Policy solutions to improve access to fertility treatment and optimise patient care: Consensus from an expert forum

WHITE PAPER

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Policy solutions to improve access to fertility treatment and optimise patient care: consensus from an expert forum

A foreword from Fertility Europe

Infertility is a complex medical, societal and psychological challenge. It profoundly impacts millions of individuals and families worldwide. It is a disease, as defined by WHO, and is often treatable, yet so many still lack access to the treatments that could allow them to conceive.

At Fertility Europe, we stand for equal access to safe and efficient treatment for all people facing involuntary childlessness. Unfortunately, many people experiencing infertility are either unable to access treatment or face insurmountable out-of-pocket costs in doing so. Already, infertility is a significant source of stress for those affected, often causing emotional distress, stigma, depression and anxiety, affecting the wellbeing of individuals as well as their relationships and even careers.

This new whitepaper from Charles River Associates and a team of acclaimed clinicians and academics, commissioned by Organon, outlines the critical policy issues that affect the treatment and care of those experiencing infertility and involuntary childlessness. Despite growing concerns at a global level regarding reproductive choices, declining fertility rates, and the implications this will have for societies and economies in the future, it seems evident that the patient perspective has not been kept at the heart of this debate, resulting in many policy gaps impacting those individuals seeking treatment today. It is alarming to see the array of challenges experienced across Europe and beyond, spanning from a lack of basic recognition of infertility as a disease in healthcare policymaking, to specific hurdles that impede the ability for those facing fertility problems to access treatment and care.

The challenges surrounding access to fertility treatments are not merely logistical or financial; they are deeply personal and profoundly impactful. But they can often be overcome. This whitepaper underscores the urgent need to address these barriers and highlights the potential transformative impact of policy interventions in broadening access to fertility treatments.

It is heartening to read the real-world examples in this whitepaper of forward-looking policy solutions that have already been implemented around the world to support access and care. This shows us that it is possible. It is important that in the future such best practices become more widely adopted, so that everyone is adequately supported to make their choices about the size of their families and timing of having children. Access to treatment and care is imperative for all individuals, irrespective of where they live, their sex, or the reason they are experiencing problems with their fertility. The healthcare professionals who contributed to this report suggested a range of relevant and necessary policy goals that would help this vision become a reality in the future.

We urge policymakers, healthcare professionals, and stakeholders across the globe to heed the call to action presented in this whitepaper. By respecting individual reproductive choices in all policies and prioritising equitable access to fertility treatments, we can pave the way for a future where every individual has an equal opportunity to try to achieve their family planning goals without undue hardship.

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Executive summary

Globally, an estimated one of every six people are affected at some point in their life by the inability to have a child, and infertility rates are rising globally.[1] Involuntary childlessness can have devastating social and psychological impacts, with couples and individuals experiencing stigma, shame, ostracism, anxiety, depression, and low self-esteem. There are also major global socioeconomic consequences of involuntary childlessness because it contributes to the expectation that 23 countries will see their populations halve by 2100.[2] While these projections are also impacted by trends in voluntary childlessness, infertility is a medical condition requiring treatment. Despite this, many governments still do not recognise infertility as a disease, so it is not deemed to be a medically necessary "covered benefit" by many public or private payers. This puts the financial burden on patients and adds to stigma around infertility.[3] Major access and affordability challenges are the result, with patients often spending over 50% of their disposable income on Assisted Reproductive Technology (ART) care in high-income countries and low- and middle-income countries.[4,5] Due to the heavy burden associated with infertility, the WHO is advocating for widening access to fertility care and for it to be made a priority by health researchers and policymakers so that safe, effective, and affordable ways to attain parenthood will be available to those who seek it.[6]

With the aim of catalysing an evidence-based global discussion on how to improve fertility care for patients, Organon commissioned Charles River Associates (CRA) to organize an expert Policy Forum to identify barriers preventing access to fertility treatment and develop policy recommendations to improve patient access and care. In this context, fertility care is defined as the "interventions that include fertility awareness, support and fertility management with an intention to assist individuals and couples to realize their desires associated with reproduction and/or to build a family", according to the International Glossary on Infertility and Fertility Care.[7]

As input to this research, a literature review was conducted at the global, regional, and national levels, followed by an interview programme with eight senior fertility experts (the Policy Forum participants). The fertility experts – Prof. G. David Adamson, Prof. Ying Cheong, Prof. Dr Human Fatemi, Prof. Rui Ferriani, Prof. Georg Griesinger, Prof. Bill Ledger, Prof. Antonio Pellicer, Prof. Luk Rombauts, and Prof Søren Ziebe – had complementary expertise covering large multinational fertility clinics, academic fertility research groups, and involvement in medical societies. Additionally, they covered different geographies – Australia, Brazil, Denmark, Germany, Italy, United Arab Emirates, United Kingdom, and the United States – which experience different underlying challenges. The Policy Forum, led by CRA, was conducted in May 2023 and enabled the experts to align on key conclusions and recommendations. The experts reached consensus on the proposed key recommendations that policymakers across the globe could use as a guide when developing local policies to address infertility.

Five themes were identified. Each includes many challenges that contribute to patients' inability to access optimal fertility treatment and care (Figure 1). The experts agreed that the identified five themes broadly represent global challenges preventing patients from accessing optimal fertility treatment and care, but the intricacies of each challenge (and thus the required policy intervention) differ between countries.

Figure 1: Key themes impacting patient access to fertility treatment and quality of care

- **Recognition and awareness**
- **Access to fertility treatment**
- **Psycho-social support**
- **Other supplementary care**
- **Ethical, religious and cultural considerations**

Recognition and awareness

Although the WHO has classified infertility as a serious disease that should be treated like any other, significant changes in national and regional legislation and attitudes to address it as a disease have not consistently occurred. In healthcare policymaking, infertility is often confused with individual lifestyle choices such that it is not viewed as a medical condition requiring investment in awareness, diagnosis, and treatment.[8] Further, low birth rates caused by infertility are fuelled by a concerningly low level of awareness among the general population of the role that infertility plays, resulting in many seeking treatment too late. According to the Policy Forum experts, this is exacerbated by the absence of well-defined national infertility plans.[9] Furthermore, infertility is fuelling the fertility gap (i.e., the difference between the number of children women would like to have and the (final) fertility rate) across most countries: one study focusing on Europe and the United States found that completed fertility was always below the mean intended family size measured in young adulthood.[10]

In addition to treating infertility in heterosexual couples, there is a need for fertility care to be available to single people and those in the LGBTQ+ community so they can realize their fundamental right to start a family.

A big part of tackling this problem is education on fertility and the prevention of sexually transmitted diseases that can cause infertility (e.g., chlamydia). Furthermore, efforts to increase awareness of the need to preserve the genetic material of oncology patients before they experience fertility loss because of cancer treatment are needed. According to the Policy Forum experts, the lack of reimbursement for cryopreservation services (such as egg and sperm freezing) is widespread and affecting a growing number of patients.

To tackle these issues, a number of interventions may be required across countries in the short to medium term:

- Development of national fertility plans that cover relevant policies and goals
- Widespread education campaigns, addressing different age groups, to improve awareness of infertility and the available treatment options
- Recognition of infertility as a disease by key national stakeholders and society, and thus categorization of infertility as a disease like any other within healthcare systems (e.g., by establishing and utilising medical codes for all infertility procedures)
- Recognition of the fundamental right of all people to found and grow a family
- Increased funding and access to fertility preservation for patients diagnosed with cancer or other medical conditions that compromise fertility

Access to treatment

In this paper, we review the extent of patient access to ART that address infertility (primarily referring to in vitro fertilisation (IVF) but also including other medically assisted reproduction (MAR) techniques and the use of donated eggs or sperm).[11] The reasons behind limited patient access to infertility treatment differ by region, with some stemming from political factors and others being fuelled by religious and cultural barriers as well as resource allocation decisions. However, a primary reason that patients cannot access treatment is insufficient or inequitable access to fertility clinics and/or a lack of public service provision and funding for fertility care, often exacerbated by stringent reimbursement criteria. To address this, and building on greater recognition of infertility as a disease by policymakers and healthcare payers, the consulted experts at the Forum set a number of policy goals to be achieved in the medium to long term:

- Diagnosis of access environments for infertility care at a local level by establishing rates of access and identifying factors contributing to low or inequitable access
- Adoption of tailored solutions to increase ART access by patients
- Global access to ART doubling within a decade.

Access to psychosocial support

Fertility treatment has a significant impact, both physical and mental, on the patients involved, with up to half of infertile patients experiencing psychiatric problems such as anxiety and depression.[12] This frequently drives discontinuation of treatment, particularly following treatment failure (which occurs in around 63% of IVF cycles).[13] However, many countries do not have psychosocial care as part of their clinical guidelines, nor do they reimburse it for patients in public care.[14]

Where services are available, patient uptake and engagement may be issues. The medical community has long stressed the importance of psychosocial support, and several recommendations emerged from the Forum:

- Expand the availability and funding of psychosocial support before, during, and after treatment through counselling sessions
- Expand patient engagement in care through availability and reimbursement of appropriate support tools (e.g., mobile apps)

The use of supplementary care

As a consequence of the general lack of funding and regulation of many aspects of infertility management, patients are faced with much uncertainty regarding their care options outside the IVF procedure. For example, access to and use of preimplantation genetic testing (a tool for the selection of healthy embryos for IVF) is regulated very differently across countries, and patients therefore experience variable degrees of access. Furthermore, because of poor education and regulation, many patients waste significant financial and emotional capacity using non-validated "add-on" treatments (i.e., optional treatments that often come with claims that they can improve fertility outcomes but that are lacking lack robust clinical evidence supporting such claims). To manage the use of supplementary care, experts have proposed the following:

- Information campaigns targeting patients and scientific communication targeting fertility healthcare professionals on the efficacy of non-validated "add-on" treatments, including over-the-counter medicines and alternative therapies
- Education campaigns targeting patients and scientific communication targeting fertility healthcare professionals on when preimplantation genetic testing (PGT) is clinically recommended
- Implementation of ESHRE guidelines on the use of supplementary care in the fertility space[15] and the updating of such guidelines as new evidence emerges
- Regulation of marketing campaigns conducted by fertility clinics to promote non-validated "add-on" treatments and introduction of regulation to control their use
- Regulation of digital applications that aim to support people around fertility and ART services
- Establishment of regulations to make add-ons that have been properly validated commercially available

Cultural, social, and religious considerations

In this paper, we focus on medical infertility and the treatment of it as a disease. The Forum concluded that the extent of access to infertility treatments greatly depends on the cultural, social, and religious context of the country or region.[16] For example, in countries with more conservative attitudes towards single mothers and same-sex couples, we typically see these values reflected in ART legislation, manifesting in certain populations not having access to treatment. The Forum agreed that, as trends in family composition (and consequently the composition of the infertility patient population) are changing, tailoring fertility policies accordingly is appropriate. However, it is important to recognise that policies on infertility are affected by local cultural and religious norms. While we can discuss the challenges and barriers certain groups face and advocate for improved and equitable access for all, it is in the remit of national stakeholders to define the most appropriate policy response locally.

Conclusions

Infertility is a serious medical condition and priority for society. Collaborative efforts and actions from many national, regional, and international stakeholders – including the academic and clinical communities, patient advocacy groups, policymakers, regulators, legislators, and the industry – are needed. This paper aims to provide a widely applicable framework for improving patient access to optimal fertility care, which regional and national stakeholders will need to tailor to the individual epidemiological, aetiological, cultural, and economic context at a local level to address the local needs of patients.

1. Introduction

Key messages:

- Infertility is an under-recognised disease that is increasingly impacting people and societies globally, so addressing infertility is becoming a global priority.
- Globally, infertility is estimated to affect one in six people. Its prevalence across regions and the extent to which patients can access treatment vary.
- Infertility can have devastating social and psychological impacts, and such consequences are more pronounced in low- to middle-income countries (LMICs) and low-income countries (LICs) due to the associated stigma and social repercussions.
- Although the WHO recognised infertility as a disease in 2009, many governments still do not perceive infertility as a disease. The result is infertility treatment not being covered by many public payers.
- An expert forum was organised by Organon and CRA in May 2023 to reach consensus on the global challenges associated with access to infertility treatment and to align on key recommendations for national policymakers.

Charles River Associates (CRA) was commissioned by Organon to organize an expert Policy Forum and develop a white paper on barriers preventing patient access to fertility treatments and policy recommendations to address them. The following are the aims of this white paper:

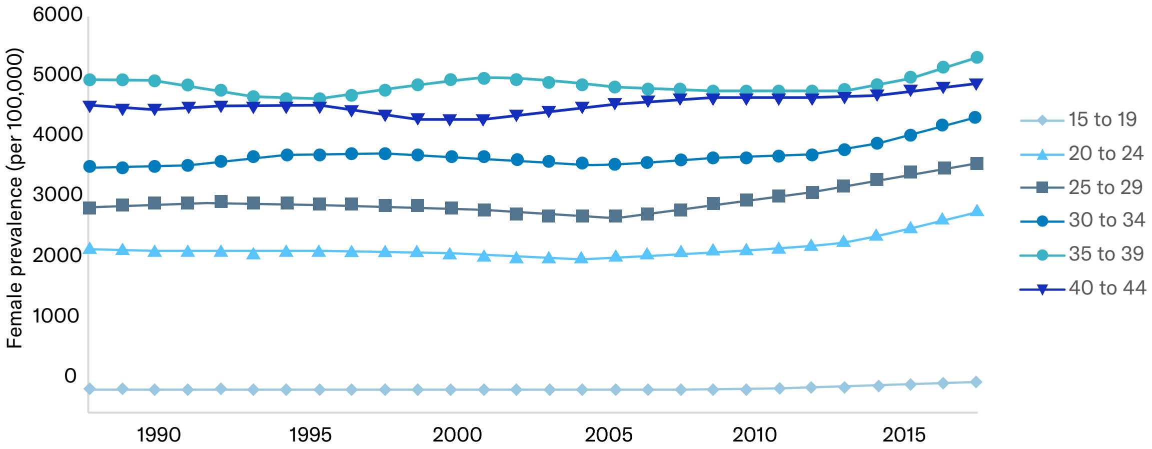
- To describe the international challenges patients experience in accessing optimal fertility treatment and care
- To highlight existing fertility policies in select countries or regions that represent a current gold standard and draw lessons from their implementation
- To bring the voices of fertility experts to the policy debate and provide action-oriented recommendations for improving access to fertility treatment globally, while highlighting instances where health system-dependent approaches will be required.

