 2% are in need of advanced infertility treatment³¹⁸.
- ▶ The number of IVF cycles needed in Poland is estimated around 30,000 cycles per year, with the number of fresh IVF cycles performed in 2013 estimated at 13,000³¹⁹.
- ▶ In 2015, there were 4 public and 37 private clinics in Poland³²⁰.

Table 2. Treatment Options Available in Poland

Intrauterine Insemination (IUI)
In Vitro Fertilisation (IVF)
Intracytoplasmic Sperm Injection (ICSI)
Gamete, Embryo Freezing, Frozen Embryo Transfer (FET)
Preimplantation Genetic Diagnosis (PGD)
Preimplantation Genetic Screening (PGS)
Microsurgical Epididymal Sperm Aspiration (MESA), Testicular Sperm Extraction (TESE)
Anonymous Gamete (including Double Gamete) and Embryo Donation



The 2013-2016 infertility programme had a number of positive effects. It changed the perception of Polish couples towards in-vitro treatment. This method was more widely accepted because the government had recognised that infertility was a medical condition and there were a number of ways to treat it.

Nasz Bocian patient association,
Poland
June 2016



Polish couples are not aware of the growing infertility problem; they believe that it doesn't concern them. ”

Nasz Bocian patient association,
Poland
June 2016

AWARENESS RAISING ACTIVITIES

- ▶ Currently, there is an absence of state funded awareness campaigns. Existing campaigns are mostly led by multi-stakeholder coalitions including: infertility clinics, scientific organisations and patient groups.
- ▶ Since 2013, the number of educational and awareness raising campaigns about infertility have risen. Campaigns target both men and women, focusing on diagnosis and protection, changing perceptions and challenging the taboos around infertility.
- ▶ Most awareness campaigns aim to support the update of screening techniques, raise awareness of infertility in general, infertility in men and the psychological aspects of infertility e.g. the 'TATA' campaign³²¹ and '1in5' campaign³²² organised by the patient group Nasz Bocian, Płodny Polak³²³ and the Płodna Polka campaign³²⁴, led by the Bocian, Gyn Centrum clinic. Since 2012, patient group Nasz Bocian has run a campaign focused on gamete and embryo donation ("Powiedzcie i Rozmawiac")³²⁵.
- ▶ Campaigns sponsored by organisations like the Catholic Church or the Mother and Father Foundation³²⁶ focus on the social consequences of postponing parenthood and promote a non-assisted approach to infertility.
- ▶ The Coalition for a holistic approach to infertility focuses on raising awareness on the need for physiological supports throughout the infertility process³²⁷.

FUTURE OUTLOOK

- ▶ Infertility treatment is surrounded by social and bioethical debates in Poland. Stigma, family pressure and competing approaches around the topic of infertility characterise these public debates.
- ▶ Even though recently withdrawn, there have been a number of attempts to amend the "Infertility Treatment" legislation³²⁸, including amending the definition of an embryo as a child, performing an embryo transfer within 72h (which excludes cryopreservation) and allowing the creation of just one embryo. Should these changes be adopted in the future, the continuity of In Vitro treatment would be uncertain in Poland.



Both long term as well as short term solutions should be considered. First, there should be strong European support for Polish couples; second, fertility should be protected; third, financial support for infertile couples should be granted and fourth, education about infertility problems should start in schools. ”

Nasz Bocian patient association,
Poland
June 2016



OVERVIEW

- ▶ The fertility rate in Romania is 1.52 (vs. 1.58 the EU average)³²⁹.
- ▶ Romania has a “National Programme for In Vitro Fertilisation (IVF) and Embryo Transfer”, which provides partial funding to some couples undergoing IVF treatment³³⁰. The Programme, however, does not cover screening procedures or medication to support fertility during treatment.
- ▶ With no state funded infertility awareness or educational campaigns, understanding of the topic remains poor among the general public. Nevertheless, both patient and healthcare professional associations are active in raising awareness. The patient association SOS Infertilitatea organises an annual National Infertility Awareness Week³³¹ and the AER Embryologists’ Association organises the annual National Infertility Day³³².
- ▶ Affordability is a limiting factor in treatment access, as patients must finance many of the costs independently. Eligibility criteria restrict access to the national reimbursement programme, with a view to maximise the results compared to the allocated budget³³³.
- ▶ While there is no indication of a future infertility strategy, an exchange of letters between SOS Infertilitatea and the Ministry of Health does offer an optimistic outlook, as they are aligned in their objective to increase the number of treatments offered³³⁴. These potential changes have also been supported by the AER Embryologists’ Association and other healthcare professional associations together with the National Transplant Agency³³⁵.
- ▶ Overall, in 2016 there were 22 licensed MAR centres³³⁶, including 13 that offer state funded IVF treatment³³⁷.

Table 1.

KEY FACTS & FIGURES

TOTAL FERTILITY RATE (TFR)³³⁸

1.52³³⁹

INFERTILITY RATE

Primary infertility 1.6%
Secondary infertility 15.9%³⁴⁰

MEAN AGE OF WOMAN AT THE FIRST CHILDBIRTH

29.9 years³⁴¹

FERTILITY TREATMENT SUCCESS RATE

41.33% success rate (from the In Vitro Fertilization Programme, of female patients under 40, with AMH >1). This is not the national average success rate, but the IVF pregnancy success rate from the reimbursed Programme (out of 251 cycles, 103 chemical pregnancies were registered – data concerning clinical pregnancies was not reported)³⁴²

REIMBURSEMENT / STATE FUNDING

State funding is capped at RON 6188 (approximately EUR 1375) per couple, with a total of 760 couples in 2016³⁴³

AWARENESS RAISING CAMPAIGNS/ INITIATIVES

Patient association campaigns:

- ▶ Since its establishment in 2008, the SOS Infertilitatea Association³⁴⁴ has organised advocacy activities including:
 - The annual National Infertility Awareness Week (since 2012)
 - ONGFest³⁴⁵ – an annual forum dedicated to NGOs (since 2010)
 - An online platform (blog, forum, newsletter) and active social media presence³⁴⁶
 - Press articles and TV interviews³⁴⁷

Healthcare professionals’ (HCP) campaigns:

- ▶ The AER Embryologists’ Association organise the annual National Infertility Days, scientific symposia, social media engagement for patients and the general public³⁴⁸
- ▶ The Romanian Society for Reproductive Medicine provides educational videos on male and female infertility³⁴⁹
- ▶ The Romanian Society of Fertility and Assisted Reproduction runs several fertility education programs³⁵⁰



INFERTILITY POLICIES

- ▶ The fertility rate in Romania is 1.52 (vs.1.58 the EU average)³⁵¹.
- ▶ Infertility is not a key health policy topic and remains absent from other related policy frameworks such as demographic or employment policies³⁵².
- ▶ There is no specific law regulating Medically Assisted Reproduction (MAR) in Romania, despite six attempts since 2004 by national MPs³⁵³. In 2009, a written question to the European Commission raised the need for a legislative framework at national level, indicating political interest amongst Romanian MEPs. A legislative draft is currently under discussion³⁵⁴.
- ▶ Currently, MAR is regulated under the general health policy framework legislation and some MAR aspects are captured under 'Transplantation legislation'³⁵⁵. Since 2017, data on reproduction has been part of the online transplant registry³⁵⁶.
- ▶ Gamete, double gamete and embryo donation lack regulation in Romania³⁵⁷.
- ▶ The 2014-2020 "National Health Strategy Action Plan" mentions the need for at least one general practitioner (GP) with specialised training to offer counselling in reproductive health or family planning. This governmental priority is part of the aim to increase access to integrated family planning/ reproductive health services³⁵⁸.
- ▶ The "National Programme for Human Organs, Tissues and Cell Transplants"³⁵⁹ includes the "Programme for In Vitro Fertilisation (IVF) and Embryo Transfer"³⁶⁰, providing rules on partial funding for IVF treatments. These advances were largely possible due to patient associations' efforts and healthcare professionals' support.
- ▶ The objective of the IVF Programme was to "increase the number of IVF procedures by 10% from previous years and increase the number of births resulting from this procedure"³⁶¹. The National Programme was first implemented between 2011-2012, resulting in more than 300 live births. Subsequently, between 2013-2014, the programme was put on hold due to political reasons and then reinstated by the Romanian Ministry of Health in 2015³⁶².
- ▶ The Romanian legal framework does not make distinctions (e.g. marital status or sexual orientation) when it comes to accessibility of MAR treatments. This may be due in part to the absence of legislation in the area. The import of embryos is not permitted and the import and export of reproductive cells require special authorisation from the competent authority³⁶³.



