

**The Burden of Infertility, Treatment Options, and Insurance Coverage: A Policy Brief and
Future Directions**

by

Xin Su

Bachelor of Management, Capital Medical University, 2018

Submitted to the Graduate Faculty of the
Department of Health Policy and Management
School of Public Health in partial fulfillment
of the requirements for the degree of
Master of Public Health

University of Pittsburgh

2022

UNIVERSITY OF PITTSBURGH

SCHOOL OF PUBLIC HEALTH

This essay is submitted

by

Xin Su

on

June 13, 2022

and approved by

Essay Advisor: Marian Jarlenski, PhD, MPH, Associate Professor, Health Policy and Management, School of Public Health, University of Pittsburgh

Essay Reader: Martha Ann Terry, PhD, Associate Professor, Behavioral and Community Health Sciences, School of Public Health, University of Pittsburgh

Essay Reader: Wesley M. Rohrer, PhD, MBA, Associate Professor Emeritus, Health Policy and Management, School of Public Health, University of Pittsburgh

Copyright © by Xin Su

2022

The Burden of Infertility, Treatment Options, and Insurance Coverage: A Policy Brief and Future Directions

Xin Su, MPH

University of Pittsburgh, 2022

Abstract

Infertility is a public health issue that affects about 10% of the world's population, causing a substantial global economic burden and a severe socio-psychological burden. Various physical and psychological reasons can cause infertility. In addition, unhealthy lifestyles and habits can also contribute to infertility. With socio-economic development and changes in people's lifestyles, the leading causes of infertility have changed from infectious factors to increased pressure and women's delayed fertility. Moreover, male factor infertility must be given attention. Infertility can be treated with medicine, surgery, intrauterine insemination (IUI), or assisted reproductive technology (ART). However, infertility treatments can be quite expensive, and many health insurance plans do not cover infertility diagnoses or treatments. Nineteen states in the United States have enacted some form of the infertility insurance mandate. This paper discusses the burden of infertility in the United States, its etiology, treatment options and associated costs of infertility, infertility insurance coverage laws in the United States and their effects. The issue of fertility preservation is also addressed. Recommendations for national-level and state-level infertility insurance policies are based on three categories: no insurance mandate, insurance mandates for women only, and insurance mandates for both men and women. This paper also proposes that attention be paid to insurance coverage for male infertility and balanced with insurance coverage for female infertility. The limitations of this paper are also discussed.

Public Health Significance: Although infertility affects only 10% of the world's population, the social and psychological burden caused by it is no less than that of malignant tumors and heart diseases. Infertility insurance mandates are critical due to the high cost and out-of-pocket expense of infertility treatments. The policy recommendations made in this paper for different states will have significant reference value for policymakers, insurance providers, health professionals, and patients toward a more accessible and high-quality health care service for infertility.

Key Words: infertility, fertility, insurance coverage, assisted reproductive technology (ART), infertility mandate

Table of Contents

1.0 Introduction.....	1
2.0 Methods.....	5
3.0 Literature Review	6
3.1 The Burden and Trends of Infertility in the United States	6
3.2 The Causes of Infertility and Trends over Time	7
3.3 The Treatment Options and Costs of Treatments.....	10
3.4 Public Insurance Coverage for Infertility Diagnostics and Treatments	14
3.5 Private Insurance Coverage for Infertility Diagnostics and Treatments.....	16
4.0 Discussion.....	23
4.1 Challenges for Infertility Treatments	23
4.2 Benefits of Infertility Insurance Mandates	25
4.3 Impact of Employer-provided Infertility Benefits on Employers and Workers	26
4.4 Insurance Coverage and Mandates for Male Factor Infertility.....	28
4.5 Impact of Assisted Reproductive Technology on Fertility Preservation.....	29
4.6 Current Status of Infertility Insurance Mandates in the United States and Other Countries with Social Health Insurance System	33
5.0 Proposed Strategies.....	36
5.1 Proposed Strategies at the National Level.....	36
5.1.1 Health Education.....	36
5.1.2 Infertility Insurance Mandates	36
5.2 Proposed Strategies at the State Level.....	38

6.0 Limitations	40
7.0 Conclusions.....	41
Bibliography	42

List of Tables

Table 1 Causes of Infertility for Female and Male	8
Table 2 Types of Infertility Treatments.....	11
Table 3 Costs of Infertility Treatments.....	13
Table 4 States with Laws Mandating Insurance Coverage for both Female and Male Factors	18
Table 5 States with Laws Mandating Insurance Coverage for Female Factors Only	21

List of Figures

Figure 1 Estimated Number of New and Prevalent Cases (3-year) Worldwide in 2020, ages	
25-44	32