1.1. Infertility as an under-recognised disease

Addressing infertility as a global priority

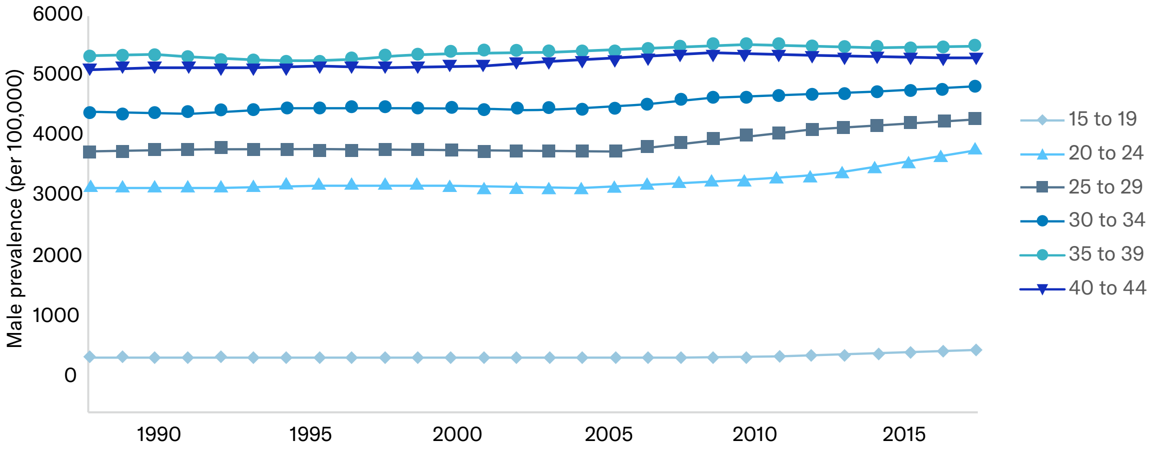
Globally, an estimated one of every six people are affected at some point in their life by the inability to have a child.[17] Infertility prevalence estimates are broadly similar across countries with different income levels, but they differ across geographies, with lifetime infertility ranging from 10.7% in the WHO Eastern Mediterranean Region to 23.5% in the WHO Western Pacific Region.[18] Furthermore, the infertility burden is rising globally (as demonstrated in Figure 2 and Figure 3), with studies estimating that the prevalence rate for females increased by 0.37% per year between 1990 and 2017.[19] Furthermore, infertility is fuelling the fertility gap (i.e., the difference between the number of children women would like to have and the (final) fertility rate) across most countries: one study focusing on Europe and the United States found that completed fertility was always below the mean intended family size measured in young adulthood.[20]

Figure 2: Global female infertility prevalence (per 100,000), 1990–2017



Source: Sun et al. (2019)[21]

Figure 3: Global male infertility prevalence (per 100,000), 1990–2017



Source: Sun et al. (2019)[22]

Addressing infertility is an important component of sexual and reproductive health and rights and is also important for achieving the health and gender-equality targets of the 2030 UN Sustainable Development Goals: addressing infertility would contribute to Sustainable Development Goal (SDG) 3 – Ensure healthy lives and promote well-being for all at all ages – and SDG 5 – Achieve gender equality and empower all women and girls.[23]

Socioeconomic burden of infertility on patients and society

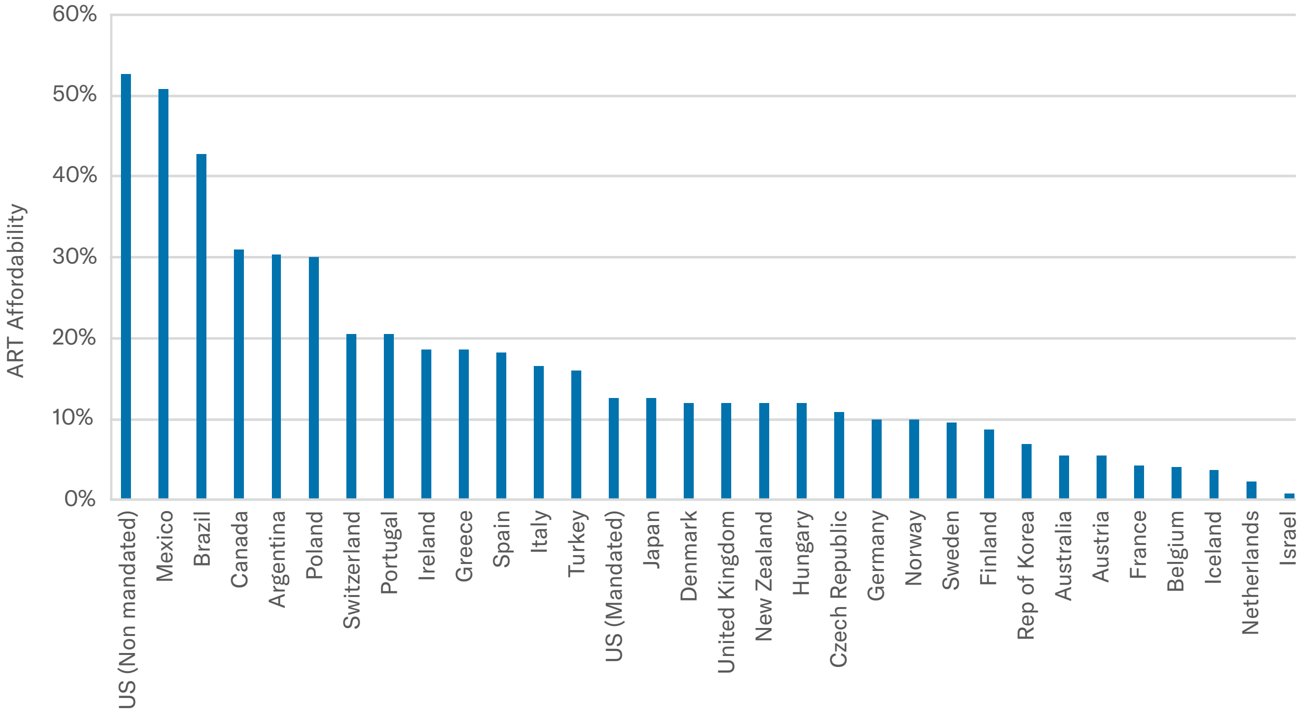
Involuntary childlessness can have devastating social and psychological impacts, with couples and individuals experiencing stigma, shame, ostracism, anxiety, depression, and low self-esteem.[24] Studies have found that women[25] with primary infertility (meaning they have never achieved a pregnancy) show a higher prevalence of depression and anxiety than fertile women, and also lower general self-esteem, sexual satisfaction, and sexual self-esteem and poorer sexual relationships.[26] The impact of infertility is also more pronounced in cultures where the continuation of the family name through the birth of a child can secure a marriage, guarantee property and inheritance rights, offer a future source of household income, and provide social security in old age.[27]

In LMICs and LICs, the consequences of infertility are particularly pronounced due to the stigma and cultural implications associated with infertility. For example, in Nigeria, a woman who has not borne children cannot be recognised as an elder because she has not been able to bear a son; therefore, she does not have a right to her husband's property, nor can she return to her parents' compound because she would be mistreated there. In many parts of India, having a child increases a woman's family's earnings; children are viewed as a source of labour and security in old age. Similarly, in Rwanda, the husband of an infertile women often refuses to buy food and clothes for her because she cannot give him a child in return; children are currency.[28] A study assessing the impact of infertility in LMICs found that one in three infertile women suffered from intimate partner violence over a 12-month period, and approximately one in two suffered from it over their lifetime, with psychological violence being the most common form of intimate partner violence, followed by physical violence, sexual violence, and economic coercion.[29]

Although the social impacts of infertility are most keenly felt in LMICs and LICs, high-income countries (HICs) are not exempt because the impact is linked largely to countries' cultural contexts rather than income level. A Japanese study assessing the impact of fertility treatment on working women found that women undergoing fertility treatment experienced harassment in the workplace and were not provided with the necessary support, resulting in one-sixth of women resigning after starting infertility treatments.[30]

Furthermore, at present, in most countries regardless of income level, fertility treatments are largely funded out of pocket. This often results in devastating financial costs.[31] One 2020 US-based study found that 21% to 29% of families making less than $150,000 reported spending more than 50% of their disposable income on IVF.[32] This echoes the findings of a 2007/2008 study in which the cost of a fresh IVF cycle represented 52% of average annual disposable income in US states without insurance coverage mandates (Figure 4). Such costs can be prohibitive for patients in LMICs and LICs; for example, one study estimated that infertile Nigerian women spend between 55% and 100% of their earnings on attempts to treat their infertility.[33]

Figure 4: Affordability of ART treatment, 2006/2007

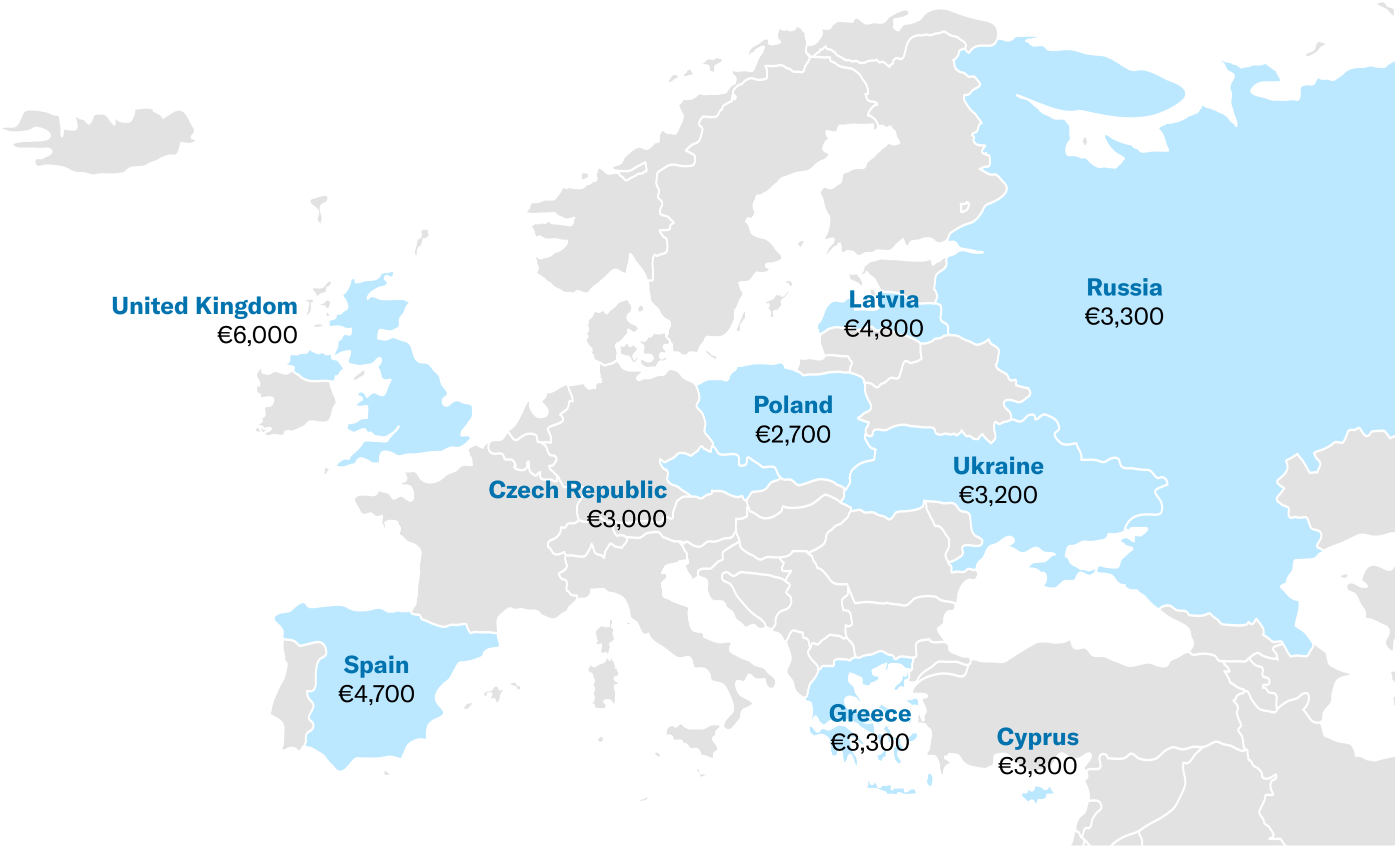


Source: Chambers et al. (2013)[34]

ART affordability is expressed as the net cost of a fresh IVF cycle as a percentage of annual disposable income of a single person with no dependent children earning 100% of average wages. Disposable income is calculated using Organisation for Economic Co-operation and Development (OECD) methods.

Although many studies have demonstrated that IVF treatment is cost-effective when medically relevant criteria are adhered to,[35] patients still face widespread access hurdles and are subject to out-of-pocket costs (Figure 5).[36] A study assessing the economic burden of infertility treatment in France found that the average infertility-related expenditure per woman is estimated at €6,996, with the economic burden for 10,000 women being €70 million.[37]

Figure 5: Average IVF treatment out-of-pocket cost with own eggs in Europe



Source: Egg Donation Friends[38]

Furthermore, increasing infertility is contributing to a gradual descent in total fertility rate (TFR), which in 2017 was only just above replacement levels (traditionally defined as 2.1 children per women).[39] Some academics have also highlighted that the target TFR for some countries may need to be higher than 2.1 if the mortality rate is higher or a skewed sex ratio at birth has been observed.[40] Projections indicate that the number of under fives will fall from 681 million in 2017 to 401 million in 2100, whereas the number of people older than eighty will soar from 141 million in 2017 to 866 million in 2100, with 23 nations – including Italy, Spain, Portugal, Japan, Thailand, and South Korea – seeing their populations halve by 2100.[41] This will create enormous social and economic change, with gaps in collected taxes – which may impact pensions and healthcare provisions for the retired – and a limited workforce to look after the elderly and support economic growth.[42] While these projections are also impacted by trends in voluntary childlessness, infertility is a medical condition requiring access to adequate treatment and care.

National and international policies addressing infertility

Since 2009, the WHO has recognised infertility as a disease and said that to effectively address infertility, health policies need to acknowledge that infertility is a disease that can often be prevented.[43] The WHO's shift to recognising infertility as a disease led to the inclusion of infertility in the International Classification of Diseases (ICD).[44] Nevertheless, many governments still do not perceive infertility as a disease, so it is not deemed to be a medically necessary "covered benefit" by some public and private payers.[45]

A few countries have implemented national plans covering fertility, frequently as part of broader women's health strategies that aim to improve access to fertility treatments. For example, the Women's Health Strategy for England is a 10-year strategy to improve women's health, and one of its aims is to support women through high-quality information and education so they can make informed decisions about their reproductive health.[46] Additionally, the strategy aims to address the current geographical variation in access to National Health Service (NHS)-funded fertility services across England and to ensure that female same-sex couples are able to access NHS-funded fertility services more equitably.[47] Similarly, Australia has a National Women's Health Strategy (2020–2030) through which it aims to engage in preventive health campaigns to promote awareness of infertility and to strengthen access pathways to sexual and reproductive health services across the country, particularly in rural and remote areas.[48] However, in most countries, infertility policies and services are broadly considered inadequate.[49] Healthcare professionals and academics across countries are advocating for the introduction of national plans or for more comprehensive infertility policies.[50,51]

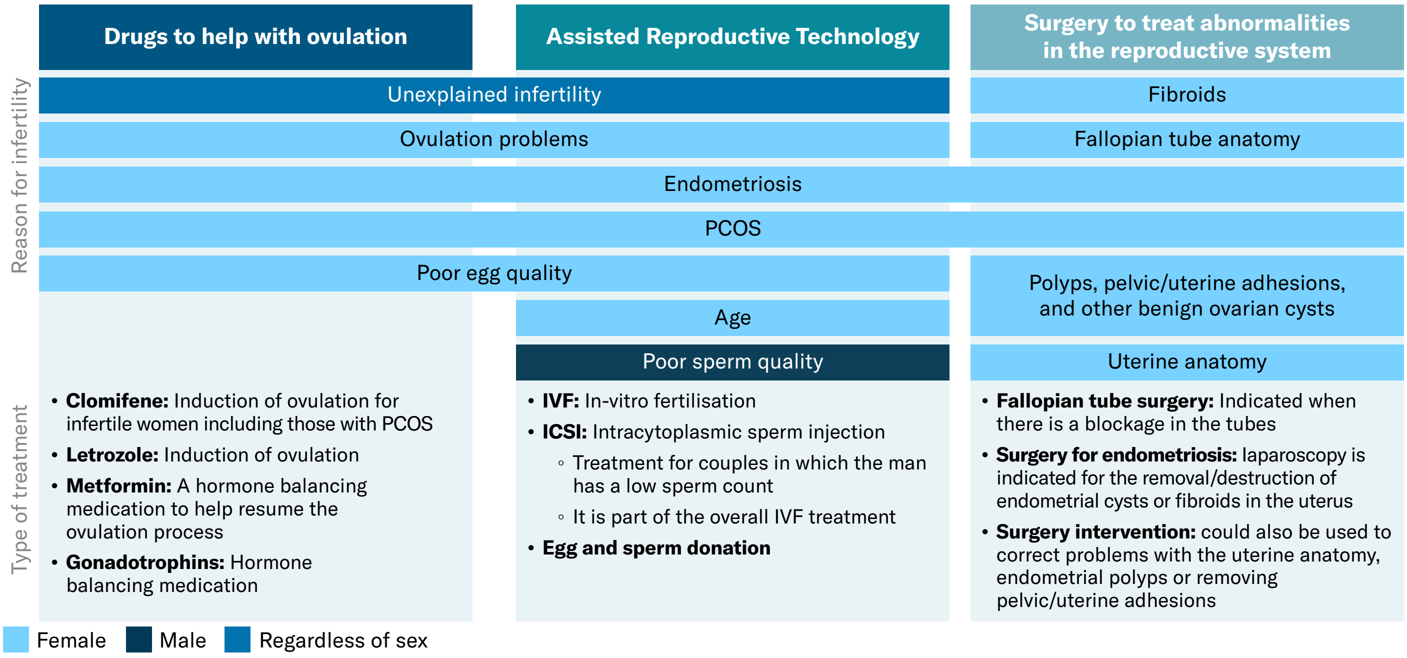
1.2. Fertility treatment options and their accessibility