Patient empowerment is a key element of a patient-centred health system. We do believe in the five 'E' of Empowerment: Education, Expertise, Equality, Experience, and Engagement. ”

SOS Infertilitatea patient association, Romania
February 2017



TREATMENT AND REIMBURSEMENT / STATE FUNDING

- ▶ Intrauterine Insemination (IUI), In Vitro Fertilization (IVF), Intracytoplasmic Sperm Injection (ICSI), Embryo Freezing, Frozen Embryo Transfer (FET), Preimplantation Genetic Diagnosis (PGD), Preimplantation Genetic Screening (PGS), gamete donation and surrogacy are the main treatments available in Romania³⁷⁰.
- ▶ IVF and Embryo transfer remain the only partially funded treatment options in Romania, with IVF partially funded under the National Programme. Funding from the National Programme covered 761 IVF procedures between 2015-2016. The maximum amount of treatment expenses covered is RON 6188 per couple (approximately EUR 1375)³⁷¹.
- ▶ In order to be accepted into the National Programme, couples must meet certain eligibility criteria (e.g. a recommendation to undergo IVF by HCP, be insured by the national healthcare system, a female between 24-40 years of age, have a body mass index between 20-25, an ovarian reserve of AMH >1.1 ng/ml, have the necessary documentation, screening results, legal documents, respective certificates and medical records etc.)³⁷².
The programme only covers part of the costs of one IVF attempt per couple, necessary medical exams and medication are not included³⁷³. A couple accepted into the programme have coverage for certain procedures that support the IVF attempt such as: egg retrieval, sperm processing, egg insemination, embryonic transfer and case evolution monitoring, up to a maximum amount of approx. EUR 1375³⁷⁴.
- ▶ Currently, the Ministry of Health has approved a list of 13 MAR clinics (11 private and 2 public clinics) to implement the state funded programme for IVF treatments. As each clinic has its own internal committee that reviews and approves applications, couples must



It is necessary that some gynaecologists and GPs undergo training to recognise the problem of infertility. This would help to know what screenings to recommend – women can go on for years getting tested, only to discover that it is their partner who has a fertility problem.

**SOS Infertilitatea patient association, Romania
July 2016**

SCREENING AND DIAGNOSIS

- ▶ There are mandatory and strict conditions that a clinic must fulfil in order to obtain license from the Competent Authority³⁶⁴. In addition, each MAR clinic has standard operating procedures and guidelines³⁶⁵.
- ▶ An embryology laboratory guideline is currently under development and expected to be available in 2017³⁶⁶.
- ▶ Screening methods are not covered under the national reimbursement programme, limiting access to treatment based on the patient's ability to pay.
- ▶ Access to infertility treatments remains low due to a lack of available information³⁶⁷. GPs and/or gynaecologist are typically the first point of contact for patients experiencing difficulties conceiving.
- ▶ The number of referrals to infertility specialists from GPs or family doctors is low³⁶⁸. However, the 2014-2020 National Health Strategy Action Plan mentions the need for at least one GP per territorial unit to have specialised training so as to offer counselling in reproductive health or family planning³⁶⁹.

undergo extensive review in order to be accepted into the programme and gain approval for partial funding by the Ministry of Health³⁷⁵.

- ▶ It is mandatory to undergo a psychological evaluation prior to MAR treatment³⁷⁶. During and after treatment, psychological therapy is not mandatory but it is recommended³⁷⁷. With regard to donation, it is mandatory to obtain psychological approval³⁷⁸. NGOs also offer psychological support and guidance programs³⁷⁹.
- ▶ IVF procedures performed through this programme have a success rate of 103 confirmed chemical pregnancies out of 251 procedures (success rate of 41.33%)³⁸⁰.
- ▶ Overall, in 2016 there were 22 licensed MAR centres³⁸¹, including 13 that offer reimbursed IVF treatment³⁸².

Table 2. Treatment Options Available in Romania

In absence of MAR legislation and no explicit restriction, the treatments below are theoretically available.

Intrauterine Insemination (IUI)
In Vitro Fertilisation (IVF)
Intracytoplasmic Sperm Injection (ICSI)
Gamete, Embryo Freezing, Frozen Embryo Transfer (FET)
Preimplantation Genetic Diagnosis (PGD)
Preimplantation Genetic Screening (PGS)
Microsurgical Epididymal Sperm Aspiration (MESA), Testicular Sperm Extraction (TESE)
Anonymous Gamete (including Double Gamete) and Embryo Donation



Romania needs a coherent public policy in order to financially support couples that want to have a child. ”

SOS Infertilitatea patient association, Romania
July 2016

AWARENESS RAISING ACTIVITIES

- ▶ There is no state funded awareness campaign on infertility. As a result, patient groups petition for more action, at both the national and European levels, in order to raise awareness on infertility issues³⁸³.
- ▶ Both patients and healthcare professionals are active in trying to raise awareness and advocate for better access to fertility treatment and a national fertility strategy³⁸⁴. The patient association, SOS Infertilitatea, has been organising annual National Infertility Awareness Weeks since 2012. As of 2016, this has been incorporated into the European Fertility Week. In 2016, the awareness campaign took place between 31 October and 6 November³⁸⁵.



Governmental and non-governmental organisations at national and European level, must work together to address the gaps in our understanding of the causes of infertility, both female and male and to increase opportunities for prevention. Important partners in these efforts should include the scientific community, health care professionals, insurance providers, industry, non-profit organisations and organisations representing people struggling with infertility. ”

ESHRE representative in Romania, July 2016

- ▶ Doctors and fertility specialists organised similar activities. With the AER Embryologists' Association, the Romanian Society of Reproductive Medicine and the Romanian Society for Fertility and Assisted Reproduction organising a National Infertility Day annually, in addition to regular social media engagement, scientific symposiums and educational videos³⁸⁶.
- ▶ Moreover, there is a need for awareness and educational campaigns in schools and universities, as well as activities aimed at informing people who wish to postpone conceiving³⁸⁷.

FUTURE OUTLOOK

- ▶ Draft MAR legislation is currently under discussion and it remains to be seen whether it will be adopted in 2017³⁸⁸. There were six other unsuccessful attempts to pass such legislation in the past.
- ▶ Currently, there is strong evidence to support the continuation of the IVF Programme in 2017 despite uncertainty around the budget allocation.
- ▶ An exchange of letters between SOS Infertilitatea and the Ministry of Health does signal positive steps towards increasing the number of infertility treatments offered³⁸⁹. SOS Infertilitatea, the AER Embryologists' Association and other healthcare professional associations together with the National Transplant Agency advocate and support an increase³⁹⁰.

OVERVIEW

- ▶ The fertility rate in Spain is 1.32 (vs. 1.58 EU average)³⁹¹.
- ▶ Access to Medically Assisted Reproduction (MAR) techniques was first regulated in 1988³⁹². At present, "Law 14/2006"³⁹⁴ provides the main legislative framework.
- ▶ Treatments range from Intrauterine Insemination (IUI) to double gamete and embryo donation. Surrogacy is not available.
- ▶ The public health system benefits from a positive reputation. Where infertility is concerned, patient representatives report couples tend to choose private fertility centres over clinics in the public healthcare system due to lengthy wait lists and information gaps³⁹⁴.
- ▶ Eligibility for state funded treatment in the public healthcare system is subject to an infertility diagnosis. Couples seem to encounter difficulties with gynaecologist referrals to fertility specialists³⁹⁵. According to patient representatives, there is a gap in accessible information on: the process (from screening and diagnosis to treatment), wait times and services offered (e.g. treatment options have limitations due to donation dependency)³⁹⁶.
- ▶ Infertility treatment services provided in a publically funded setting are fully covered by the Spanish national healthcare system. Couples need to pay for medicines. Medicine reimbursement schemes vary by region (e.g. Cataluña reimburses 25%).
- ▶ There is no state funded campaigns on infertility. Healthcare professional organisations, patient associations and foundations provide information to the public through their websites.
- ▶ Spain is one of the main destination countries for infertility treatment.

Table 1.