Overview of fertility treatment options

The most common reasons for infertility are unexplained infertility, ovulation problems, endometriosis, poor egg quality, polycystic ovarian syndrome (PCOS), fallopian tube problems, and poor sperm quality.[52] Treatment options differ based on the reason for infertility, and sometimes they will be used in sequence (Figure 6). The options can be summarised as treatment with drugs (to help with ovulation), ART, or surgery:

- **Drugs to help with ovulation**: To address ovulation problems, drugs such as clomiphene, letrozole, metformin, and gonadotrophins may help to induce ovulation in women who do not ovulate regularly or at all.[53]
- **ART**: ART is defined as all interventions that include the in vitro handling of both human oocytes and sperm or of embryos for the purpose of reproduction. Such interventions include, but are not limited to, IVF and embryo transfer (ET); intracytoplasmic sperm injection (ICSI); embryo biopsy; preimplantation genetic testing (PGT); assisted hatching; gamete intrafallopian transfer (GIFT); zygote intrafallopian transfer, gamete and embryo cryopreservation; semen, oocyte, and embryo donation; and gestational carrier cycles. ART does not, and ART-only registries do not, include assisted insemination using sperm from either a woman's partner or a sperm donor (see the broader term "Medically Assisted Reproduction").
- **Medically Assisted Reproduction** (MAR): MAR is reproduction brought about through various interventions, procedures, surgeries, and technologies to treat different forms of fertility impairment and infertility. They include ovulation induction; ovarian stimulation; ovulation triggering; all ART procedures; uterine transplantation; and intrauterine, intracervical, and intravaginal insemination with semen of husband/partner or donor.
- **Surgery**: Several types of surgical procedure may be used to address fertility problems and to help with fertility.[54] Fallopian-tube surgery is often used when the fallopian tubes have been shown to be blocked or scarred, whereas laparoscopic surgery to destroy or remove endometrial cysts is often used for women who have endometriosis. It may also be used to remove fibroids (benign growths in the womb), large polyps, or scar tissue or to treat uterine septum. In women with PCOS, a minor surgical procedure called laparoscopic ovarian drilling can be used if ovulation drugs have not been successful. Additionally, surgical intervention could be used to correct problems with the uterine anatomy, for endometrial polyps, or to remove pelvic or uterine adhesions.[55]

Figure 6: Available fertility treatment options (non-exhaustive)



- **Clomifene:** Induction of ovulation for infertile women including those with PCOS
- **Letrozole:** Induction of ovulation
- **Metformin:** A hormone balancing medication to help resume the ovulation process
- **Gonadotrophins:** Hormone balancing medication

- **IVF:** In-vitro fertilisation
- **ICSI:** Intracytoplasmic sperm injection
  - Treatment for couples in which the man has a low sperm count
  - It is part of the overall IVF treatment
- **Egg and sperm donation**

- **Fallopian tube surgery:** Indicated when there is a blockage in the tubes
- **Surgery for endometriosis:** laparoscopy is indicated for the removal/destruction of endometrial cysts or fibroids in the uterus
- **Surgery intervention:** could also be used to correct problems with the uterine anatomy, endometrial polyps or removing pelvic/uterine adhesions

■ Female ■ Male ■ Regardless of sex

Source: CRA analysis

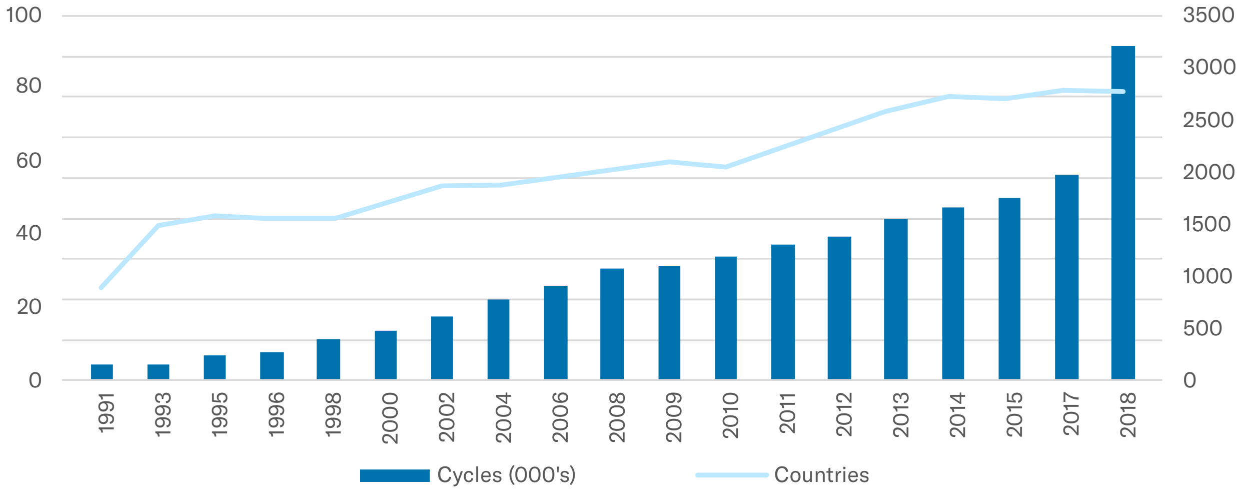
Note: Surgery could also address fallopian tube problems; however, this is not performed as frequently today because of higher pregnancy rates following ART.

Furthermore, much innovation is occurring in the fertility treatment space, including in-vitro gametogenesis (IVG), an experimental technique that allows scientists to grow embryos in a lab by reprogramming adult cells to become sperm and egg cells. This technology carries great therapeutic promise while at the same time posing some legal and ethical dilemmas.[56] Innovative developments are also taking place in precision medicine, nutritional interventions, and diagnostic tools to improve fertility, and researchers are also researching the possibility of an artificial uterus.[57] Some of these technologies may prove successful (after extensive research and clinical testing for safety and effectiveness), but they will not likely be in widespread clinical use for many years.

Variations in access to fertility treatments and their availability

Reflecting the growing burden of infertility, demand for the above-mentioned fertility treatments is growing globally. ART utilization (expressed as the number of IVF cycles) is reported annually by national and regional ART registries and globally by the International Committee for Monitoring ART (ICMART).[58] ICMART has reported that 3,196,685 cycles took place in 2018 across 79 countries, an increase of 63.4% from 2017 (Figure 7).[59],[60] A limitation of these findings is that the global ART results are limited to reporting countries and clinics representing approximately three-quarters of global cycles,[61] and the number of participating countries is not consistent across years so the number of cycles cannot be precisely compared across years.

Figure 7: Number of cycles registered in the ICMART World Registry (1991–2018)



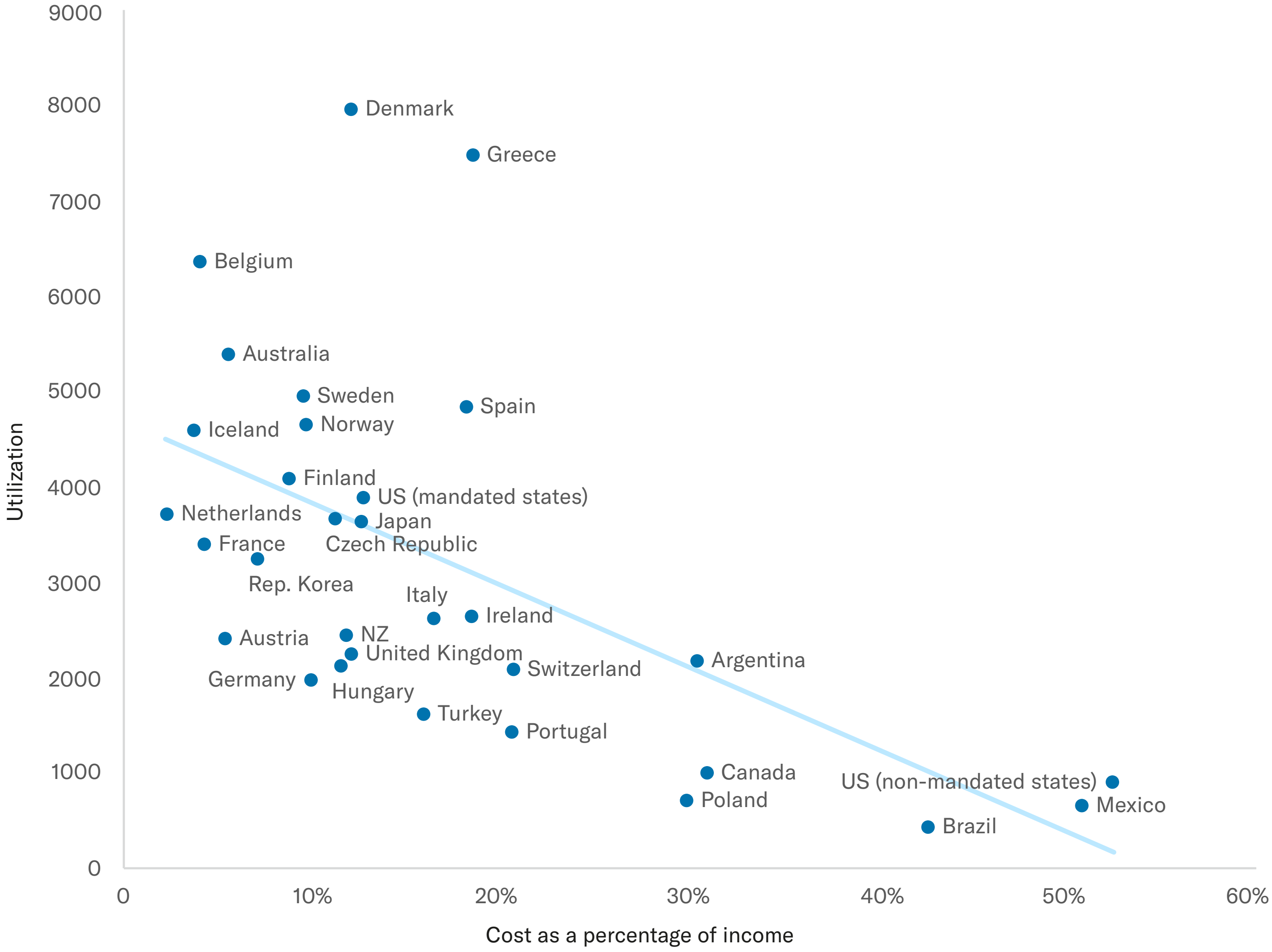
Source: ICMART (2022)[62]

Note: China began registering its number of cycles with the ICMART World Registry in 2018. This explains the sharp rise in the number of cycles registered that year.

Despite this growing global trend, there are still notable discrepancies in the access and availability of fertility treatments globally and within countries. Economic factors are the chief contributors to disparities in access to effective treatment; however, social and cultural factors, including individual or systemic discrimination that disadvantages certain people because of their race, ethnicity, sexual orientation, or gender identity, play a role as well.[63]

Across most countries, ART remains underfunded, resulting in public healthcare systems not fully reimbursing the treatment, so ART is inaccessible to many due to the high out-of-pocket costs and limited availability of publicly funded ART centres.[64] We have observed that the high out-of-pocket cost impacts the utilization of ART services, leading to low uptake of ART in countries or regions where ART services are unaffordable (Figure 8). Patients within a single country therefore also experience inequity in access to care that is linked to their ability to pay; for instance, in Japan, women from lower-income households seek less medical help for their infertility.[65]

Figure 8: ART affordability and utilization, 2006/2007



Source: *Chambers et al. (2013)*[66]

The affordability issue is more pronounced in LMICs and LICs; for instance, in Ghana, all IVF clinics are private, and there is no insurance coverage for infertility treatment. Therefore, two voluntary and nonprofit organizations have had to intervene to assist those with the greatest need.[67]

The WHO is advocating for widening access to fertility care and for it being made a priority by health researchers and policymakers so that safe, effective, and affordable ways to attain parenthood are available to those who seek it.[68]

The need for policy intervention to support better access to fertility treatments

The prevalence of infertility is rising globally, resulting in an increase in associated socioeconomic consequences. Therefore, there is a need for global action to address infertility, which in turn would help in achieving the health and gender-equality targets of the 2030 UN Sustainable Development Goals. Although the WHO recognised infertility as a disease in 2009, few countries have implemented national plans covering fertility, and access to treatment remains insufficient in LICs, LMICs, and most HICs. There is a long way to go before patients with infertility experience levels of funding and access to treatment similar to those experienced by patients in other disease areas. This white paper aims to identify the existing policy barriers that prevent or impede infertility patients' ability to access optimal care and to propose policy recommendations to address these barriers. The proposed recommendations aim to support informed policymaking decisions in the future.

1.3. Methodology for the research

The findings of this white paper derive from a three-step approach culminating in an expert forum. As input, we conducted a review of the recent literature (published in the last 10 years) on fertility policy challenges and best practices, including literature on fertility recognition and awareness; cultural and religious considerations around fertility; and access to ART treatment, psycho-social care, and supplementary care. To find relevant publications, the search terms “assisted reproductive technology”, “fertility policy”, and “challenges” or “best practices” were used in Google Scholar and PubMed. The retrieved publications were ranked according to their relevance to the search terms and used as a basis for discussion with an expert panel (described below), along with additional articles located through a targeted search.

In the second step, one-to-one interviews were scheduled with eight fertility experts (Table 1) who participated in the Policy Forum. The interviewed experts had a variety of complementary expertise covering large multinational fertility clinics, academic fertility research groups, and involvement in medical societies. Additionally, the fertility experts covered different geographies that experience different fertility challenges. Through the one-to-one interviews, we obtained initial feedback on the barriers to ART access and care and discussed possible best practices in policymaking to support optimal access and care in the future.

Table 1: List of experts who participated in the one-to-one interviews

Name	Country of residence	Bio
Prof. G. David Adamson	United States	▪ Clinical Professor at Stanford University School of Medicine and Associate Clinical Professor at University of California San Francisco School of Medicine
Prof. Ying Cheong	United Kingdom	▪ Professor of Reproductive Medicine, University of Southampton
Prof. Dr. Human Fatemi	United Arab Emirates	▪ Medical Director of ART Fertility Clinics
Prof. Rui Ferriani	Brazil	▪ Professor Obstetrics Gynaecology, University of Sao Paulo
Prof. Georg Griesinger	Germany	▪ Professor at Luebeck University
Prof. Bill Ledger	Australia	▪ Head and Professor of Discipline of Women’s Health, School of Clinical Medicine, University of New South Wales ▪ Director of Reproductive Medicine, Royal Hospital for Women, Sydney
Prof. Antonio Pellicer	Italy	▪ IVIRMA Executive Chair
Prof. Luk Rombauts	Australia	▪ Adjunct Clinical Professor in the Department of Obstetrics and Gynaecology at Monash University ▪ Head of Reproductive Medicine at Monash Health, Southern Health
Prof. Søren Ziebe	Denmark	▪ Head of the Fertility Department, Juliane Marie Centre – Rigshospitalet, Copenhagen University Hospital, Denmark

The final step was to convene a virtual group forum of the above experts, which was facilitated by Charles River Associates on 24 May 2023. During the Policy Forum, in addition to reaching consensus on the barriers to ART access and identifying existing best practices, the experts discussed the factors a fertility policy needs for it to be successful and co-developed implementable and actionable (national, regional, and global) policy goals to support optimal patient access and care.

Finally, an additional two one-to-one geographical tailoring sessions were conducted with two of the experts to obtain regional perspectives on the policy recommendations developed in the Policy Forum.

2.4. Structure of the white paper

The rest of the white paper is structured as follows:

- Chapter 2 covers challenges in accessing fertility treatment and care, particularly those associated with the recognition and awareness of infertility; the cultural, social, and religious considerations around fertility treatment; and challenges in accessing ART treatment, psychosocial care, and supplementary care.
- Chapter 3 covers the principles of optimal fertility policy design by identifying factors associated with successful policies and existing innovative policy solutions that have already been developed and implemented at country, regional, or global levels.
- Chapter 4 sets out the goals that policymakers should aim to achieve to optimise access to fertility treatment and care and identifies the key regional and international stakeholders that should be involved in the implementation of such policies.

2. Challenges in accessing infertility treatment and care

Key messages:

- Infertility is widely not recognised as a disease across the globe, which hinders the extent and quality of care that patients can receive.
- Over 50% of countries surveyed by the International Federation of Fertility Societies (IFFS) reported a lack of funding for IVF or other infertility treatments.
- Where treatment is available, a lack of adequate psychosocial support often leads to premature discontinuation of treatment, significantly reducing fertility success rates.
- Lack of clear guidance and monitoring around add-on treatments inflicts an additional financial and clinical burden on infertility patients.
- The absence of access to infertility treatment for certain demographics (such as single women and same-sex couples) leaves a large portion of the patient population unserved.

A multitude of challenges contribute to patients' inability to access optimal infertility treatment and care. In this white paper, we have segmented challenges into five categories as a tool to help us discuss them and to diagnose country-specific access barriers (Table 2). While affordability and availability of treatment are the primary access barriers in many countries, other factors such as education, local cultural and religious considerations, and psychosocial support can also restrict patients from receiving optimal treatment and care in many situations.

Table 2: Summary of challenges impeding patient access to infertility treatment

Challenge	Summary
Recognition and awareness	▪ Lack of awareness of fertility treatments and their availability ▪ Lack of education aimed at preserving fertility ▪ Limited or absent reimbursement of fertility preservation services
Access to fertility treatment	▪ Insufficient or inequitable access to infertility treatment centres ▪ Lack of public service provision and funding ▪ Over stringent IVF reimbursement restrictions (age, BMI, cycle, number of children)
Psycho-social support	▪ Lack of psycho-social care
Other supplementary care	▪ Variable access to preimplantation genetic testing ▪ Use of non-validated treatments as "add-ons"
Ethical, religious, and cultural considerations	▪ Restrictive legislation based on marital status, same sex, and single-parenting policies ▪ Ethical considerations around gamete donation, personhood of gametes, and surrogacy ▪ The burden of cross-border reproductive care ▪ Ambiguity of legislation on posthumous reproduction

To analyse the extent of the problem, we will delve deeper into the specifics of each challenge and how it can manifest at a country level (based on input from the expert Policy Forum) and review evidence of how it impacts patient access to treatment.

2.1 Recognition and awareness

According to the experts from the Policy Forum, underpinning all access challenges are the limited extent of recognition of infertility as a disease, awareness of infertility treatments, and personal and societal barriers.[69] In 2009, the WHO classified infertility as a serious disease that should be treated and regulated like any other.[70] However, relative to other disease areas, infertility has not been given priority by policymakers and governments, resulting in decreased investment into the support of research initiatives, preventative programmes, and treatment. While some countries, such as Australia, France, and Poland, are beginning to actively advocate for increasing population fertility rates and aim for reimbursement of services, little is done to boost access to fertility treatment.[71] This situation is exacerbated in countries where healthcare resources are scarce and there are many other competing healthcare priorities. For example, in many African countries, the focus often remains on infectious and life-threatening diseases, often deprioritising fertility.[72]

As a result, even though infertility has been formally recognised as a disease that requires healthcare intervention and political attention, decision-making stakeholders such as policymakers, governments, and local authorities have yet to address it.

Education on fertility preservation

Where infertility is recognised as a disease, according to the Policy Forum experts, little has been done globally to address the rising demand for fertility treatments. There is a widespread lack of education about how to promote and preserve fertility and limited efforts to offer fertility preservation to those who need it.

Fertility rates in most countries continue to fall, with the European continent demonstrating the lowest aggregate fertility rate; the average number of children born per woman is 1.6 in the EU (the minimum viable rate to replace the current generation is 2.1).[73] In the current economic and social environment, women around the world are giving birth later in life (Figure 9); in high-income countries the average age at first giving birth is 30 for women and 33 for men.[74] Due to the inverse relationship of age and fertility, the data imply that people are likely to have fewer children than they planned. The decision to have children at a later age creates another issue: older women are relying on fertility centres and treatments to mitigate age-related infertility. However, according to medical experts, past the age of 40, the chance of conceiving, even through infertility treatment, is very low. Therefore, increasing awareness of infertility and making access to fertility treatment easier are greatly needed.

Figure 9: Mean age at first birth

Source: *OECD (2022)*[75]

Although these trends are also influenced by changing social norms and lifestyle choices, they are underpinned by a lack of investment in public education about fertility and infertility. Public education usually focuses on contraception rather than fertility and family forming. According to experts from the Policy Forum, while the former is important in young people's education, the latter are too little covered.

Lack of reimbursement of fertility preservation

Cryopreservation is a unique treatment because it allows the patient to avoid the consequences of infertility later in life. Cryopreservation of sperm and eggs has been available since the 1950s, but medical egg freezing was seldom offered to women before 2012, when it was no longer considered an experimental treatment.[76] Since then, medical freezing has become increasingly important for women at risk of becoming infertile due to cancer treatment or fertility-threatening medical conditions. The latter include but are not limited to autoimmune disorders, BRCA1/2 carrier status, and severe endometriosis. Medical cryopreservation can preserve the ability to conceive a genetically related child and provide psychosocial support and assurance to patients. However, without reimbursement, medical cryopreservation is prohibitively expensive for most patients: up to $15,000 per cryopreservation cycle, plus maintenance costs.[77]

According to the IFFS, only 35% of countries offer some form of reimbursement of medically indicated egg preservation.[78] One country where medical egg freezing is not government funded is Canada; women who are seeking onco-fertility care face significant affordability issues.[79] Importantly, costs are less prohibitive for men because retrieval of genetic material costs significantly less and is not associated with any risks.[80]

According to experts from the Policy Forum, the lack of funding for medical cryopreservation services is concerning because cancer is being diagnosed and treatment begun in increasingly younger patients.[81] Earlier diagnosis and treatment lead to early loss of fertility for many, which leads to significant challenges later in life. Additionally, survival rates of cancer patients have improved, which results in a larger pool of patients seeking fertility treatment.[82]

Different types of cryopreservation services exist, including preservation of eggs, sperm, and embryos, and this plays a role in the level of reimbursement available. Some countries do not allow, and therefore do not reimburse, cryopreservation of embryos. All IVF patients are affected because embryo freezing maximises the chance of pregnancy and reduces the incidence of multiple gestations.[83]

The objective of cryopreservation may be to preserve eggs in the face of an immediate medical condition that threatens the future availability of viable gametes or economic, educational, career, or relationship issues that make pregnancy impossible or inadvisable in the immediate future. Some countries that reimburse cryopreservation of sperm and eggs for immediate medical reasons do not reimburse for cryopreservation done for the purpose of delaying pregnancy. This lack of reimbursement presents a crucial affordability challenge to patients seeking to preserve their fertility, regardless of their need. The demand for egg freezing has increased dramatically; between 2010 and 2015 the number of egg-freezing cycles grew by approximately 300% in Australia and New Zealand and by 900% in the United States.[84] Recent studies indicate that this spike in demand is primarily fuelled by patients seeking to delay pregnancy until a more appropriate time in their reproductive life.[85] Young women are interested in egg freezing to preserve their fertility potential at a younger age and delay pregnancy until they are economically, socially, and mentally prepared to have a child. Choice benefits the parents, the child, and society.

2.2. Access to treatment

Insufficient or inequitable access to fertility treatment centres

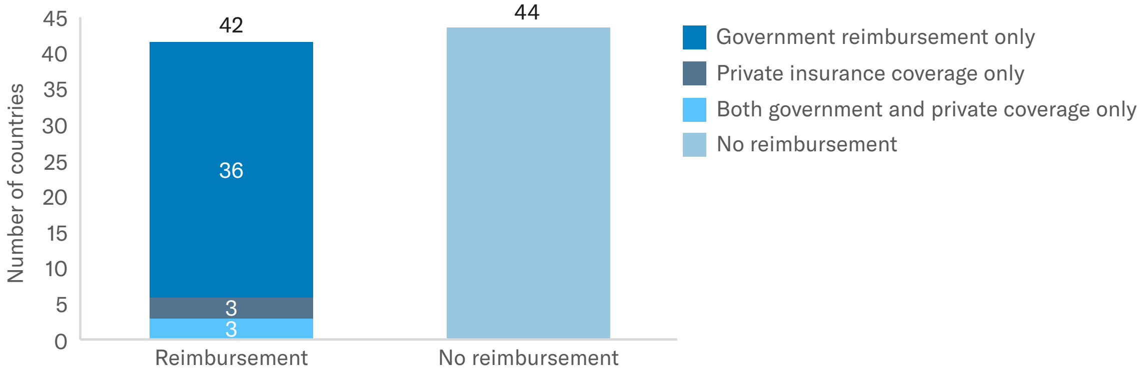
The reasons behind the limited patient access to infertility treatment differ by region, with some stemming from political factors while others are fuelled by resource allocation decisions. However, a primary hurdle is the availability of appropriate services—the existence and accessibility of ART clinics. Access to fertility treatments is often considered from an economic and legislative point of view, but the geographical dimension is paramount in countries with a well-defined urban/rural divide.[86] An example is Brazil, a large country with a few urban clusters and a multitude of rural ones, which have no convenient access to ART treatment. Most ART treatments are provided in large IVF centres in the south and southeastern regions of the country where the largest cities (Sao Paolo and Rio de Janeiro) are located; the northern regions are deprived of access.[87] Rural patients must travel long distances for their consultations, which puts more financial and emotional strain on them. Successful outcomes from fertility treatment require the utmost engagement from the patient and therefore are associated with multiple consultations, appointments, and procedures. Extensive travel is likely to increase economic, social, and emotional costs.[88] To receive treatment, patients have to take time off work, disconnect from their social community, and reserve accommodation.

Lack of public service provision and funding

According to experts from the Policy Forum, reimbursement of treatment is a key determining factor of patient access to fertility treatment. Studies have shown that having little to no public coverage acts as a significant barrier to fertility treatment.[89] The financial structure of a country's fertility funding scheme enables or impedes patient access to care. Ultimately, two broad archetypes of fertility treatment funding systems exist: a generally government-funded system, and one driven by out-of-pocket payment by patients. How reimbursement is granted and for what type of care varies, but, broadly, the archetypes apply to most countries.

Countries with a fertility market driven by private care face inequity challenges, creating affordability concerns for patients because the cost of many ART treatments, such as IVF and cryopreservation, can be prohibitive. For instance, in Columbia, 100% of centres are private and no insurance coverage is provided, so the centres are unavailable to most patients. According to the IFFS, more than 50% of countries do not have any available funding for IVF or other types of fertility treatments (Figure 10). Therefore, lack of reimbursement is a prominent access issue across regions.

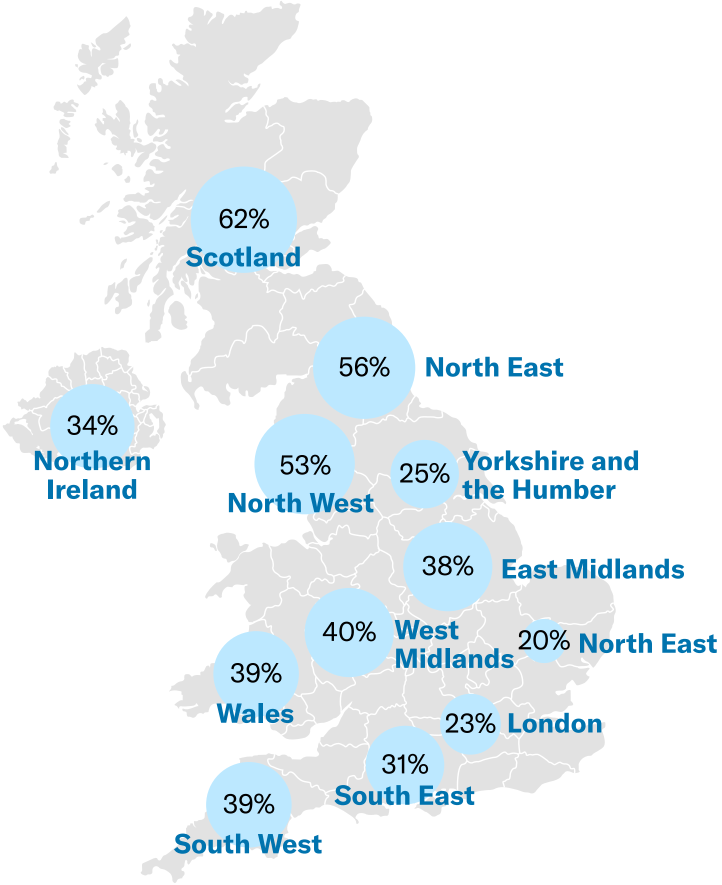
Figure 10: Reimbursement of infertility treatment across 86 countries



***Source**: CRA analysis of IFFS Surveillance Report 2022*[90]

Patients in countries with a public-centred system also may experience access challenges, including long waiting lists and restrictive reimbursement criteria. For instance, fertility treatment in England is supported by government funding, as the National Institute for Health and Care Excellence recommends that up to three IVF cycles be covered by the NHS.[91] However, the extent of government funding varies greatly by region (Figure 11). According to experts, due to cost-saving measures, some regions reimburse only one cycle of IVF and only for a specific type of person. Such criteria narrow the pool of patients who are eligible to receive treatment, significantly reducing the equity of access. Even with such stringent restrictions in place, the average waiting list for ART treatment can reach three years.[92] In the quickest region, it takes on average 21 weeks to access NHS treatment after being referred by a GP; in the slowest regions, up to 73 weeks.[93]

Figure 11: NHS funding of IVF cycles in UK nations and English regions, 2019



Source: *HFEA (2021)*[94]

The direct, negative effect that low or no government reimbursement of fertility treatments has on the number of successful IVF cycles has been amply recorded in literature and pointed out by fertility experts. For example, in 2004, as a cost-saving measure and influenced by low prioritisation of infertility as a disease, the German government halved ART treatment reimbursement. As a result, a year after the introduction of the policy, Germany saw a 53% reduction in IVF cycles, which demonstrates the short-term responsiveness of patient demand to a change in cost of treatment.[95] According to fertility experts, the increased cost of treatment borne by the patient may result in postponement; patients will wait longer before going to an ART centre as they will not feel financially prepared. Some may continue attempting pregnancy without medical intervention without establishing the probability of success. Because infertility is a highly age-sensitive disease, this exacerbates low fertility rates and worsens patient outcomes, potentially reducing the cost-effectiveness of treatment that patients do eventually receive.