KEY FACTS & FIGURES

TOTAL FERTILITY RATE (TFR) ³⁹⁷	1.32 ³⁹⁸
INFERTILITY RATE	800,000 couples ³⁹⁹
MEAN AGE OF WOMAN AT THE FIRST CHILDBIRTH	31.8 years ⁴⁰⁰
FERTILITY TREATMENT SUCCESS RATE	24.4% success rate with In Vitro Fertilisation (IVF), Intracytoplasmic Sperm Injection (ICSI) or combination therapy) at national level – this rate refers to pregnancy per initiated cycle ⁴⁰¹
REIMBURSEMENT / STATE FUNDING	Public health services, including infertility treatment, are free for Spanish residents, with approximately 25% reimbursement for medications depending on the region ⁴⁰²
AWARENESS RAISING CAMPAIGNS/ INITIATIVES	<p>MAR centres:</p> <ul style="list-style-type: none"> ▶ Information platform by Institute for the Study of Infertility⁴⁰³ ▶ Infertility education blogs by Gestar MAR Group⁴⁰⁴ <p>Foundations:</p> <ul style="list-style-type: none"> ▶ Information portal by Fundació Puigvert⁴⁰⁵ ▶ Information portal by Fundación Jiménez Díaz⁴⁰⁶



INFERTILITY POLICIES

- ▶ More than 800,000 couples are estimated to be infertile^{407,408}. The fertility rate in Spain is 1.32 (vs. 1.58 EU average)⁴⁰⁹.
- ▶ The national health authority addresses infertility as part of reproductive and sexual health, placing a stronger emphasis on family planning⁴¹⁰. Issues around infertility are not addressed in other policy frameworks such as, healthcare or demographic policies (e.g. "Integral Support Plan to the Family")⁴¹¹. There are some workplace measures that are directed at maternal health (e.g. maternity leave, reduced working hours for child rearing), but policies and strategies informing the public about infertility and the consequences of certain practices, on reproductive capacity, remain absent⁴¹².



There is a general issue with recognising infertility as a problem. Infertility treatments are regarded as a choice, similar to aesthetic treatments. ”

Dr Diana Guerra, Spanish Infertility Patient Association - Genera (dissolved in 2016), Spain
July 2016

- ▶ Access to Medically Assisted Reproduction (MAR) is addressed under the "National Law 14/2006"⁴¹³, which evolved from the "National Law 35/1988"⁴¹⁴. The law authorises the National Commission for Assisted Human Reproduction⁴¹⁵ to provide advice and guidance on the use of MAR. The same law requires establishment of an Official Registry that records donor information, type of donation and MAR centres' activities. In 1993, the Spanish Society of Fertility, the professional organisation representing fertility healthcare providers, established a parallel official registry⁴¹⁶. This registry is now official and mandatory for all MAR centres. It includes information on the activity of MAR centres but not donor information⁴¹⁷. All Spanish clinics are required to submit cycle data to the registry⁴¹⁸.
- ▶ According to a 2009 comparative legal study, the "National Law 14/2006" is more flexible and permissive compared to other EU countries⁴¹⁹. The law regularly updates its treatment listings as science evolves, subject however to the authorisation of the National Commission for Assisted Human Reproduction⁴²⁰. The law allows access for single women (with the help of "embryo banks") and donation is free and anonymous. Surrogacy is not available⁴²¹.



There is a public view that infertility arises from the freely-taken decision by couples to postpone maternity and that as a result, couples must accept the consequences of this decision. ”

Jose A. Castilla,
ESHRE representative in Spain
September 2016

- ▶ Additionally, the "Royal Decree Law 9/2014"⁴²², establishes standards of quality and safety for donation, procurement, testing, processing, preservation, storage and distribution of tissues and human cells, as well as coordination and operating standards for working with patients.
- ▶ There are no legal barriers in accessing MAR based on sexual orientation or marital status⁴²³.

SCREENING AND DIAGNOSIS

- ▶ MAR guidelines for healthcare professionals are established by regional communities. For example, the Andalusian Health Authority published guidelines⁴²⁴ in 2006 to support gynaecologists and obstetricians in the screening and diagnosis process.
- ▶ The Spanish national health system covers basic infertility screening for couples experiencing difficulties conceiving. Tests are only conducted when symptoms present (e.g. varicoceles detected through semen analysis or hormonal analysis in response to amenorrhoea). At present, there are no proactive screening procedures for couples not actively trying to conceive⁴²⁵.
- ▶ General practitioners (GPs) or gynaecologists are the first point of contact for patients. The screening and diagnostic process begins with an informational consult, during which time a patient's clinical and family history is taken, as well as information on environmental factors, work routine and lifestyle choices, so as to ascertain how fertility may be affected. Post consult, the patient receives an infertility certificate, confirming the diagnosis and is then referred to a fertility specialist.
- ▶ Due to the lack of preventive screening procedures⁴²⁶ and lengthy wait times for diagnostic services within public healthcare settings, the process to referral can be extensive⁴²⁷.
- ▶ Patient preference for private fertility centres for screening and diagnosis, is largely due to the fact that majority of the techniques offered are free of charge and therefore, widely accessible⁴²⁸.



In general, patients lack information about their rights regarding fertility services. ”

Dr Diana Guerra, Spanish Infertility Patient Association - Genera (dissolved in 2016), Spain
July 2016

TREATMENT AND REIMBURSEMENT / STATE FUNDING

- ▶ The following treatments are available: Intrauterine Insemination (IUI), IVF, ICSI, pre-embryo transfer, Embryo Freezing, Frozen Embryo Transfer (FET), Preimplantation Genetic Diagnosis (PGD), Preimplantation Genetic Screening (PGS), gamete, double gamete and embryo donation⁴²⁹. Surrogacy is not available in Spain⁴³⁰. ICSI is the most widely used treatment procedure⁴³¹. According to patient and healthcare professional organisations, egg donation is less frequent due to limited altruistic donations^{432,433}. Assisted insemination can be performed with the sperm of the male partner or with a donor.
- ▶ MAR treatments are state funded for therapeutic purposes (e.g. individuals diagnosed as infertile due to medical condition(s) or if hereditary diseases are suspected to impact the pregnancy or child).
- ▶ In order for couples or single women to be eligible for treatment, certain criteria must be fulfilled (e.g. females aged 18-40 years, men aged 18-55 at the start of infertility screening, no previous children and at least one year of actively trying to conceive spontaneously)⁴³⁴. Marital status and sexual orientation are not factors in determining eligibility. MAR clinics must have approval to operate from the Ministry of Health.
- ▶ Treatment reimbursement schemes differ by regional community⁴³⁵. While the Spanish health system is highly regarded in terms of quality, safety, effectiveness and patient-centricity, couples face long wait times to undergo treatment. Couples with means often choose private clinics for treatment, as they have competitive service offerings⁴³⁶.
- ▶ The national average success rate of fertility clinics in Spain is approximately 24.4% with IVF, ICSI or combination therapy⁴³⁸.



Patients tend to seek diagnosis and treatment at private clinics to avoid long wait lists in publicly-owned hospitals and ensure access to an effective and rapid fertility technique. ”

Dr Diana Guerra, Spanish Infertility Association - Genera (dissolved in 2016)
July 2016

- ▶ Spain is a preferred destination for infertility treatment because of its progressive legal framework compared to other EU countries (e.g. treatment access for women over the age of 18 despite marital status or sexual orientation and free anonymous donation, high quality of care and treatment success rate⁴³⁸). Spain has a high level of infertility professionals, excellent facilities and advanced medical technologies⁴³⁹.
- ▶ As of 2015, Spain had 41 public and 197 private clinics⁴⁴⁰.
- ▶ According to ESHRE data, the number of fresh and FET cycles performed in 2012 was 31,203 and 11,736 respectively⁴⁴¹.
- ▶ It is estimated that 3% of new-borns were conceived through fertility treatments (116,688 cycles performed in 2014⁴⁴²).

Table 2. Treatment Options Available in Spain

Intrauterine Insemination (IUI)
In Vitro Fertilisation (IVF)
Intracytoplasmic Sperm Injection (ICSI) and pre-embryo transfer
Embryo Freezing; Frozen Embryo Transfer (FET)
Preimplantation Genetic Diagnosis (PGD)
Preimplantation Genetic Screening (PGS)
Gamete, Double Gamete and Embryo Donation (anonymous)

AWARENESS RAISING ACTIVITIES

- ▶ There is currently no state funded awareness campaigns on infertility. According to patient associations, in the past there were multiple government led education campaigns aimed at pregnancy prevention and family planning, but nothing on infertility education⁴⁴³.
- ▶ The healthcare professional association that represents infertility specialists, the Spanish Society of Fertility,⁴⁴⁴ undertakes awareness raising activities that provide information on infertility, MAR techniques and current legislation through its website⁴⁴⁵.
- ▶ According to patient organisations, patient groups are not very active in Spain⁴⁴⁶. This is mainly due to the

novelty of patient advocacy in Spain, as well as insufficient public funding for patient organisations. There are however two patient organisations that regularly undertake awareness raising activities in the area of infertility, namely the National Association for Infertility Problems⁴⁴⁸ and the National Infertility Network Association,⁴⁴⁹ which also serves as support group for couples affected by infertility.

- ▶ Patient organisations, healthcare professional associations and foundations^{449,450,451} run online information portals and offer support (sometimes psychological). Hospitals, fertility centres and clinics have their own educational campaigns about infertility and MAR techniques. The aim of these informational websites is to raise confidence in the efficacy of treatments, particularly within public hospitals, centres and clinics^{452,453,454,454,456,457,458}.
- ▶ Most awareness raising activities focus on female infertility, however some centres have launched initiatives that address the causes of male infertility.

FUTURE OUTLOOK

- ▶ National debate remains active around patient choice and reproductive rights^{459,460}. Although this is a social debate, it has influence on access and availability of MAR treatments.
- ▶ Private clinics are expected to continue to lead in the area of infertility practice, due to lengthy wait times and limited information on treatment access and availability in publically funded hospitals.
- ▶ Healthcare professionals advocate on the importance of: national campaigns to combat lifestyle behaviours that affect reproductive capacity (obesity, smoking, sexually transmitted diseases, etc.), gamete donation and the need for increased human and physical resources within the publically funded system.
- ▶ Spain's "modernised" law⁴⁶¹ and reputation for high quality clinical standards, continues to attract single women, infertile and same sex couples, to its treatment centres⁴⁶².



OVERVIEW

- ▶ The fertility rate in Sweden is 1.88 (vs. 1.58 EU average)⁴⁶³.
- ▶ Access to Medically Assisted Reproduction (MAR) is guided by the 2014 "Nationwide Infertility Recommendation" from SALAR, the Swedish Association of Local Authorities and Regions⁴⁶⁴, which outlines the framework for cooperation between regions and local communities and their respective healthcare programmes and supporting guidelines.
- ▶ The following treatments are available in Sweden: hormonal treatment, surgical treatment, Intrauterine Insemination (IUI), In Vitro Fertilisation (IVF), Intracytoplasmic Sperm Injection (ICSI), Embryo Freezing, Frozen Embryo Transfer (FET), Preimplantation Genetic Diagnosis (PGD) and non-anonymous gamete donation. Embryo donation and surrogacy are not available.
- ▶ There are no legal barriers to accessing treatment based on marital status or sexual orientation.
- ▶ MAR is state funded under the public healthcare system. All authorised clinics in Stockholm and some private clinics on contract with the public healthcare authority offer tax subsidises for MAR⁴⁶⁵. Otherwise, reimbursement for treatment in private clinics is limited to medication (if prescribed in Sweden).
- ▶ Awareness raising activities are carried out by several stakeholders, with governmental guidelines, patient organisation campaigns and healthcare provider initiatives, playing a significant role in understanding regional variation in patient access to MAR treatments.
- ▶ Key issues around infertility treatment include: significant regional variation in access to MAR treatments, wait times and availability of psychological counselling, as well as age restrictions and non-anonymous gamete donation.

Table 1.

KEY FACTS & FIGURES

TOTAL FERTILITY RATE (TFR)⁴⁶⁶	1.88 ⁴⁶⁷
INFERTILITY RATE	8-9% of all couples (c.723,370 couples, out of a population of 9 644,864) ⁴⁶⁸
MEAN AGE OF WOMAN AT THE FIRST CHILDBIRTH	31 years ⁴⁶⁹
FERTILITY TREATMENT SUCCESS RATE	28% with standard In Vitro Fertilisation (IVF), 27% with Intracytoplasmic Sperm Injection (ICSI), 22% with treatments using 'fresh' eggs and 21% with treatments using frozen eggs ⁴⁷⁰
REIMBURSEMENT / STATE FUNDING	<ul style="list-style-type: none"> ▶ Almost complete coverage within public healthcare system. ▶ Reimbursement is limited only to medication (if prescribed in Sweden) in private clinics.
AWARENESS RAISING CAMPAIGNS/ INITIATIVES	<ul style="list-style-type: none"> ▶ SRHR initiative: implementing national sexual and reproductive health rights strategy (Government-sponsored)⁴⁷¹ ▶ 'Longing' campaign: raising patients legal right to MAR (Third party-sponsored)⁴⁷² ▶ 'Support line' initiative: Allows single women talk to healthcare professionals (third party-sponsored/ HCP-led)⁴⁷³



INFERTILITY POLICIES

- ▶ The fertility rate in Sweden is 1.88 (vs. 1.58 EU average)⁴⁷⁴. It is estimated that 8-9% of couples are infertile⁴⁷⁵.
- ▶ In 2014, the Swedish Association of Local Authorities and Regions (SALAR) published a "Nationwide Infertility Recommendation"⁴⁷⁶, which outlines the national policies for Medically Assisted Reproduction (MAR), including: eligibility criteria, age restrictions and number of treatments covered by public reimbursement⁴⁷⁷. Though not mandatory, local authorities and regions across Sweden are currently implementing the SALAR recommendations⁴⁷⁸.
- ▶ In 2014, the Public Health Agency of Sweden and the Swedish Board of Health and Welfare presented a "National Strategy for Sexual and Reproductive Health and Rights (SRHR)"⁴⁷⁹ for consideration by government, with the aim of alignment with international guidelines on SRHR.
- ▶ The "Generic Integrity Act (2006:351)"⁴⁸⁰ stipulates that married couples, registered partners, cohabiting partners and single women may undergo IVF⁴⁸¹.
- ▶ As of 2005, same sex couples may also access MAR treatments⁴⁸² and in January 2016, the Swedish Parliament adopted legislation increasing access for

single women to MAR treatments. The legislation came into effect on 1 April 2016. The standard medical evaluation (taking into account both physiological and psychological conditions) used for couples, is also employed when assessing single women⁴⁸³.

SCREENING AND DIAGNOSIS

- ▶ The "National recommendation"⁴⁸⁴ allows couples to seek help/treatment after one year of attempted conception without success. Diagnosis in Sweden is determined through an 'infertility investigation', where both physiological and psychological conditions are evaluated⁴⁸⁵.
- ▶ The infertility investigation takes approximately four weeks and includes the following examinations⁴⁸⁶:
 - For both men and women: HIV, hepatitis B, hepatitis C, HTLV I-II, syphilis (if IVF is expected)
 - For men: sperm test (as per WHO and ESHRE guidelines regarding the test⁴⁸⁷). Stockholm and Gotland Regional Healthcare schemes offer full andrological investigation for patients with abnormal results⁴⁸⁸.
 - For women: examination of the ovaries and uterus with ultrasound, blood test to determine ovulation function and examination of the fallopian tubes are among the most common tests performed.
- ▶ Infertility investigations are provided by both public and private healthcare professionals. Private clinics are overseen by local authorities. Couples and single women may apply for an infertility investigation through the local authorities, but may receive evaluation and eventually treatment by a private clinic, with financing from the former. According to IVF Sweden, medical investigations by a private clinic cost between EUR 300–500 per couple, as compared to a public medical investigation, where the patient fee ranges from EUR 30–40⁴⁸⁹.
- ▶ The referral process is relatively the same, regardless of a patient's choice to use the public healthcare system or private clinic. Infertile couples begin by contacting a healthcare professional (HCP) in order to initiate an infertility investigation. This can be performed at a gynaecological clinic, a hospital women's clinic or in private clinics with fertility specialists. Patients may also go to a health centre, where a doctor will refer them to a specialist⁴⁹⁰.



The reimbursement condition of upper age limit excludes a lot of women at this early stage. Since the mean age at first birth is almost 30 years old, a woman who undergoes both investigation and IVF might very well be over 40 at the time of the treatment even if she starts at a 'usual age'.