Stringent IVF reimbursement restrictions

Where public funding is available for infertility care, reimbursed services typically include IVF and IUI. However, experts in the Policy Forum highlighted that the level of reimbursement differs greatly across countries as well as patient type. Different types of reimbursement limitations exist. The following are examples:[96]

- **Age**: Maximum female or male age; e.g., treatment may be reimbursed only for women over 35 but under 45
- **BMI**: A patient must have a BMI between 19 and < 25 for at least 6 months to qualify for IVF reimbursement
- **Number of treatment cycles**: A limited number of IVF cycles may be reimbursed, after which the patient must fund any remaining treatment privately
- **Marital status**: Reimbursement may be offered only for heterosexual, married couples
- **Bureaucracy**: Only patients who can obtain proof of their infertility may receive treatment, e.g., they have been trying to get pregnant for over one year or have proof of a medically indicated reason for infertility (which may be difficult or impossible to clinically demonstrate)
- **Number of children**: Funding may be provided only to people with no other living children, irrespective of the present reason for infertility

All or some of these factors may be used to decide whether the patient is eligible for government reimbursement. While some criteria may be required to maximise cost-effectiveness, strict criteria for reimbursement create inequity challenges for patients who do not meet them and push them into the private sector, exacerbating affordability concerns. For instance, unmarried women are becoming a sizeable share of patients seeking IVF treatment. Human Fertilisation and Embryology Authority data have shown that the number of IVF cycles and donor insemination instances has increased by over 100% between 2008 and 2020, and by 44% between 2019 and 2021 alone.[97] In the many countries that refuse reimbursement to such a large group, policymakers may be significantly reducing the national fertility rate, as many of these patients will be unable to afford private treatment.

An example of a country with complex restrictions is Italy, where couples, before being classified as eligible for partial reimbursement of ART treatments, must present a certificate of infertility that notes the clinical reason for infertility.[98],[99] Spain has a similar policy. This raises a hurdle for patients, as the reason for infertility is often difficult to establish and multiple tests must be conducted to diagnose an abnormality that may be causing the condition.[100] Consequently, their access to treatment will be significantly delayed. Alternatively, they may find solutions outside their country and resort to cross-border care.

2.3. Access to psychosocial support

Experts from the Policy Forum agreed that any type of fertility treatment has a significant impact on the patients involved, both physically and mentally. Due to the remaining stigma surrounding infertility, it can be stressful and daunting for patients to accept their disease and choose to take up treatment, pursue a long treatment journey (seven-and-a-half months on average for IVF), and accept treatment failures.[101] Therefore, fertility treatment patients are at high risk of developing psychiatric disorders such as depression and anxiety or experiencing related symptoms.[102] Studies have shown that 24% to 50% of infertile patients may display psychiatric symptoms.[103] Depression, anxiety, and distress may decrease a patient's fertility and thereby become a major driver of discontinuation of infertility care as patients become disincentivised by failed cycles of treatment; 20% of evaluated US couples who dropped out of treatment cited emotional distress as the primary reason.[104]

The challenge of addressing patients' emotional distress is twofold. First, although ESHRE has issued guidelines on the effective implementation of psychosocial care in fertility practices, many countries do not have psychosocial care as part of their fertility clinical guidelines, nor do they offer it for patients in public care.[105] One example is Denmark, a country in which national reimbursement of infertility is comparatively high. However, according to experts in our Policy Forum, counselling is not offered or reimbursed for infertility patients, even though studies have indicated high levels of demand for it. In this case, financially well-off patients may self-refer to therapists who may not have experience with the issue of infertility, leading to further unresolved stress.

Second, there are countries where some form of psychosocial care is reimbursed and offered but issues concerning patient uptake and engagement exist. According to experts from the Policy Forum, in instances where psychosocial care is provided, a lack of patient engagement can still result in fertility treatment cessation. One example of this is the UK, where the National Institute of Health Care and Excellence (NICE) has issued official recommendations for all fertility centres to provide psychosocial support before, during, and after treatment; this also mandated by HFEA.[106] Nonetheless, experts have pointed out that this recommendation is vague, as it suggests the centres "offer" counselling, not ensure that it is sufficiently available for all patients. While NICE issues national recommendations, regional integrated care boards are responsible for the level of reimbursement in their respective areas. Many clinics offer some complimentary sessions (usually one to two), but the rest must be paid for out-of-pocket by the patient. According to experts, due to the financial burden of payment and the additional stigma around mental health, many patients also choose to forgo counselling.

2.4. The use of supplementary care

Variable access to preimplantation genetic testing

Preimplantation genetic testing (PGT) is a tool for prenatal diagnosis that detects abnormal embryos and thereby allows the selection of normal ones for IVF cycles. The goal of PGT is to prevent the transmission of pathologic genetic conditions and to improve outcomes of fertility treatment. In essence, it is meant to improve IVF outcomes by decreasing the number of failed cycles, reducing the stress associated with failure, and to prevent a child from inheriting a genetic condition from one of the parents. Previously, PGT was used only for couples with a known genetic disease who turned to IVF to prevent the child from inheriting it. However, technology has come far since then, and numerous types of testing currently exist:

- **PGT-A**: a test for aneuploidy which assesses the embryo's chromosomes, detecting whether the embryo is normal or abnormal
- **PGT-M**: a test that screens tested embryos for genetically transferable conditions such as cystic fibrosis so an unaffected embryo can be selected
- **PGT-P**: a test for polygenic disorders, e.g., diabetes, schizophrenia, and several types of cancer
- **PGT-SR**: a test for chromosomal structural rearrangements

Discussions are ongoing regarding which types of PGT must be offered to patients, which should be treated as supplementary, and which should not be provided at all. Consequently, the challenges around provision of and access to PGT are driven by the variation in legislation and reimbursement of it. According to Fertility Forum Experts, while PGT is an efficacious and important technique for patients with genetic predispositions, it may be ineffective in patients without them.

As demonstrated in Table 3, countries may have a soft or a hard approach towards regulation of and access to PGT:

- A soft approach is characterised by guidelines and recommendations that are not binding, thereby leaving the decision up to treating healthcare professionals (HCPs). This includes statements from professional organisations such as the American Society for Reproductive Medicine (ASRM), which may indicate best practices suggested by the clinical community. One example is Brazil, a country in which no laws have been enacted regarding the provision of PGT. Instead, there are guidelines or recommendations issued by the ethical community, which encourage HCPs and fertility centres to follow them.[107] While a soft approach allows for flexibility around provision of PGT, it also allows – in some cases – misinformed patient demand to drive supply. According to experts in the Policy Forum, in counties where various types of PGT are offered freely, patients may go through numerous cycles of IVF attempting to conceive a child with specific traits, which raises ethical concerns in the medical community.
- A hard approach, on the other hand, is legally binding. In Germany, PGT is heavily regulated under the Preimplantation Act, instated in 2011.[108] PGT can be carried out only in specific genetic institutes and clinics, and only after approval from the regional ethics committee. The Preimplantation Act 2011 was an update of the Embryo Protection Act of 1990, which prohibited PGT entirely, and substantial regulations around the procedure still exist. The restrictive nature of such laws severely limits access of infertility patients, preventing them from pursuing further treatment. Table 3 below details examples of criteria that countries may use to determine whether PGT is allowed and for which patients.

Table 3: Criteria for allowing PGT in different countriesSource: Ginoza et al (2020)[109]

Criteria	Countries/states
Concerns around welfare of the child/embryo	Australia, Singapore, Switzerland, United Kingdom
Genetic defect (no severity criteria)	Brazil, United States
"Serious" or "severe" conditions	Australia, Austria, Quebec (CA), Germany, Japan, Netherlands, Singapore
Treatability	Austria, France, Germany, Netherlands,
Specified conditions	South Korea, United Kingdom

Overall, both soft and hard approaches to regulating PGT are associated with various challenges that worsen barriers to optimal treatment access.

Use of non-validated treatments as "add-ons"

Non-validated treatments or "add-ons" are optional treatments which often come with claims that they can improve fertility outcomes, however, they lack robust clinical evidence to support this. Because there are no high-quality, robust clinical trials confirming the value of optional treatments, their efficacy and safety profiles are unknown.[110] In most cases, these optional treatments involve an additional cost on top of the fertility treatment, to be paid out-of-pocket by the patient, generating affordability challenges for potentially misinformed patients. Supplementary treatments are often weakly regulated, leaving individual ART centres and providers to be the decision-makers. ESHRE has highlighted efficacy and safety issues regarding some supplementary treatments and urges that all treatments offered be thoroughly analysed with respect to their efficacy, safety, cost-effectiveness, and relevance before they reach patients.[111] According to experts, provision of add-on treatments is fuelled by both demand and supply. From one perspective, patients often search for information on fertility treatments online, which leads them to "success stories" on social media featuring similar patients who were able to conceive with the help of a supplementary treatment. This pushes patients to seek out these treatments in private clinics with the hope of increasing their chances of fertility success, creating unrealistic expectations about their treatment outcomes and causing them to spend money that could be used on more IVF cycles instead.

Additionally, according to the Policy Forum, some private fertility centres are incentivised to provide supplementary services due to high demand and high potential profits. According to HFEA, the cost of supplementary treatments may range from a few hundred pounds to a couple of thousand.[112] Therefore, such clinics may advertise add-ons without providing robust, clinical information about their efficacy and safety. Recent studies have shown that of 258 reviewed infertility clinic websites, almost 80% provided an accurate description of the offered supplementary procedures, but only 12% mentioned the lack of evidence that they are effective. Most importantly, none of the websites listed the pregnancy rate following the supplementary treatments.

The key issue of providing and advertising supplementary treatments is that even if the supply is motivated by patient demand, some add-ons may be harmful to the patient, which introduces ethical concerns.[113]

2.5. Cultural, social, and religious considerations

Restrictive legislation based on marital-status, same-sex, and single-parenting policies

The extent of access to fertility treatments greatly depends on the cultural, social, and religious context of a country or region. Many countries adhere to the traditional view of a family: a married man and woman and their child who is biologically related to both. However, it is important to note the stance of the WHO on this matter: all people should have access to health care without discrimination, regardless of their sexual orientation.[114] The evolution of technology and civil rights are changing the traditional narrative, thereby driving the demand for fertility treatment from members of different demographic groups, including same-sex couples, unmarried couples, and single women. For example, in the UK, between 2019 and 2021, the number of infertility patients in female same-sex partnerships increased by 33%, while the number of single patients increased by 44%.[115] This is further fuelled by the general global trend of postponement of parenthood by women choosing to further their career development before becoming a parent. However, in countries with more conservative attitudes towards single mothers, same-sex couples and marriage, these values are typically reflected in ART legislation, according to experts in the Policy Forum. Consequently, a large share of patients seeking fertility treatment face significant access hurdles.

While it is useful to discuss some of the challenges that different patient groups face due to existing restrictions and how they affect their fertility, it is also necessary to recognise that such challenges are religiously and culturally motivated, and ethical considerations arising from such motivations are outside the scope of this white paper. In particular, for cultural and/or religious reasons, some countries restrict fertility treatment access to married, heterosexual couples, thereby excluding single women and unmarried couples. The main guiding principle behind such restrictions is the welfare of the future child and concerns that it will up in an "incomplete" and nontraditional family.[116] However, arguably, the trends in family composition (and consequently the composition of the infertility patient population) are changing and thus the existing policies are unsuitable for newly emergent segments of the population. In the UK, the demand for IVF and donor insemination (DI) by single women has grown by 44% and 26% respectively, between 2019 and 2021 (Table 5). From a fertility rate–maximising perspective, the needs of this segment of the population should be addressed.

Table 5: Fertility treatment uptake in the UK, 2019–2021

Treatment		2019	2020	2021	% change from 2019 to 2021
IVF	**Male partner**	46,035	37,357	46,911	+2%
	Female partner	1,649	1,624	2,201	+33%
	No partner	2,001	1,986	2,888	+44%
DI	**Male partner**	507	407	485	-4%
	Female partner	1,334	1,272	1,565	+17%
	No partner	1,197	1,136	1,504	+26%

Source: *HFEA (2020)*[117]

.Similarly, the data show that the demand for fertility treatment of same-sex female couples has increased. While this is only one example, it demonstrates that the changing concept of a traditional family is driving changing demand for ART services. Consequently, regulatory access limitations reduce the fertility rate of the country.

Restrictive legislation on gamete donation and surrogacy

Gamete donation involves the donation of eggs or sperm from fertile donors to infertile patients. The recipients are given an opportunity to conceive when their own eggs and/or sperm are not suitable for a successful pregnancy. Services of donors are often sought out by cancer patients for whom cryopreservation was not an option, same-sex couples, and those with medical conditions rendering their gametes inappropriate for fertility treatments, such as cancer patients.[118] However, due to cultural, social, and/or religious reasons, many countries, such as Germany, prohibit donation of gametes, making it impossible for these patient groups to take advantage of fertility opportunities.[119]

In addition to legal access challenges, gamete donation is associated with hurdles related to anonymity. While in some countries, such as Brazil, donors must remain anonymous, in others, such as Australia, there is increasing advocacy for non-anonymity between the donor and the offspring.[120] Anonymity decisions are driven by the cultural context and prompt challenging discussions of the ethics of both options. Given the dramatic increase in genetics-testing technology, its availability to consumers, and social media use, the concept of anonymity with gamete donation is no longer viable and donors should be thought of as non-directed (formerly anonymous) or directed (formerly known). Even if all parties desire a non-directed donor, anonymity cannot be guaranteed and, indeed, is likely not possible. Furthermore, many countries have established or are establishing regulations giving children born as a result of gamete or embryo donation rights to know about their donor to varying degrees.[121]

Surrogacy is a service used when patients are not able to carry a child for medical or other physical reasons. This affects same-sex male couples and women who are unable to carry a child; for example, a woman with an absent or malformed uterus, recurrent pregnancy loss, or repeated IVF failures could benefit from seeking out a surrogate.[122] An example presented by experts in the Policy Forum mentions that while women can receive a uterus transplant, this surgery is much more invasive for the patient and may lead to more complications than pregnancy does for a surrogate.

Two broad types of surrogacy services exist:

- Traditional surrogacy: The surrogate is genetically related to the patient, uses her own eggs, and receives insemination, either cervical or intrauterine.
- Host surrogacy (also known as gestational carrier): IVF is used with the eggs of the patient or donated eggs. The surrogate does not use her own eggs.

Currently, host surrogacy is practiced more frequently. In some cases and countries, the surrogate can be reimbursed for her expenses while pregnant or even be paid for her services. The latter is called commercial surrogacy and is allowed in only a few countries, including Ukraine, Mexico, and some parts of the United States.[123] At the other end of the spectrum, some countries, including France, Italy, and Germany, prohibit all forms of surrogacy. Prohibition of surrogacy, even based on cultural, social, or religious grounds, presents a challenge for many patients who are incapable of carrying a child for physical or medical reasons. With growing demand for surrogates, challenges around access are becoming more prominent.

Table 6: Examples of more and less legally restrictive countries regarding surrogacy

More legally restrictive countries	**All types of surrogacies are forbidden by law:**
	• Europe: Germany, France, Spain, Italy, Switzerland, Austria, Norway, Sweden, Iceland, Estonia, Moldova, Turkey • Middle East: Saudi Arabia, Egypt, other Arab Countries, Pakistan • Asia Pacific: China, Japan • Americas: Canada (Quebec), US (Arizona, Michigan, Indiana, North Dakota)
	Only altruistic surrogacy is permitted by law:
	• Asia Pacific: Australia, New Zealand, India • Americas: Canada (except Quebec), US (New York, New Jersey, New Mexico, Nebraska, Virginia, Oregon, Washington) • Europe: United Kingdom, Netherlands, Denmark, Hungary, Israel, Belgium
Less legally restrictive countries	**Both commercial and altruistic surrogacy are permitted:**
	• Europe: Russian Federation, Ukraine, Belarus, Georgia, Armenia, Cyprus • Africa: South Africa • Americas: US (Arkansas, California, Florida, Illinois, Texas, Massachusetts, Vermont)

***Source**: Salama et al (2018)*[124]

The burden of cross-border reproductive care

Experts in the Policy Forum positioned cross-border reproductive care as both a challenge in itself and an outcome of the previously discussed access challenges. If patients are not able to receive the treatment they are looking for in their country but they have the financial means to afford it, they may choose to travel to another country that does provide such treatments. However, this presents several challenges for patients, including additional cost and emotional burden.