Barnlängtan patient association,
Sweden
July 2016

TREATMENT AND REIMBURSEMENT / STATE FUNDING

- ▶ The following MAR treatments are available in Sweden: Intrauterine Insemination (IUI), IVF, ICSI, Embryo Freezing, Frozen Embryo Transfer (FET), Preimplantation Genetic Diagnosis (PGD) and non-anonymous gamete donation. Embryo donation and surrogacy are not available under the law. Non-anonymous sperm and egg donation is available. At the age of maturity, a child has the right to know who their donor was. He/she may refer to the clinic where the treatment was performed to gain this information⁴⁹¹.
- ▶ Based on the results of the infertility investigation, couples and single women are recommended various MAR treatment options across the country.
- ▶ In accordance with the SALAR recommendation, the public healthcare system covers the following treatments: an infertility investigation within 3 months of initiating the process, six IUI treatments, three IVF cycles (where necessary an AID, IVF-D, and/or IVF combination therapy) and Embryo Cryopreservation after adequate IVF. The recommendations also state that all cryopreserved embryos should be used before a new treatment of follicle stimulating hormones begins⁴⁹².
- ▶ Reimbursement covers all MAR treatments performed in the public healthcare system. Private clinic costs are generally paid out of pocket by patients, with costs varying by region and reimbursement limited to medication⁴⁹³. All authorised clinics in Stockholm and some private clinics on contract with the public healthcare authority offer tax subsidises for MAR⁴⁹⁴. Three fresh IVF cycles and all frozen cycles from these treatments are free of charge for infertile couples and single women under the following conditions: women below 40 and men below 56 years of age, at least one year of infertility, no children of their own and a BMI for women below 35kg/m²⁴⁹⁵. As of 2005, IVF treatments are considered a fringe benefit by the Skatteverket (Swedish public tax authority). Couples/single women can benefit from a salary deduction of approximately 30-55% of their cost, if an agreement is reached beforehand with their employer⁴⁹⁶.
- ▶ There is regional variation in access to MAR treatments, especially with regards to wait times and psychological counselling availability⁴⁹⁷.
- ▶ According to a patient organisation representative, the quality of MAR treatments is generally high, but many patients lack psychological counselling support⁴⁹⁸.

- ▶ Success rates in Sweden are generally high: 28% with standard IVF and 27% with ICSI. In 2013, 3.6% of all children in Sweden were considered an "IVF baby"⁴⁹⁹.
- ▶ As of 2015, Sweden had 6 public and 10 private infertility clinics⁵⁰⁰.
- ▶ According to ESHRE data with regard to IVF, the number of cycles performed in 2012 was 11,132 of fresh cycles vs. 5,809 of Frozen Embryo Transfer (FET)⁵⁰¹.



Many of our members give examples of MAR treatment processes with zero psychological support. All focus is on the medical aspect of the treatment, an issue for many patients. ”

Barnlängtan patient association, Sweden
July 2016

Table 2. Treatment Options Available in Sweden

Hormonal Treatment
Surgical Treatment if: (Woman) fallopian tubes are damaged, endometriosis has occurred or to correct changes in the uterine cavity; (Man) surgical sperm recovery is needed
Intrauterine Insemination (IUI)
In Vitro Fertilisation (IVF)
Intracytoplasmic Sperm Injection (ICSI)
Embryo Freezing; Frozen Embryo Transfer (FET)
Preimplantation Genetic Diagnosis (PGD)
Microsurgical Epididymal Sperm Aspiration (MESA); Testicular Sperm Aspiration (TESE); Percutaneous Epididymal Sperm Aspiration (PESA)
Non-anonymous Gamete Donation

AWARENESS RAISING ACTIVITIES

- ▶ Awareness raising of infertility in Sweden is carried out by several stakeholders. Governmental guidelines, patient organisation campaigns and healthcare provider initiatives all play a significant role. Efforts are generally focused on addressing regional variation and the country wide adoption of national guidelines and recommendations.
- ▶ The SRHR report highlights the need to raise awareness about male infertility. One particular suggestion is to strengthen knowledge about andrology and male infertility options as well as counselling on wanting or not wanting children⁵⁰².
- ▶ Barnlängtan (meaning 'Child longing') is a patient organisation focused on infertility issues, whose advocacy work aims to raise awareness among healthcare providers. According to the organisation, the biggest challenges are in regional variation of treatment availability and the 'general ignorance of infertility issues within the public healthcare system'. One campaign in particular, 'Längtan' (meaning 'Longing'), focuses on the patient's right to treatment⁵⁰³.
- ▶ IVF Sverige (IVF Sweden), an IVF treatment provider in the Nordic region, focuses on increasing the availability of IVF with donated sperm, currently only two clinics in the country offer this treatment⁵⁰⁴.
- ▶ Statens medicinsk-etiska råd (SMER, the Swedish National Council on Medical Ethics), regularly provides reports on the ethical aspects of infertility, raising awareness on the scientific progress made in MAR treatments⁵⁰⁵.

FUTURE OUTLOOK

- ▶ As acknowledged by IVF Sweden and the media, sperm donation is not anonymous under the law, resulting in single women and/or same sex couples depending on, to some extent, sperm banks in other countries. A development to observe over the coming years⁵⁰⁶.
- ▶ According to Barnlängtan, a Swedish patient organisation, there are a few 'quick fixes' that could improve MAR conditions, namely: raising the age limit, as the mean age of women at first childbirth is steadily increasing, allowing embryo donation and publicly funded 'sibling treatments' (intra-family gamete donation)⁵⁰⁷, as well as a uniform compensation fee for donors regardless of region.
- ▶ A proposed change to the legislation is currently under review. Areas under review include: extending the freezing time of embryos from 5 years to 10 years, allowing the donation of embryos and double gamete donation and the prohibition of surrogacy for both commercial and altruistic reasons⁵⁰⁸.



In the western region of Västra Götaland, a patient might need to wait up to two years for donated eggs, while the corresponding wait time in the southern region of Skåne is only three months. The measures taken to achieve this in Skåne was simply to drastically increase compensation to donors, creating a new will to donate and hence, more eggs. ”

Barnlängtan patient association, Sweden
July 2016

OVERVIEW

- ▶ The fertility rate in the United Kingdom (UK) is 1.81 (vs. 1.58 EU average)⁵⁰⁹.
- ▶ The legislative framework is set out within statute of the "Human Fertilisation and Embryology Act"⁵¹⁰.
- ▶ Clinical guidelines⁵¹¹ established by the National Institute for Clinical Excellence (NICE) make recommendations for state funded treatments in England. Scotland, Wales and Northern Ireland have their own specific processes to establish guidelines. In Scotland, the National Infertility Group provides a series of recommendations based on but not limited to NICE guidelines⁵¹². Wales produces its own guidelines in consideration of NICE guidelines⁵¹³ and Northern Ireland takes notice of NICE recommendations leaving the Health and Social Care Board to make the final decision and recommendations on infertility treatments⁵¹⁴.
- ▶ A full range of treatments are available in the UK. Intrauterine Insemination (IUI) and In Vitro Fertilisation (IVF) are the first lines of treatment offered to infertile couples. As of 2005, egg and sperm donations are not anonymous and there are no legal barriers to treatment based on marital status or sexual orientation.
- ▶ While state funded treatment is available, it varies between England, Scotland, Wales and Northern Ireland with respect to the number of treatments covered. IVF treatment is consistently funded in Scotland, Wales and Northern Ireland, while in England, access varies from region to region.
- ▶ Aside from the National Health Service (NHS) public website on the condition, there are no state funded initiatives on infertility. The Fertility Fairness campaign aims at raising awareness on regional disparities and the inconsistent application of NICE guidelines across England, while the National Fertility Awareness Week campaign focuses on all aspects of infertility.
- ▶ A key challenge in accessing publically funded infertility treatment in the UK is the inconsistent implementation of the NICE guidelines and lack of funding in England⁵¹⁵. Services in Scotland, Wales and Northern Ireland are more consistent by comparison.
- ▶ Ongoing budgetary pressures on the NHS are likely to make access to funded treatment more difficult in the coming years.

Table 1.

KEY FACTS & FIGURES

TOTAL FERTILITY RATE (TFR) ⁵¹⁶	1.81 ⁵¹⁷
INFERTILITY RATE	2.10% (primary) 8.60% (secondary) ⁵¹⁸
MEAN AGE OF WOMAN AT THE FIRST CHILDBIRTH	30.2 years ⁵¹⁹
FERTILITY TREATMENT SUCCESS RATE	27% with In Vitro Fertilisation (IVF) and 27.8% with Intracytoplasmic Sperm Injection (ICSI) ⁵²⁰
REIMBURSEMENT / STATE FUNDING	<ul style="list-style-type: none"> ▶ England: Varies by region, for example Camden Clinical Commissioning Group (CCG) in London offers three full IVF cycles, while North East Essex CCG does not offer IVF cycles⁵²¹ ▶ Scotland: Two cycles of IVF are fully state funded up to 40 years of age⁵²² ▶ Wales: Two cycles of IVF are fully state funded up to 40 years of age⁵²³ ▶ Northern Ireland: One two-part cycle of IVF (one fresh and one frozen transfer cycle) is fully state funded up to 40 years of age⁵²⁴
AWARENESS RAISING CAMPAIGNS/ INITIATIVES	<ul style="list-style-type: none"> ▶ National Fertility Awareness Week⁵²⁵, led by Fertility Network UK, the main patients' associations for people with infertility. ▶ The Fertility Fairness Campaign⁵²⁵, is a multi-stakeholder campaign focused on access to infertility treatment.



INFERTILITY POLICIES

- ▶ There are approximately 3.5 million infertile couples in the United Kingdom (UK)⁵²⁷. The fertility rate in the UK is 1.81 (vs. 1.58 EU average)⁵²⁸.
- ▶ The UK Government has a junior minister for public health whose portfolio covers fertility⁵²⁹. The ministers' predecessors had a similar portfolio. The few debates on fertility over the last few years within the House of Commons have largely focused on ethical issues such as mitochondrial replacement⁵³⁰.
- ▶ The quality and safety of reproductive technologies are governed by the "Human Fertilisation and Embryology Act" of 2008⁵³¹. Clinical guidelines were developed by the National Institute for Clinical Excellence (NICE), last updated in 2016⁵³². NICE is an England Special Health Authority whose guidance is a source of reference but not mandatory in application. Scotland, Wales and Northern Ireland all have various domestic processes in place for establishing clinical guidelines.
- ▶ In Scotland, the National Infertility Group provides a series of recommendations based on, but not limited to, NICE guidelines⁵³³. The National Health Service (NHS) in Scotland expects healthcare professionals to make use of most up to date and appropriate evidence and guidance, including NICE guidelines.
- ▶ Wales produces its own recommendations taking into account NICE guidelines⁵³⁴. The Welsh Health Specialised Services Committee issued CP38 Specialist Fertility Services guidelines, last updated in September 2016⁵³⁵.
- ▶ Northern Ireland takes notice of NICE recommendations leaving the Health and Social Care Board to make the final decision and recommendations on infertility treatments⁵³⁶.
- ▶ NHS England operates via regional 'Clinical Commissioning Groups' (CCGs), who decide what treatments to prioritise and fund. CCGs do not necessarily adhere to NICE guidance set out by the Department for Health. Individual CCGs make their own decisions about which treatments to fund, which may disregard the NICE guidelines. Infertility stakeholders view these decisions as opaque and at times illogical⁵³⁷. Infertility treatments are not included within the basket of services commissioned centrally, thereby bypassing CCGs⁵³⁸.
- ▶ The austerity policies of the last two governments had a smaller impact on healthcare services as compared to other sectors. However, CCGs are expected to firmly control costs. Infertility stakeholders believe that infertility treatments are not a high priority for CCGs or the national government⁵³⁹.

- ▶ Infertility stakeholders believe that CCG funding policies are not reflective of demographic and societal needs, but rather of cost containment⁵⁴⁰.
- ▶ While there are no legislative acts or strategies that reference an individual's right to infertility treatment, there are also no legal restrictions to the availability of Medically Assisted Reproduction (MAR) based on marital status or sexual orientation⁵⁴¹.

SCREENING AND DIAGNOSIS

- ▶ A system for population-wide infertility screening does not exist in the UK.
- ▶ The following screening and diagnosis tests may be offered to women: test of ovarian reserve, a tubal and/or uterine abnormalities test, cervical smear test, cervical cancer screening, urine analysis for chlamydia, blood test to check ovulation, blood test to check for German measles (Rubella), and blood tests during a woman's period to check for hormone imbalances⁵⁴². The following screening and diagnosis tests may be offered to men: sperm test to check for abnormalities and urine analysis for chlamydia⁵⁴³.

- ▶ Infertility screening is performed by General Practitioners (GPs). A GP consultation will usually address lifestyle factors, but may also include some standard screening tests. If infertility is diagnosed, patients will be referred to a specialist, either in hospital or specialist fertility clinic. A GP's understanding of infertility can vary significantly, which may affect a patient's access to adequate screening and diagnostic services⁵⁴⁴.
- ▶ The initial GP appointment is free at the point of delivery under the standard NHS service. Any further treatment required by the patient may be available under the standard NHS service or may require private payment.



When people decide not to fund infertility treatment they think 'no one has the right to a child'; most people with infertility don't think of it as their right to have a child; what they want is access to a medical treatment for a medical condition that could help them.

Fertility Network UK patient association,
United Kingdom
July 2016

TREATMENT AND REIMBURSEMENT / STATE FUNDING

- ▶ The following treatments are available: fertility drugs, surgery, Intrauterine Insemination (IUI), IVF, Intracytoplasmic Sperm Injection (ICSI), Embryo Freezing, Frozen Embryo Transfer (FET), Preimplantation Genetic Diagnosis (PGD), Preimplantation Genetic Screening (PGS), gamete donation,

surrogacy⁵⁴⁵. NICE guidelines suggest that women under 40 who experience unexplained infertility should undergo three full cycles of IVF treatment⁵⁴⁶. As of 2005⁵⁴⁷, sperm and egg donation is no longer anonymous. Advertising for surrogacy (both requesting and offering) is illegal.

- ▶ There is consistent state funding of infertility treatment in Scotland, Wales and Northern Ireland, as compared to England, where funding varies by region.
- ▶ Funded treatment policies vary across the UK with regards to eligibility based on age, weight and other lifestyle factors, as well as marital status (e.g. options for single women and individuals with children from a previous relationship) amongst other criteria⁵⁴⁸. Eligibility criteria for funded treatment requires that the woman be under 40 years of age at the time of treatment and that she or her partner have been diagnosed as infertile for longer than two years⁵⁴⁹.
- ▶ In England, CCGs decide on which treatments to fund and often diverge from the recommendation outlined by NICE guideline (e.g. three courses of IVF)⁵⁵⁰. Infertility stakeholders believe that CCGs do not view infertility treatment as a priority medical condition that requires a medical solution⁵⁵¹.
- ▶ In Scotland, Wales, and Northern Ireland, there is a consistent approach:
 - In Scotland, women under 40 are fully funded for two cycles of IVF, though a new policy is set to be implemented, raising the number of cycles to three⁵⁵².
 - In Wales, women under 40 are fully funded for two cycles of IVF⁵⁵³.
 - In Northern Ireland, women under 40 are fully funded for one two-part cycle of IVF (one fresh and one frozen transfer cycle)⁵⁵⁴.
- ▶ Funding for treatments in England varies between CCGs, with a patchwork of different approaches.
- ▶ The Fertility Fairness campaign conducts an annual audit of how different CCGs approach funding, presenting an overview of the regional disparities. Their data suggests some CCGs do not offer IVF treatment at all, while only 18% of CCGs provide the recommended three cycles as outlined by NICE guidelines.

The audit also noted that some CCGs do not use the appropriate definition for a 'full cycle' of treatment⁵⁵⁵.