Cross-border reproductive is a complex issue and therefore, should be discussed in two dimensions[125]:

- Legal dimension: Many aspiring patients are unable to receive the desired care in their home country because the treatments are not offered for legal reasons. This includes PGT, surrogacy, and IVF for certain patient groups (such as older women, unmarried couples, and homosexual and transgender patients).
- Economic dimension: Another leading cause of cross-border reproductive care is the goal to minimise costs associated with treatment. Patients who face prohibitive costs or lack of reimbursement in their home country sometimes seek care in a destination country with comparatively lower costs.

Regardless of the reason for seeking out cross-border reproductive care, patients are faced with both monetary and emotional costs. While some patients need only cross over to a neighbouring country, for others it requires flights, visas, and long periods of time away from their home. For instance, most East Asian countries have restrictive laws on surrogacy and gamete donation, meaning that patients may have to travel far to overseas countries such as Ukraine, Belarus, or the United States to receive treatment (Table 6).

Therefore, travel for infertility treatments may inflict heavy costs on patients because they must sponsor their own journeys, accommodations, and treatments. In addition to affordability concerns, travel for invasive fertility treatment may increase the risk of complications and therefore decrease the success rate. This is driven by short timelines (patients wish to receive treatment and return home as soon as possible), inability to receive a second medical opinion, and lack of a social support system to guide them through the process.[126]

Consequently, while experts believe that the burden of travel for cross-border reproductive care is not the most prominent challenge in the fertility space, it still has detrimental impacts on patients.

Ambiguity of posthumous reproduction laws

While posthumous reproduction (PHR) has been practiced for over 60 years, it remains a controversial topic in most countries. PHR involves the use of cryopreserved genetic material in fertility treatments of the spouse or partner of the deceased. Genetic material is usually collected and preserved while the person is still alive or right after death. ESHRE defines three broad types of PHR:[127]

- Fertilisation of the egg and the pregnancy occur before the death of the partner, but the birth occurs after it
- Fertilisation occurs before the death of the partner, but the embryos are cryopreserved; therefore, both pregnancy and birth occur after the death
- Fertilisation and pregnancy occur after the death of partner

To discuss PHR challenges, contextualising it is important. As already discussed, cancer treatment and cancer itself are often gonadotoxic, which leaves patients with limited options if they wish to conceive a genetically related child. Patients who can undergo cryopreservation may not survive, in which case they will leave their preserved gametes or embryos behind. If PHR is prohibited, the spouse of the deceased partner will be unable to proceed with the planned fertility treatment, preventing their access and emotionally affecting them.

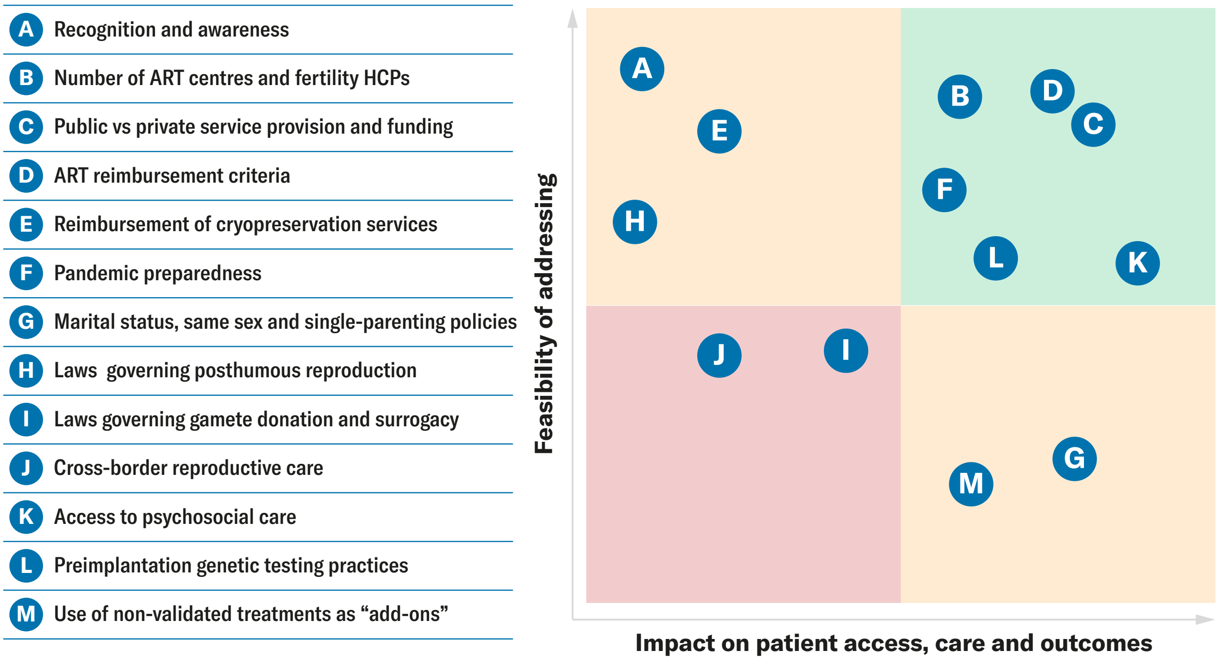
In addition, in countries where PHR is allowed, the challenge lies in the ambiguity of the laws and/or guidelines governing the treatment. Laws on posthumous reproduction separate the procedure into two parts, which are approached differently: the retrieval of genetic tissue, and its use. If the retrieval is done post-mortem, the procedure is time sensitive because to maximise fertility success, gametes must be retrieved within 36-72 hours.[128] The separation of retrieval and use often leads to legal ambiguity. For instance, in parts of Australia (Western Australia, Queensland, and South Australia), posthumous retrieval is governed by organ donation law—it must be conducted only for therapeutic, medical, or scientific purposes.[129] The courts of the respective states have deemed the retrieval of gametes a medical purpose and therefore allow it in most cases, unless there are grounds to believe the deceased did not wish to have children. The ambiguity lies in the laws that govern the use of the retrieved gametes. In Western Australia, use of posthumously retrieved gametes is prohibited, while in South Australia it is permitted only with sperm retrieved before the individual's death (the provision does not discuss egg use).[130] The ambiguity of laws and recommendations leads to ethical challenges and resulting decisions that may not align with the deceased person's will.

2.6. Summary

In conclusion, the challenges pertinent to the fertility space are multifaceted and differ greatly based on geography. Experts note that lack of patient access to fertility treatment and optimal care remains a global issue, as it is driven both by affordability and availability challenges. Diagnosing and addressing these challenges on a country-by-country basis would have a significant impact on patients' ability to access high-quality care and therefore could positively impact global fertility rates.

During the Policy Forum, the participants were prompted to rank the discussed challenges based on their impact on patient access and the feasibility of addressing them. This allows us to see which challenges are the most impactful to patients and the most practical to address, i.e., those that should be made high priorities for policy intervention. The framework below (Figure 12) provides a high-level overview of the discussion and its outcomes. Similarly, this framework may be used on a country level to assess the most pertinent challenges locally.

Figure 12: Global assessment of impact and feasibility of fertility policy challenges



Addressing these challenges will be a difficult task for policymakers, as each challenge is associated with country-specific intricacies and drivers that must be considered when developing policies. In some countries, religion and culture play a significant role in fertility-related laws, so great care must be taken when discussing reforms and changes. Any proposal to address challenges must be appropriate in relation to the local religious and cultural beliefs. In more secular countries, the macroeconomic and political contexts play important roles.

3. The principles of optimal infertility policy design

Key messages:

- Defining a universally applicable “optimal” policy (or set of policies) that would ensure patients have greater access to fertility treatment and care in the future is impossible, because the underlying challenges (and thus appropriate policy interventions) vary significantly across countries.
- Instead, it is more practical to define the characteristics of what “optimal” policy should achieve: it needs to be tailored to address a relevant challenge and be holistic, equitable, ethical, implementable, scalable, and measurable.
- Across these dimensions, many countries have already adopted proactive and forward-looking policies to support patient access and care.
- These existing policy examples can be used as a guide for decision-makers in other regions and countries to formulate effective policy interventions.

To support policymakers in navigating the complexity of challenges so they can provide access to fertility treatment and develop appropriate country-specific solutions, this chapter covers the general components that an infertility policy, or set of policies, needs to have to be successful and contribute to optimal fertility treatment and patient care. The definitions used to characterise a successful policy are broad to ensure their applicability across different geographies and healthcare system settings. They were developed based on the literature review and consensus from our panel of fertility experts during the Policy Forum. Additionally, examples of existing successful policies at the country, regional, and international levels are provided, together with rationales for why each policy is deemed successful and contributes towards optimal fertility treatment and care.

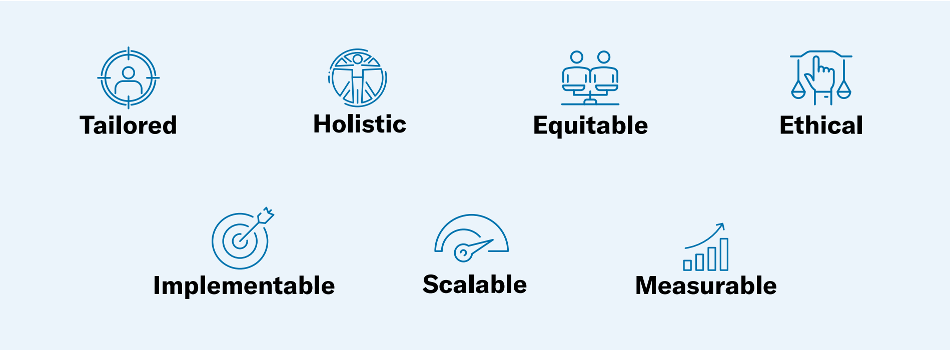
Despite the inclusion of “best practices” at the country and regional levels, we do not aim to guide specific country or regional policy recommendations through this white paper. Instead, we aim to articulate general principles that country-level stakeholders can bear in mind when designing and implementing policy improvements for patients experiencing infertility.

3.1. Infertility policy success factors

Although the most appropriate policy response to rising infertility rates will differ across countries, the success of these policies could be more systematically assessed across countries by defining and adopting a common set of principles.

In general, there was consensus during the Policy Forum that for an infertility policy to successfully contribute to optimal fertility treatment and care for patients, it needs to consider various factors: it needs to be tailored to address a relevant challenge and be holistic, equitable, ethical, implementable, scalable, and measurable (Figure 13).

Figure 13: Fertility policy success factors



***Source**: CRA analysis*

Tailored policy: Novel fertility policies clearly should be tailored to address a country's most significant challenges or policy gaps around the recognition and awareness of infertility, access to fertility treatment and psychosocial support, the use of supplementary care, or cultural, social, and religious considerations.

Holistic policy: A holistic fertility policy is one that is not developed with a siloed mindset and that can address more than one barrier to patient access and care. For example, in Table 7, the first policy could address the challenges associated with both lack of awareness of infertility and lack of knowledge about the correct use of supplementary care. The last policy in Table 7 provides legal clarity on two topics (gamete donation and PHR). This approach – of developing and implementing policies addressing more than one policy gap – allows a more coordinated response, provides more clarity to stakeholders (including patients), and drives more optimal fertility treatment and care.

Table 7: Examples of holistic fertility policies

Challenge	Examples of holistic policies
Recognition and awareness The use of supplementary care	An education campaign targeting couples who may be facing fertility issues regarding fertility treatment options and that also aims to educate people about the improper use of "add-on" treatments that have not been validated
Access to treatment Access to psychosocial support	A policy that aims to improve the affordability of fertility treatment and that also allocates funding to psychosocial support to patients undergoing fertility treatment
Cultural, social, and religious considerations	Legislation that clarifies patient access to gamete donation and does not set stringent criteria

Source: *CRA analysis and input received during expert forum*

Equitable policy: An equitable fertility policy is an inclusive one that does not discriminate against unmarried couples, same-sex couples, or people who would like to be single parents, while considering the social norms and customs of the region and country. Table 8 provides some examples of equitable policies addressing different challenges; such policies do not discriminate against subpopulations, and they foster diversity in family structure.

Table 8: Examples of equitable fertility policies

Challenge	Examples of equitable policies
Recognition and awareness	An education campaign on (in)fertility that addresses social and educational inequity while incorporating targeted messaging to same-sex couples and single women on their fertility treatment options
Access to treatment	A policy that facilitates same-sex couples and single women accessing fertility treatment
Access to psycho-social support	A policy that provides additional psychosocial support to same-sex couples and single women accessing fertility treatment to address the unique hurdles they experience when accessing fertility treatment
The use of supplementary care	An educational campaign on the efficacy of the supplementary care provisions available, ensuring that all patients across all private and public clinics have access to the same information
Cultural, social, and religious considerations	A law that enables heterosexual couples, same-sex couples, and single women to have access to gamete donations and surrogacy where appropriate

Source: *CRA analysis and input received during the expert forum*

Ethical policy: The Policy Forum experts defined an ethical fertility policy as one that considers the ethical considerations and social norms of the region or country while facilitating access to fertility treatment for individuals or couples who require it. Furthermore, ethical policies may also consider the best interest of the unborn child. Table 9 provides some examples of policies that consider ethical considerations.

Table 9: Examples of policies that facilitate fertility treatment while remaining sensitive to ethical considerations

Challenge	Examples of ethical policies
Recognition and awareness	Education campaign on (in)fertility that consider the social norms of the region or country
Access to treatment	IVF should be terminated only when it becomes reasonably clear that the patient(s) no longer needs the service, is not likely to benefit, or is being harmed by continued service
Access to psychosocial support	Psychosocial support to couples or individuals undergoing fertility treatment should be terminated only when it becomes reasonably clear that a patient no longer needs the service, is not likely to benefit, or is being harmed by continued service
The use of supplementary care	A policy that facilitates access to PGT, following recommendations set out by ethical committees, to reduce health risks to children born through ART
Cultural, social, and religious considerations	A law on posthumous reproduction that considers the wishes of the deceased and social norms

***Source**: CRA analysis and input received during the expert forum*

Implementable policy: An implementable fertility policy is one that incorporates a workable plan for how it can be implemented in a given country. Table 10 provides some examples of how policies can be implemented in stages across different patient subpopulations or different healthcare settings. This approach ensures that any learnings from the implementation of the policy in its initial stage(s) could be applied to the subsequent stages of the policy's implementation.

Table 10: Examples of policies that can be implemented in stages across target patient subpopulations or healthcare settings

Challenge	Examples of implementable policies
Recognition and awareness	An educational campaign on (in)fertility that is implemented in stages. For example, initially the campaign aims to improve awareness of infertility, and the second stage aims to educate the target population on fertility treatment options
Access to treatment	A policy that aims to improve access to fertility treatments in stages; for example, by initially focusing on expanding access to one fertility treatment, followed by expanding access to another fertility treatment
Access to psychosocial support	A policy that aims to expand a country's psychosocial support during fertility treatment by first focusing on the public healthcare setting and then expanding the policy to cover the private healthcare setting
The use of supplementary care	A policy aiming to reduce the use of unvalidated "add-on" treatments that can be implemented in multiple stages, incorporating patient awareness, physician education, and potentially more stringent regulation as a final phase
Cultural, social, and religious considerations	A law on facilitating gamete donation (e.g., for single women) can be implemented in two stages, first focusing on a specific age range and then expanding it to a broader age range

***Source**: CRA analysis and input received during the expert forum*

Scalable policy: A scalable fertility policy is one that can be scaled up to broader patient subgroups and geographical regions. Table 11 provides some examples of scalable policies in the fertility space, with some initiating as a pilot study and the findings being scaled up to a broader/national policy. Like the implementable factor, scalable policies enable the learnings from the smaller study/implementation to be applied to the broader setting. **Table 11: Examples of scalable fertility policies**

Challenge	**Examples of scalable policies**
Recognition and awareness	An educational campaign that initially targets students at secondary schools, but which later can be scaled up to target university students or the wider population (within an age range)
Access to treatment	A policy that initially increases the number of reimbursed IVF cycles to three to eligible patients can be scaled up to provide a larger number of reimbursed IVF cycles if certain criteria are met
Access to psychosocial support	A pilot study that provides a number of government-funded psychosocial sessions to patients undergoing fertility treatment in a geographical region can be scaled to all the clinics within the country after the pilot study is deemed successful
The use of supplementary care	A policy that provides publicly funded PGT in one region of the country is scaled up to all clinics in the country
Cultural, social, and religious considerations	A law on facilitating gamete donation to same-sex couples is scaled up to make it also available to single people

***Source**: CRA analysis and input received during the expert forum*

Measurable policy: Experts agreed that, ideally, the success of a policy should be measurable qualitatively or quantitatively across time, so it is possible to better understand the impact a policy is having on the targeted patients. Table 12 provides some examples of quantitative measures that could be used to measure the success of policies through time; the findings from these measures could guide policymakers on improvements in the policy.