- ▶ In England, fertility clinics are often private and have a contract with the NHS to deliver services, however, which services are funded under the NHS varies between clinics depending on which CCG catchment area they fall under. In 2013, 41.3% (approximately 25,571) of IVF treatment cycles were funded by the NHS, while 58.7% (approximately 36,292) were funded privately⁵⁵⁶.
- ▶ Psychological counselling is provided as part of treatment. All Human Fertilisation and Embryology Authority (HFEA) licensed centres must have a counselling service and most provide one session free of charge. Some clinics offer evening appointments for an additional fee⁵⁵⁷. In October 2016, Fertility Network UK published a report presenting the psychological impact associated with infertility treatment and consequently the need for free psychological support at an appropriate time and with an appropriate focus to maximize effectiveness, especially after unsuccessful treatment⁵⁵⁸.
- ▶ The HFEA website is the main source of information on available infertility treatments⁵⁵⁹, however, couples can seek advice from licensed fertility clinics in their area, as they offer advice on what treatments are available from the NHS.
- ▶ The success rate of infertility treatments in the UK is comparable with the highest European standards, with a 27% success rate with IVF treatment, as compared to the European average of 21.9%⁵⁶⁰.
- ▶ Infertility stakeholders believe CCGs do not consider the issues around cost. Costs identified by CCGs for a course of IVF treatment vary by thousands (GBP), suggesting that some CCGs are not well informed of the overall costs. Additionally, infertility stakeholders consider the decision to only cover one cycle of IVF by some CCGs to be financially misguided, given that the likelihood of successfully conceiving is only increased with subsequent cycles. In this way, cost increase is likely to be insubstantial relative to the outcome. The NICE Costing Report, published in February 2013, outlines total infertility treatment

costs in terms of direct, indirect and recurrent cost⁵⁶¹.

- ▶ Infertility stakeholders assert that many women in the UK seek treatment privately in other EU member states as the cost of treatment is significantly lower as compared to privately funded treatment in the UK⁵⁶².
- ▶ In total, there are 78 private and public clinics in the UK⁵⁶³.



Years and years are spent drawing up the NICE guidance, with the best possible research, then the CCGs are turning around and saying ‘well actually we know better’, and that’s one of the really sad things; what’s the point of having this really well-thought-out guidance if regionally it is not being implemented? ”

Fertility Network UK patient association,
United Kingdom
July 2016

Table 2. Treatment Options Available in the United Kingdom

Fertility drugs
Surgery
Intrauterine Insemination (IUI)
In Vitro Fertilisation (IVF)
Intracytoplasmic Sperm Injection (ICSI)
Embryo Freezing; Frozen Embryo Transfer (FET)
Preimplantation Genetic Diagnosis (PGD)
Preimplantation Genetic Screening (PGS)
Gamete Donation (including Double Gamete Donation)
Surrogacy

AWARENESS RAISING ACTIVITIES

- ▶ Awareness raising in the UK is led by two different campaigns:
 - Fertility Network UK, the main organisation representing people with infertility, whose key annual activity is the National Fertility Awareness Week.
 - The Fertility Fairness campaign, which campaigns more specifically on access to treatment issues.
- ▶ Aside from the NHS public website on the condition, there are no state funded awareness campaigns on infertility⁵⁶⁴.
- ▶ The annual National Fertility Awareness Week campaign and Fertility Network UK operate without government support in England. Some government support is available in Scotland and Northern Ireland⁵⁶⁵.
- ▶ The National Fertility Awareness Week aims to provide information and statistics on infertility and promote the importance of infertility education by increasing young people’s awareness. In 2016, the National Fertility Awareness Week focused on: infertility in young people, IVF failure and facing multiple rounds of treatment, male infertility, dealing with childlessness and life after successful IVF⁵⁶⁶.
- ▶ Established in 1993, Fertility Fairness (originally the National Infertility Awareness Campaign) campaigns for increased funding of treatments, consistent access to state funded treatment across the UK, and consistent implementation of NICE guidelines. Their activities focus primarily on services in England due to variation in application. Fertility Fairness is supported by patients’ organisations, healthcare practitioner groups and researchers, with funding support from pharmaceutical manufacturers.
- ▶ Infertility stakeholders consider the stigma of childlessness to be a significant issue that remains unaddressed. Many (including men) experience difficulty discussing infertility with their partner and/or healthcare provider⁵⁶⁷.

- ▶ The stigma of childlessness also varies significantly between ethnic groups. In some groups, for cultural reasons, infertility is not openly discussed either within the relationship or with a healthcare practitioner. Infertility stakeholders consider the lack of access to state funded treatment options to also be a factor in perpetuating stigma.
- ▶ The media portrayal of infertility treatments further diminishes public awareness of infertility by highlighting unique cases that portray infertility treatment as an unjustified burden on public finances, or by emphasising novel ‘miracle’ treatments that inappropriately raise public expectations⁵⁶⁸.

FUTURE OUTLOOK

- ▶ Infertility stakeholders expect access to state funded treatment to become increasingly difficult in the coming years, in the absence of clear government direction in infertility policies (beyond those established in the devolved governments of Scotland, Wales and Northern Ireland)⁵⁶⁹.
- ▶ Infertility stakeholders would like infertility treatments to be commissioned centrally, with payment tariffs decided centrally, thereby creating a level playing field for patients seeking treatment across the UK. Such a change is not expected in the short or medium term⁵⁷⁰.
- ▶ Infertility stakeholders consider the psychological consequences of childlessness to be underestimated and hope that future health policies recognise the effect that infertility can have on mental health⁵⁷¹.
- ▶ Brexit poses uncertainty for UK patients in being able to work closely with patients from other EU member states on common objectives. Infertility stakeholders in the UK have benefited greatly from learning how services are funded elsewhere in the EU as well as highlighting opportunities for more progressive policy development.



ANNEXES



ANNEX I:

Organisations and respective experts consulted

FERTILITY EUROPE

- ▶ Satu Rautakallio-Hokkanen, Chairperson of Fertility Europe
- ▶ Elín Einarsdóttir, Vice-chairperson of Fertility Europe
- ▶ Klaudija Kordic, Secretary of Fertility Europe
- ▶ Isabelle Chandler, Policy and Government Relations Adviser to Fertility Europe
- ▶ Monika Bulmańska-Wingett, member of the WGs POLI and COMM, Fertility Europe
- ▶ Kate Brian, Infertility Network UK
- ▶ Nicoleta Cristea - Brunel, Asociatia SOS Infertilitatea, Romania
- ▶ Filomena Gallo, Amica Cicogna, Italy
- ▶ Marta Górna, Nasz Bocian, Poland
- ▶ Maria Jönsson, Barnlängtan, Sweden
- ▶ Hana Konečná, Adam Česká republika, Czech Republic
- ▶ Anna Krawczak, Nasz Bocian, Poland
- ▶ Tomáš Kučera, Adam Česká republika, Czech Republic
- ▶ Rebecca Nielben, Maia, France
- ▶ Kajsa Nordahl, Barnlängtan, Sweden
- ▶ Laetitia Poisson Deleglise, Maia, France
- ▶ Susan Seenan, Infertility Network UK



EUROPEAN SOCIETY OF HUMAN REPRODUCTION AND EMBRYOLOGY

- ▶ Dr Roy Farquharson, ESHRE Chairman elect
- ▶ Dr Tatjana Motrenko, ESHRE Executive Committee Member
- ▶ Bruno Van den Eede, ESHRE Managing Director
- ▶ Helen Kendrew, ESHRE Ex officio Chair of the Paramedical Group
- ▶ Lars Björndahl, Sweden
- ▶ Ernesto Bosh, Spain
- ▶ Dr Pierre Boyer, France
- ▶ Monica Dăscălescu, Romania
- ▶ Lucia De Santis, Italy
- ▶ Salut de la Dona Dexeus, Spain
- ▶ María José Gómez Cuesta, Spain
- ▶ Cristina Magli, Italy
- ▶ Ass. Prof. Tonko Mardesic, Czech Republic
- ▶ Verena Nordhoff, Germany
- ▶ Dr Catherine Rongieres, France
- ▶ Ioana Adina Rugescu, Romania
- ▶ Prof. Dr Robert Spaczyński, Poland
- ▶ Thomas Strowitzki, Germany
- ▶ Andreas Tandler-Schneider, Germany



Interviews were also carried out with Gabriele Ziegler, Wunschkind e.V. patients' association in Germany and Dr Diana Guerra, Spanish Infertility Association – Genera (dissolved in 2016).

ANNEX II:

Glossary

► Infertility

Infertility is “a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse.”

WHO, LINK:<http://www.who.int/reproductivehealth/topics/infertility/definitions/en/>.

► Primary infertility

“When a woman is unable to ever bear a child, either due to the inability to become pregnant or the inability to carry a pregnancy to a live birth she would be classified as having primary infertility. Thus women whose pregnancy spontaneously miscarries, or whose pregnancy results in a still born child, without ever having had a live birth would present with primarily infertility.”

WHO, LINK:<http://www.who.int/reproductivehealth/topics/infertility/definitions/en/>.