Table 12: Examples of quantitative measures that could be used to measure the success of a policy through time

Challenge	**Examples of ways in which policies could be measured**
Recognition and awareness	The number of people reached through an educational campaign on (in)fertility
Access to treatment	The number of IVF cycles performed at a country level
Access to psychosocial support	The average number of psychosocial sessions taken by individuals or couples undergoing fertility treatment
The use of supplementary care	The reduction (as a percentage) of the uptake of unvalidated “add-on” treatments
Cultural, social, and religious considerations	The number of years since fertility laws have last been updated to reflect new scientific evidence or new social norms

***Source**: CRA analysis and input received during the expert forum*

3.2. Existing innovative policy solutions

To achieve these goals, we can look to existing examples of success. Various governments have expanded maternity and paternity leave and job security, introduced flexible working arrangements, introduced financial incentives (child or family allowances, baby bonus, tax credit), improved childcare offerings and subsidies, and improved access to fertility preservation to attempt to address falling birth rates.[131,132] Such social welfare policies can have a marginally positive impact on fertility rates, but more can be done to ensure that patients have access to fertility treatments when they need them, which would in turn have a measurable impact on fertility rates.

In this section we cover some best-practice policies across countries that were implemented to address the challenges identified above in relation to (i) the recognition and awareness of infertility; (ii) access to treatment; (iii) access to psychosocial support; (iv) the use of supplementary care; and (v) cultural, social, and religious considerations.

3.2.1. Recognition and awareness

Experts in the Policy Forum agreed that fertility education needs to be at the top of the agenda of policymakers to make a major impact in preventing infertility and ensuring that patients seek fertility treatment.[133] At the moment, sexual and reproduction education at school typically focuses on contraception and does not cover infertility and fertility care in depth or at all, resulting in many couples seeking medical help for infertility too late because they are unaware of the risks of delay. Furthermore, in some communities, there is still a stigma around ART and IVF is not openly discussed. However, some countries have adopted more proactive approaches to public education and fertility preservation, as described in Box 1.

Box 1: Best-practice examples of infertility recognition and awareness

The Australian organisation Your Fertility – which is funded by the Australian Government Department of Health and the Victorian Government Department of Health – has developed a national public health education programme. The programme aims to educate the general population on fertility and how a person can try to improve their chance of pregnancy and having a healthy baby.134 This programme addresses the challenge of a lack of recognition and awareness of infertility, is equitable as it is accessible to all online, and is ethical as it considers the local cultural norms. The programme has the potential of being scaled up to cover more targeted educational campaigns.

In the UK, the NHS funds fertility preservation for patients diagnosed with cancer. Guy's and St Thomas' NHS Foundation Trust also offers the innovative ovarian tissue cryopreservation service to women undergoing cancer treatment. This service was implemented in stages, with the latest expansion offering young women aged 14 and over who are going through chemotherapy treatments the chance to preserve their fertility and freeze their ovaries at Evelina London Children's Hospital.[135] This policy is equitable as it provides cancer patients with opportunities to have biological children in the future and reflects societal desires for healthcare professionals to support cancer patients in preserving their fertility. It is also scalable, as the service was initially provided to patients within a narrower age bracket and then expanded to those 14 and older.

Source: *CRA analysis and input received during the expert forum*

3.2.2. Access to treatment

At an international level, various initiatives are monitoring the extent of access to IVF treatment across countries, including the International Committee for Monitoring Assisted Reproductive Technologies, International Federation of Fertility Societies, and European IVF Monitoring Consortium. However, it is the responsibility of national governments and payers to introduce policies to improve access to ART locally, and we have observed decision-makers in some countries adopting forward-looking approaches to achieve this (Box 2).

Box 2: Best-practice policies for enabling access to fertility treatment

In Denmark, the cost of three fresh IVF transfers or five started cycles is publicly funded by the public health service, provided that female patients are between the ages of 18 and 40. Since 2018, a new, equitable law enables heterosexual couples, single women, and lesbian couples to access infertility treatment. Furthermore, the success of this legislation is measurable; it is estimated that one in ten of all births in Denmark involve ART or MAR.136,137

In France, a new Bioethics Law was introduced in August 2021. It widened the access conditions to ART, enabling a couple formed by a man and a woman or two women or an unmarried woman to access ART.138

In Israel, IVF treatments are funded for couples who have no children from their current marriage, as stated in the State Health Insurance Law. Funding is also available to a woman without children who is interested in raising a family headed by an independent parent ("one-parent family") for her first and second children.139 This funding provision has led to Israel having around 5,000 IVF cycles per million inhabitants.140 This policy addresses the access to treatment challenge, is equitable as it enables single women to have access to treatment, and is measurable (the number of IVF cycles conducted per year).

Since 2022, Japanese public health insurance has reimbursed 70% of the costs of ART (although coverage excludes procedures such as genetic screening and the use of donor eggs).[141] In addition, new legislation has been introduced to allow national public employees up to ten days of paid leave a year to receive fertility treatment, addressing the fact that 62.5% of people who undergo IVF in Japan say it is very difficult to balance it with work and 11.3% say it is near impossible.[142] In conjunction, these two polices aim to address the challenge in accessing treatment holistically, as in addition to the financial constraints it take into account the difficulties that patients face in balancing fertility treatment with work. The success of these policies could be measured through the percentage of newborns conceived through IVF, which in 2019 was estimated to be one in 14.[143]

Greece, Malta, Portugal, Italy, Ukraine, and France also have introduced legislation to provide a right to time off work for fertility treatment. In some additional countries (such as the UK and Ireland), similar legislation has been under consideration. In Spain, the courts have ruled that employers cannot dismiss employees for repeated absences due to fertility treatments.[144]

Source: *CRA analysis and input received during the expert forum*

3.2.3. Access to psychosocial support

Experts in the Policy Forum agreed that the psychosocial support provided to patients undergoing fertility treatment is inadequate in many countries, and this impacts fertility treatment outcomes because some patients discontinue treatment due to its psychosocial toll. There was consensus among the fertility experts that in public clinics, psychosocial sessions should be provided free of charge or subsidised, whereas in private clinics the cost of these sessions needs to be incorporated into the service. Some existing policies aimed at supporting patients throughout their treatment journey can be looked to for lessons (Box 3).

Box 3: Best-practice policies for enabling access to psychosocial support

In Australia, IVF clinics provide psychosocial care: it is customary for a fertility counsellor to work with the nursing team to support the patients throughout their journey. Counselling is provided free of charge during and after an IVF cycle, and it is available at all clinics. Such psychosocial support helps patients develop strategies for different scenarios, including preparing for fertility treatment and making decisions about the treatment; coping with unsuccessful treatment cycles or pregnancy losses; addressing specific concerns related to donor treatment cycles or feelings of anxiety or loss of control.[145] This right to psychosocial care is enshrined in Victorian fertility law.[146]

Similarly, Brazilian private and public clinics provide psychosocial support during IVF treatment, as standard practice.[147] Policies that ensure that patients undergoing fertility treatment have access to psychosocial support can result in a greater likelihood of patients staying on their treatment plan. Additionally, the policies are equitable and ethical as everyone has access to these psychosocial sessions, irrespective of whether the patient is accessing treatment in a public or private clinic, and they ensure that patients have the necessary support to undergo fertility treatment.

In the UK, a fertility app developed by a fertility company aims to provide women with personalised, 24/7 support; access to therapists, nurses, and nutritionists; and optimised fertility outcomes.148 If the app flags a patient as severely struggling, the app will contact their IVF clinic to make sure they receive the right support. Additionally, users will be able to see how many counselling sessions they have available via their clinic, and if they have none, the app will show them the closest registered practitioners. This solution is arguably less equitable than the policies implemented in Australia and Brazil because if the patient does not have sessions available via their clinic, they must pay out of pocket. On the other hand, this solution could be implementable in stages (i.e., the coverage of the app could be expanded in stages, reflecting different geographical regions within the UK). Such apps were deemed to improve patients' engagement with their fertility treatment and could improve health outcomes.[149]

Source: *CRA analysis and input received during the expert forum*

3.2.4. The use of supplementary care

Access to PGT when it is clinically recommended is not uniform across countries. In some countries, access to PGT varies significantly between the private and public setting. Furthermore, across all countries, patients using non-validated "add-on" fertility treatments have limited knowledge of the efficacy of these treatments or may have been misinformed about their efficacy through marketing campaigns and digital applications. As described in Box 4, a range of approaches have been utilised to guide and manage the use of supplementary care.

Box 4: Best-practice policies on the use of supplementary care

Preimplantation genetic testing (PGT): In Australia, since November 2021, patients who meet a set of criteria have been able to claim a Medicare rebate for several PGT services, including PGT-M (monogenic) for couples at risk of passing on recessive, autosomal dominant, or mitochondrial disorders; PGT-SR (structural rearrangements) for carriers of chromosomal rearrangements; and PGT for sex selection for couples at risk of passing on X-linked disorders.[150]

Preimplantation genetic testing (PGT): In Spain, PGT is available to various patient groups, including couples having ART who are at risk of chromosomal abnormalities, women aged 35 and over, couples with a history of chromosomal problems, and couples who have had repeated miscarriages.[151] This policy has facilitated access to PGT to patient subgroups with an underlying clinical rationale. Additionally, this policy is considered equitable as various patient subgroups can have access to the test.

"Add-on" treatments: The UK's Human Fertilisation and Embryology Authority (HFEA) has developed traffic-light ratings for supplementary care that is claimed to improve the chances of having a baby (live birth rate) but for which supportive evidence for most fertility patients is usually missing or not very reliable. The ratings are decided by HFEA's Scientific and Clinical Advances Advisory Committee subcommittee, which every 12 months reviews the available research for each treatment add-on in its traffic-light-rated list to determine whether the evidence base has changed.[152] A limitation of this framework is that the evidence is reviewed only every 12 months and thus may hinder the uptake of innovative treatments or existing treatments for which new evidence is available.[153]

In general, HFEA's traffic-light-ratings framework addresses the hurdle that some patients undergoing fertility treatment utilise non-validated treatments. The framework is equitable as its findings are available to all free of charge on the HFEA website. In addition, it can be scaled up to be used to assess other add-on treatments, and the organisation invites individuals to request that treatments of interest be added to its list. Furthermore, the framework's findings are measurable, as each add-on treatment is ranked as green, amber, grey, black, or red, depending on the evidence available.

***Source**: CRA analysis and input received during the expert forum*

3.2.5. Cultural, social, and religious considerations

Various best practices exist for countries and regions advancing local legislation to reflect a country's or region's cultural norms. For example, as demonstrated in Box 5, the EU introduced legislation to standardise clinical practices of ART centres, whilst ESHRE launched an ART Centre Certification (ARTCC) to improve such practices. Denmark and Australia have introduced legislation on donor donations and donor identification that reflect each country's norms.

Box 5: Best-practice policies on cultural, social, and religious considerations

Guidelines on offering PGT-M: The American Society for Reproductive Medicine (ASRM) develops practice guidelines to assist practitioners with clinical decisions. The most recent one was published in 2023. It details the "[i]ndications and management of preimplantation genetic testing for monogenic conditions".[154] The new guidelines have been issued as an update to the 2008 PGT guidelines since the patient demand for PGT-M is increasing. Because PGT-M is a highly technical procedure, ASRM recommends that it be offered only if a significant reproductive risk is identified. These guidelines will allow practitioners to balance patient demands and clinical efficacy in adhering to ethical standards.

🇪🇺	Standards of the clinical practice of ART centres: The European Union Tissue and Cells Directives (EUTCDs) legislation has included ART activities. This requires national EUTCD authorities to conduct standardised inspections regarding documentation, laboratory environment, handling of reproductive cells and tissues, traceability, coding, and patient testing. However, the EUTCDs do not cover all ART-specific aspects. For this reason, the ESHRE ARTCC was established to focus on particular areas, including relevant staff qualifications, training, continuing professional development, workload, equipment suitability, (non)-evidence-based laboratory and clinical methods used, and treatment approaches according to ESHRE guidelines, recommendations, and laboratory and clinical key performance indicators.[155] The law in conjunction with the ESHRE certificate provides a holistic methodology for ensuring ART centres use good laboratory and clinical practices. Furthermore, this approach provides a measure (in the form of a certificate) of the standards of the ART centre. In the future, the ESHRE certification could guide other organisations to adopt a similar certificate in other geographies (so this policy has the potential of being scalable).
🇩🇰	Double donation: In 2018, the Danish parliament legalised double donation (both the egg and sperm cells come from donors).[156] Before 2018, Danish law stipulated that a child must be genetically linked to at least one of its parents via either their mother's egg or father's sperm. This presented a problem for three groups: heterosexual couples who both suffered from fertility issues, single women with poor egg quality, and lesbian couples in which the designated birth mother could not conceive using her own eggs.[157] This equitable legislation is ethical, as it reflects the liberal views of Danes and addresses concerns raised by patient groups about Danish women travelling abroad for treatment with double donation.[158]
🇦🇺	Donor identification: In Australia, a person born from donor gametes is entitled to know who their donors are, should they want this information, once they turn 18. Therefore, donors must consent to their identifying information being held by each fertility IVF clinic and state registry. Western Australia, New South Wales, and Victoria have donor registries in which children born from donor gametes can access their records beginning at 16 years old. The information includes all medical and family history, identifying information about the gamete donor, and the number and gender of persons conceived using the gametes provided by the same gamete donor.[159] This legislation addresses the questions that people born from donor gametes may have around their genetic origins and is equitable in that all donor-conceived people in Australia can have the same type of information. Furthermore, the law is ethical, as its guiding principle is what is in the best interest of the child (the person born from donor gametes).

Source: *CRA analysis and input received during the expert forum*

3.3. Summary

As outlined in this chapter, although it is not possible to develop a globally applicable definition of what optimal fertility policy is, it is possible to learn from the experiences of different countries and develop a set of widely applicable principles. Policymakers need to collaborate with other stakeholders in the fertility community to develop policies that can address the challenges that patients face. The best practices outlined in this chapter aim to provide some examples of policies that have been successfully implemented at the country level and that can serve as guides to decision-makers in other regions/countries developing their own optimal fertility policies.

4. Goals for optimising patient access and care

Key messages:

- Experts participating in the Policy Forum co-established a set of policy goals to help ensure that patients suffering from infertility have wider access to better-quality care in the future.
- These goals are intended to provide a widely applicable framework for improving patient access to optimal fertility care that regional and national stakeholders can tailor to meet the needs of local patients.
- To ensure that patients have access to fertility treatment, many national, regional, and international stakeholders – including the academic and clinical communities, patient advocacy groups, policymakers, regulators, legislators, and the pharmaceutical and tech industries – need to collaborate.
- To improve access to fertility treatment, these stakeholders need to recognise infertility as a disease, work together to improve levels of awareness of infertility, ensure that patients have access to psychosocial support while undergoing fertility treatment, and ensure that legal frameworks are in place to reflect countries' evolving societal norms around fertility treatments and to regulate the use of supplementary care.

After reviewing the barriers to optimal fertility care and looking to examples of best policies that already exist across different regions, we will delve into potential policy goals as suggested by our panel of fertility experts. Specifically, we will discuss their importance, their geographical relevance, and the approximate timeline required to implement them. Country-specific tailored recommendations are outside the scope of this paper. Instead, we aim to offer high-level global goals to support and guide the direction of local policymaking. Therefore, the following section should be interpreted as a general guide rather than formal policy recommendations.

4.1. Setting relevant goals for optimising access and care

4.1.1. Recognition and awareness

Experts reached a consensus on the fact that raising awareness about infertility and how to mitigate it is one of the most important goals that exists. Consequently, they proposed that increasing political recognition and establishing education campaigns for different demographic groups is an actionable goal that should be undertaken globally in the short term. Specifically, experts believe that many patients come to them with little awareness of their fertility status and that infertility is largely not recognised as a disease at a political level (thus impacting the funding and resources that are available to treat it).

Over the short to medium term, there are opportunities to improve the recognition and regulation of infertility as a disease by regional and national stakeholders across the globe. While the WHO has recognised infertility as a disease, an additional push is required to align local decision-makers. This is paramount for improving patient access and helping resolve the growing infertility crisis. Recognition and regulation of infertility as a disease will set the path for the resolution of challenges related to the availability and affordability of treatment by potentially enabling legislative change and increasing the proportion of the healthcare budget allocated to tackling infertility. Nonetheless, the extent of action will inevitably vary based on geographic region and level of economic development; some countries, particularly LMICs, may have too many competing health priorities to substantially increase the allocation of the share of their finite healthcare budget that goes to infertility.

Policymakers, together with the stakeholders involved in providing fertility services, can develop national infertility plans to set evidence-based goals for fertility-specific policies, treatment, and care. This goal ensures that the fertility challenges observed locally are adequately addressed through the national plan. Additionally, national policymakers can seek the support of international organisations when drafting such plans. These plans will support local stakeholders in having a unified vision and working towards the same goals.

As mentioned in Section 2.1, experts in the Forum highlighted the importance of investment in awareness campaigns to avoid exacerbating the trends (and problems associated with) ageing populations and postponement of childbearing. Based on their geographic region and local disease aetiology, patients need to be informed of the factors that could affect their fertility. That will give patients the opportunity to have more control over their fertility. Moreover, different demographic groups, including adolescents and adults, must be covered within targeted education campaigns. Such educational campaigns should inform couples and individuals facing fertility challenges but who have not yet accessed medical support of the treatment options available to encourage them to seek medical advice within an appropriate time frame.

Governments should increase funding to fertility preservation for patients diagnosed with cancer or other conditions that compromise fertility to ensure that such patients have access to fertility services. Oncofertility-specific funding will help alleviate the stress cancer patients face throughout their cancer treatment and give them the opportunity to achieve their family goals.

To conclude, Table 13 provides a summary of the covered fertility policy goals to improve the recognition and awareness of fertility.

Table 13: Fertility policy goals to improve the recognition and awareness of fertility

Fertility policy goal	Geographical relevance	Timeline
Recognise infertility as a disease by key national stakeholders (e.g., policymakers and payers) and society	Global	Short to medium term
Prioritise infertility as a disease like any other within healthcare systems (e.g., by establishing and utilising medical codes for all fertility procedures)	Global	Short to medium term
Develop national plans on infertility covering fertility specific policies, treatment and care, and the stakeholders involved in providing an organised service	Global	Medium to Long term
Establish widespread education campaigns, addressing different age groups, to improve awareness of infertility and fertility	Global	Short term
Establish targeted information campaigns on available ART options for couples and individuals experiencing infertility	Global	Short term
Increase funding and access to fertility preservation for patients diagnosed with cancer or other conditions that compromise fertility	Global	Medium term

***Source**: CRA analysis and input received during the expert forum*

4.1.2. Access to treatment

As discussed in Section 2.2, patients around the globe are facing various challenges in accessing fertility treatment, primarily due to a lack of public and private service provision and restrictive reimbursement criteria. There was consensus among fertility experts that international stakeholders should set ambitious targets and aim for global access to ART to at least double within a decade.

National- and regional-level stakeholders need to find locally specific solutions to meet this global goal. For example, depending on the country's healthcare system framework, this goal could be achieved in the following ways:

- Establishing or increasing the proportion of the healthcare budget that is allocated to tackling infertility
- Scaling up public service provision and availability to reduce wait times at public ART clinics
- Introducing affordability schemes for patients with the least ability to pay to tackle access inequities
- Expanding reimbursement criteria to ensure that they reflect international medical standards for optimal access and care (regarding which patients can access treatment and for how many cycles)

By taking the financial burden of the disease away from patients, policymakers will make treatment more accessible for a larger pool of patients and boost local fertility rates.

Recognising that the underlying access challenge varies significantly across countries, experts in the Policy Forum developed a set of goals to reflect the need to first diagnose what is currently failing in the access environment and thus inform policy interventions that will address these underlying failures (Table 14).

Table 14: Fertility policy goals to improve access to fertility treatment

Fertility policy goal	Geographical relevance	Timeline
Conduct robust assessments of the prevalence of infertility at a national level and assess the ability of fertility services to meet this demand	Global	Short term
Diagnose access environments for infertility care at a local level by establishing rates of access (e.g., number of cycles, wait times, out-of-pocket costs) and identifying factors contributing to low or inequitable access	Global	Short term
Adopt tailored solutions to increase ART access for patients (e.g., by introducing affordability schemes, increasing government funding, expanding reimbursement eligibility)	Global	Medium term
Double global access to ART within a decade	Global	Medium to long term

***Source**: CRA analysis and input received during the expert forum*

4.1.3. Access to psychosocial support

Across most healthcare systems globally, access to mental health care is poor. However, the scope of this white paper includes discussing the psychosocial support provided to patients undergoing fertility treatments, as it can directly affect the success rate of the treatment. Experts stressed that simultaneously, patient engagement determines the uptake of the provided support and, thus, also affects fertility outcomes. To minimise cessation of treatment, patients must be offered psychosocial support before and during treatment, as it helps set realistic expectations. However, as covered in Section 2.3, patients undergoing fertility treatment in most countries are not receiving the psychosocial support they require.

There was consensus among the fertility experts during the Policy Forum that in the short to medium term, patients need to have better access to psychosocial care before and during treatment. This goal can be achieved by allocating targeted funding to boost support and emphasising the importance of psychological support to providers and patients. While some countries already offer an introductory counselling session for patients, there needs to be more encouragement of patients to engage in it so they will see the benefits of psychosocial support.

Furthermore, patients can become better engaged with their treatment if they have frequent check-ins and digital support that can guide and support them throughout the treatment journey. This will allow patients to have more control over their care and ease into treatment on their own terms and timeline. Within the medium term, the availability of digital tools (e.g., online support, mood trackers) used to support patients undergoing fertility treatment needs to be monitored and funding allocated to support the use of effective tools. To be successfully integrated into the pathway, digital tools need to adhere to quality standards and be accessible by patients.

These goals are summarised in Table 15. The success of their implementation could be measured by the change in IVF cycle uptake across all involved regions, given the link between treatment uptake and availability of support. However, it is important to recognise that, in some countries, these goals may be deprioritised due to more persistent access or affordability challenges; access to treatment is a priority and must be solved before the improvement of psychosocial support to patients can take precedence. Therefore, the below mentioned goals could be first achievable in the short term in regions that already have reasonable access to fertility treatment (e.g., public reimbursement of treatment, sufficient service availability). In countries where access to treatment is still a major challenge (e.g., no public reimbursement, major affordability concerns), psychosocial support goals may be more reasonably prioritised for addressing in the medium to long term.

Table 15: Fertility policy goals to improve access to psychosocial support

Fertility policy goal	Geographical relevance	Timeline
Expand the availability of psychosocial care before, during, and after treatment through counselling sessions	Region-specific	Short to medium term
Increase funding allocated to psychosocial care for patients undergoing fertility treatment	Region-specific	Short to medium term
Expand patient engagement offerings through access to appropriate tools (e.g., mobile apps)	Region-specific	Short to medium term
Allocate funding to the reimbursement of digital tools to support patients undergoing fertility treatment	Region-specific	Medium term
Ensure that all patients undergoing fertility treatment have access to psychosocial support across all regions	Global	Medium to long term

***Source**: CRA analysis and input received during the expert forum*

4.1.4. The use of supplementary care

As discussed in Section 2.4, patients undergoing fertility treatment often feel influenced to use “add-on” treatments at their own expense, but they are not made aware of those treatments’ unproven efficacy. To curb the global use of “add-on” treatments – including over-the-counter medicines and alternative therapies – in the short term, there need to be education campaigns targeting patients and scientific communication targeting fertility healthcare professionals on the efficacy and safety of such treatments. Such campaigns will help tackle both the demand for add-ons and the supply of them at fertility clinics. Similar campaigns can be launched to educate patients and healthcare professionals about when preimplantation genetic testing (PGT) is clinically recommended. This will help to prevent patient requests for unnecessary PGT services that could potentially burden both the patient and any child.

In the short term, the ESHRE guidelines on the use of supplementary care should be systematically used by healthcare professionals in fertility clinics.[160] These guidelines feature information about the efficacy and safety of the add-on service and when it should be used. Importantly, these guidelines should be frequently renewed to avoid misinformation being publicized and so both patients and HCPs can easily access them.

Furthermore, regulations prohibiting marketing campaigns and digital applications that convey misinformation on supplementary care, together with regulation of supplementary care, can eliminate or reduce the use of non-validated add-ons in the medium to long term. As discussed in Section 2.4, many clinic websites feature advertisements for supplementary treatments they offer but do not provide relevant information about the efficacy and safety of these treatments. To avoid misinforming patients, regulations must be put in place to prevent such marketing.

These goals are summarised in Table 16.

Table 16: Fertility policy goals to improve the use of supplementary care

Fertility policy goal	Geographical relevance	Timeline
Information campaigns targeting patients and scientific communication targeting fertility healthcare professionals on the efficacy of “add-on” treatments	Global	Short term
Education campaigns targeting patients and scientific communication targeting fertility healthcare professionals on when preimplantation genetic testing (PGT) is clinically recommended	Global	Short term
Implementation of the ESHRE guidelines on the use of supplementary care in the clinical setting and the updating of such guidelines as new evidence emerges	Global	Short term

Regulation of marketing campaigns conducted by fertility clinics regarding add-on treatments (e.g., material posted on their websites or social profiles)	Region-specific	Medium to long term
Regulation of digital applications that aim to support people using fertility and ART services	Region-specific	Medium to long term
An enhanced and improved regulatory and research environment to assess the clinical utility of novel treatments	Region-specific	Medium to long term
Promulgation of regulations to make commercially available add-ons that have been properly validated	Region-specific	Medium to long term

***Source**: CRA analysis and input received during the expert forum*

4.1.5. Cultural, social, and religious considerations

Goals related to cultural, social, and religious considerations should be formulated at a national level to align with the general sociocultural context of the country. While we can discuss the challenges and barriers certain groups face and advocate for improved and equitable access for all, it is in the remit of national stakeholders to define the most appropriate policy response locally. However, national stakeholders should aim to advance legislation on fertility treatment to reflect the country’s evolving cultural, social, and religious considerations (Table 17).

Table 17: Fertility policy goals around cultural, social, and religious considerations

Fertility policy goal	Geographical relevance	Timeline
Advance legislation on fertility treatment to reflect the country’s and region’s evolving cultural, social, and religious norms	Global	Variable

***Source**: CRA analysis and input received during the expert forum*

4.2. The roles of stakeholders

For fertility goals outlined above to be realised, many national, regional, and international stakeholders will need to collaborate. Table 18 provides an overview of the potential roles of the stakeholders involved in making this a reality. The fertility space features an intricate conjunction of challenges: as discussed, access, affordability, legislation, and ethics are involved. Consequently, stakeholders from different parts of the healthcare ecosystem need to work collaboratively to achieve the aforementioned goals.

First, there needs to be strong collaboration between the academic community, clinical community, and industry for innovative treatments to be developed, tested, commercialised, and made available to patients in the clinic. It is paramount for the academic and clinical communities to conduct the anticipated research and generate evidence to support the adoption of safe and effective innovative technologies and inform the development of fertility policies that consider upcoming innovation and developments in clinical practice.

Second, close collaboration between the clinical community, international organisations, patient advocacy groups, and policymakers will ensure that the developed policies address the needs of patients and the nation’s most pressing policy gaps. Many experts perceive that patient advocacy groups are often one of the strongest voices in renegotiations of legislation and reimbursement provision, as they have experienced these challenges firsthand. With the support of the clinical community, patient advocacy groups can better formulate the objectives and needs of patients and feed them into policymaking discussions. The involvement of the clinical community will also help highlight the medical impact of outlined goals, thereby evidencing the importance of achieving them.

Furthermore, the industry can inform policymakers of any access challenges in fertility care, provide international lesson sharing, and keep decision-makers up to date on any upcoming innovations.

To summarise, while stakeholders have different roles, it is paramount for policymakers to collaborate across the board to develop and enforce optimal fertility policies that maximise patient access.

Table 18: The roles of stakeholders in achieving the fertility policy goals

Stakeholder	Role
Academic Community	▪ Generate evidence to support informed policy decision-making and to guide clinical guidelines ▪ Drive basic research in the fertility space
Clinical Community	▪ Maintain up-to-date clinical guidelines on fertility treatment and supplementary care ▪ Contribute in academic research to advance innovation ▪ Develop material for targeted education campaigns ▪ Disseminate scientific communication targeting healthcare professionals ▪ Strive for technology improvements to improve live-birth rates and drive down costs by increasing the scale of care ▪ Support policymakers in the development and implementation of fertility policies
International Organisations	▪ Encourage governments to address infertility, an important component of sexual and reproductive health and rights (as highlighted in the WHO report)[161] ▪ Generate evidence to support informed policy decision-making ▪ Develop reports that highlight international, regional, and national fertility policy gaps ▪ Set fertility targets and goals that support improved access to fertility treatment globally ▪ Support policymakers in the development and implementation of fertility policies
Patient Advocacy Groups	▪ Raise awareness about infertility and existing treatments ▪ Disseminate educational campaigns targeting patients and the general population ▪ Drive policymakers to implement policies that address the nation's fertility policy gaps ▪ Advocate for expansions in funding allocated to infertility and for broader reimbursement criteria
Policymakers	▪ Recognise infertility as a disease ▪ Develop cohesive, forward-looking fertility policies and fertility national plans ▪ Establish public information campaigns and improve school education ▪ Increase funding allocated to fertility treatments and services, including psychosocial support services and fertility preservation services for cancer patients ▪ Increase funding allocated to fertility research
Regulators and Legislators	▪ Recognise infertility as a disease ▪ Regulate supplementary care and its marketing ▪ Regulate digital tools used to support patients undergoing fertility treatment ▪ Advance legislation on fertility treatment and update it to keep it up to date on latest developments
Pharmaceutical, Digital and Tech Industries	▪ Inform policymakers about access challenges in fertility care ▪ Inform policymakers, regulators, and legislators of upcoming innovation (for horizon-scanning exercises) ▪ Recognise their role in facilitating access to sexual and reproductive health services ▪ Develop and implement strategies to improve access to sexual and reproductive health services ▪ Develop innovative products for fertility treatment and to support patients throughout their patient journey

Source: *CRA analysis and input received during the expert forum*

4.3. Conclusion

Infertility is a serious medical condition and priority for society. Collaboration by leading experts in the field has resulted in ambitious and relevant policy goals being established. However, to achieve them, we need collaborative efforts and action from various national, regional, and international stakeholders – covering the academic and clinical communities, patient advocacy groups, policymakers, regulators, legislators, and the industry – to ensure that all patients have access to optimal fertility care. Policymakers should address fertility policies holistically by ensuring that patients have access not only to fertility treatment but also to psychosocial support. Furthermore, frameworks need to be in place to ensure that patients utilise only care that is efficacious and clinically recommended. These fertility goals can be achieved only if all key stakeholders recognise infertility as a serious disease that requires investment to address the needs and rights of affected individuals and benefit society today and in the future.

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