► Secondary infertility

“When a woman is unable to bear a child, either due to the inability to become pregnant or the inability to carry a pregnancy to a live birth following either a previous pregnancy or a previous ability to carry a pregnancy to a live birth, she would be classified as having secondary infertility. Thus those who repeatedly spontaneously miscarry or whose pregnancy results in a stillbirth, or following a previous pregnancy or a previous ability to do so, are then not unable to carry a pregnancy to a live birth would present with secondarily infertile.”

WHO, LINK:<http://www.who.int/reproductivehealth/topics/infertility/definitions/en/>.

► Total Fertility Rate

“The mean number of children who would be born to a woman during her lifetime, if she were to spend her childbearing years conforming to the age-specific fertility rates, that have been measured in a given year.”

Eurostat, LINK:<http://ec.europa.eu/eurostat/statistics-explained/index.php/Glossary:Fertility>.

► Mean Age of Women at Childbirth

“The mean age of women when their children are born.”

Eurostat, LINK:<http://ec.europa.eu/eurostat/web/products-datasets/-/tps00017>.

► Reimbursement

We use the term reimbursement to mean overall coverage of the medical service rendered. Therefore, the use of the term reimbursement is wider than out of pocket payments that are returned to the beneficiary.

► State Funding

We use the term state funding to refer to specific cases where the state funds medical services.

ANNEX III:

Fertility Europe's Positions on Ethics, Access to Treatment and Fertility Protection

13/8/16

Fertility Europe (FE) is the umbrella organisation of European associations involved with infertility issues with members from over 20 European countries. In our national organisations, we are all involved on a daily basis with assisting those affected by difficulties in conceiving. Our goals are to improve the rights of those affected by difficulties in conceiving; to build a strong cross border network amongst European patients in order to achieve the sharing of best practices; to promote social change regarding the perception of infertility; to promote education in the area of the protection of reproductive health.

Infertility is classified as a disease by both regional and world agencies such as the World Health Organization (International Classification of Disease register). The European Parliament points out that infertility is on the increase occurring in approximately 15 % of people (2008 European Parliament's resolution*). The main reasons, especially as we refer to involuntary childlessness as being a medical condition, are female, male or joint factors.

This medical condition prevents people of reproductive age from fulfilling one of the most important life goals of becoming a parent. The prolonged uncertainty of involuntary childlessness can affect every aspect of a person's life, as well as impacting on relationships with partners, family members and friends. If infertility is prolonged, it can affect a person's sense of self identity and their meaning and purpose of life may be challenged. People may experience an impaired ability to function normally in society for long periods of time. Medical treatments have been developed which can help to resolve this problem. However, all too often infertility is a socially taboo subject.

Patient associations contribute to the reduction of anxiety levels by informing those affected of the reproductive biology, the pathology and the options available. They also offer support groups which provide additional information on various areas of reproductive medicine and the impact of related techniques.

Men and women have resorted to reproduction techniques when they faced difficulties to conceive. Since 1978, advanced Medically Assisted Reproduction techniques have been developed by introducing in vitro fertilisation (IVF). IVF is a process by which an egg is fertilised by sperm outside the body. As with every medical treatment, Medically Assisted Reproduction (MAR) is qualitative requiring four dimensions from the patient's perspective: safe, technically effective, patient centred and evidence-based medical care.

* <http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2007/2156%28INI%29&l=EN>

IVF may also offer, for those who are not able to use their own gametes (egg and/or sperm), the use of donated gametes. Moreover, IVF opens up the possibility to become parents to those women and men that are past the natural age of conceiving or are of the same sex. FE sees the need for regulation, best practice exchange and ethics on a European level.

There is inequality of access to fertility treatments across Europe. Some countries offer good provision, some do not. Inequalities include disparity in the types of treatment offered, variations in eligibility criteria to access treatment and reimbursement policies. FE sees a need throughout Europe to ensure the rights of those affected for equitable access to stated funded, evidence based infertility treatments.

Public reproductive health awareness has been inadequate to date. Its importance has not been significant enough to governments, health agencies and social organisations dealing with fertility. Preventive measures can start before conception, perhaps even before people realize that they wish to have children. Preventive thinking may also be

important for people who intend to have children much later in life. Education should include information on the types of fertility disorders, the opportunities for early diagnosis, possible success rates and risks of treatments, their psychosocial and ethical context. This knowledge is essential for informed decision-making and to overcome the dilemma that such decisions may cause. FE has identified a huge need for raising awareness and education.

The following ethics and policy statements might guide all stakeholders concerned (patients, health professionals, policy makers, government agencies, etc...) and provide them with principles and measures to ensure the rights of those affected.

** Access has three dimensions (according to the WHO)

- ▶ Physical accessibility. This is understood as the availability of good health services within reasonable reach of those who need them and of opening hours, appointment systems and other aspects of service organization and delivery that allow people to obtain the services when they need them.
- ▶ Financial affordability. This is a measure of people's ability to pay for services without financial hardship. It takes into account not only the price of the health services but also indirect and opportunity costs (e.g. the costs of transportation to and from facilities and of taking time away from work). Affordability is influenced by the wider health financing system and by household income.
- ▶ Acceptability. This captures people's willingness to seek services. Acceptability is low when patients perceive services to be ineffective or when social and cultural factors such as language or the age, sex, ethnicity or religion of the health provider discourage them from seeking service.

ETHICS

- 1 People, regardless of their reproductive health condition, have the fundamental right to decide on the number of children they have, and when they have them. Thus those affected by infertility should be ensured access to Medically Assisted Reproduction to enable them to try to become parents. The needs of the living and future children of the couples and individuals should be taken into account while exercising the above rights.
- 2 There are different ways of resolving involuntary childlessness; these include a range of Medically Assisted Reproduction (MAR) treatments, as well as adoption. Those affected should also have the option of deciding against these treatments and alternatives, and opting to live a life without children. All options can lead to a happy and fulfilled life.
- 3 There are known risks in pregnancy in relation to age and therefore relevant information as well as public debates on national level are required before decisions about assisting not only women past the natural age of conceiving to become parents but also men past the natural age of conceiving to become parents.
- 4 Nobody should be discriminated against because of the way in which they were conceived and/or in the way they make an addition to their family.
- 5 Only explicitly voluntary, free from any form of exploitation and non-commercial donation of gametes and embryos is ethically acceptable.
- 6 Gametes and embryos donation should be conducted in a manner that respects the rights and the current and future well-being of all involved and affected, i.e. donors, recipients, donor conceived children and their siblings.

ACCESS TO INFERTILITY TREATMENTS

- 7** Where individuals cannot conceive spontaneously, appropriate infertility treatment should be covered as such by the national social insurance system. A range of Medically Assisted Reproduction (MAR) treatments should be included in the provision of basic health care and be provided universally to patients under public health insurance scheme. Fertility investigations and treatment should be reimbursed across Europe, and state funded treatments of proven benefit to patients should be made available, irrespective of the patient's income and place of residence.
- 8** All those undergoing infertility treatment should be entitled to equal access to safe, clinically efficient, patient focused and evidence-based medicine care.
- 9** People with difficulties in conceiving should be given accurate information in a range of formats and languages on all assisted reproduction possibilities, as well as adoption and a life without children. They should also be allowed to accept or to reject any of the alternatives without discrimination.
- 10** Those undergoing MAR as well as those donating gametes should sign an informed consent document ensuring that the risks and benefits of treatment have been described in a balanced, evidence-based framework, and that appropriate warnings have been given when evidence is inadequate to assess the efficacy and/or safety of specific drugs, devices or procedures.
- 11** Access to psychological counseling should be offered in the framework of fertility investigations and treatments. People should be offered implications counseling, particularly if their treatment includes the use of donated and/or donating gametes and embryos. They should be informed about any potential long term risks and psychological, social and medical ramifications.

PREVENTION AND EDUCATION

- 12** Governments along with stakeholders concerned have a responsibility to promote unbiased, rational and age adapted information about all causes, implications and treatment options to help remove the myths and misunderstandings related to infertility. Patient associations across Europe should be recognized as a driving force behind multi-stakeholders awareness campaigns to ensure that education programmes happen.
- 13** Education of the next generation about infertility and its implications needs to start now. This material should be widely available, evidence based and free from any form of indoctrination.
- 14** Male infertility needs to be highlighted as a growing factor. Infertility can no longer be seen as a 'woman's problem'.

ANNEX IV:

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