1.0 Introduction

Infertility affects roughly 10% of the world's population. According to the Maternal Health Task Force 2010, 50 million couples worldwide are infertile.¹ Infertility is a health issue with a substantial psychosocial burden, which has been compared to the effects of some severe diseases such as cancer and heart disease. For example, a study found that infertile women had rates of anxiety or depression equivalent to those of patients diagnosed with cancer, hypertension, myocardial infarction, or HIV.²

Infertility is a reproductive disorder caused by a variety of reasons. According to the World Health Organization (WHO) "infertility is a disease of the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected intercourse".³ Despite this definition, many people have the common misperception that access to infertility care is a lifestyle choice rather than an intrinsic healthcare right for women and men.⁴ Both male and female factors can lead to infertility. Among infertile couples, female factors account for 33%, the male factors account for about 33%, and factors for both female and male or unknown factors accounts for 33%.⁵

Over the last several decades, both delays in childbearing and fertility problems have quickly increased in developed countries, and the infertility rate has increased yearly. Infertility currently affects more than seven million individuals in the United States.⁶ According to data from the United States Centers for Disease Control and Prevention (CDC), among heterosexual women aged 15 to 49 years with no prior births, about 19% cannot get pregnant after one year of trying. Also, about 26% in this group have difficulty getting pregnant.⁷ Among women aged 15 to 49 years with one or more prior births, about 6% of married women cannot get pregnant after one year of trying, and about 14% have difficulty getting pregnant or carrying a pregnancy to term.⁷

Therefore, attention must be paid to infertility by the whole society, because it significantly affects the harmony of society and families.

There are many reasons for infertility. Conditions affecting a woman's ovaries, fallopian tubes or uterus can contribute to female infertility, including polycystic ovary syndrome (PCOS), premature ovarian insufficiency (POI), fallopian tube obstruction (gonorrhea, chlamydia, endometriosis, or prior abdominal surgery), and physical characteristics and environment of the uterus (fibroids, intrauterine adhesions, endometrial polyps, adenomyosis).^{1,7} The most common reason for female infertility is ovulation disorder.¹

Infertility is not just a women's problem. Some of the factors contributing to infertility in men are disruption of testicular or ejaculatory function (varicocele, anabolic steroid use, certain types of cancer treatment, and other medical conditions), hormonal disorders such as an improper function of the hypothalamus or pituitary glands, and genetic disorders (Klinefelter's syndrome, Y-chromosome microdeletion, and myotonic dystrophy).^{1,7} The most common reasons for male infertility are the production of none, too few, or damaged sperm cells.¹

In addition to physiological causes, some lifestyle-related reasons can also lead to infertility, including obesity, age, tobacco and excessive alcohol consumption.¹ Obesity affects fertility in both men and women.^{1,8} The influence is mainly due to the abnormal metabolism of sugar, lipid, and protein caused by obesity and its damage to the endocrine system.⁸ In addition, obesity can easily lead to insulin resistance. Elevated insulin levels will stimulate the ovaries and promote the synthesis and secretion of androgens.^{1,8} For men, obesity can affect sexual function and sperm quality.⁸ Age also has a significant impact on fertility.⁹ Generally, the best period of ovarian function in a woman's life is between the ages of 22 and 28, egg quality is good, fertilization ability is strong, and the level of ovarian hormones is relatively stable. After the age

of 30, women's ovarian function begins to decline. After the age of 35, women's fertility decreases more significantly, making it more difficult to conceive.⁹ Moreover, tobacco use and excessive alcohol consumption can affect people's basic reproductive activities and functions.¹⁰

Causes of infertility are different in different countries and population-dependent. For example, a study from India showed that polycystic ovarian syndrome (PCOS) accounted for 46.6% of cases.¹ Infectious causes such as pelvic inflammatory disease and tuberculosis were significantly associated with tubal factor infertility. Male factors contributed to 20% of infertility cases, and tobacco and excessive alcohol consumption were significantly associated with abnormal semen reports.¹ Another study from Israel found that the male factor accounted for 45% in 2515 couples who attended the fertility clinics in Israel between 1999 and 2007, and ovulation disorders accounted for 37%, and tubal contributed to 18%.¹¹

The rate of infertility is increasing, and at the same time, technological changes have made many more options available to individuals experiencing fertility problems. It is helpful for a woman and her partner to seek health care before trying to get pregnant and identify any possible fertility problems.¹² In that case, physicians will begin by collecting medical and sexual histories from both partners and conducting an initial evaluation, which usually includes a semen analysis, a tubal evaluation, and ovarian reserve testing.¹²

Infertility can be treated with medicine, surgery, intrauterine insemination (IUI), or assisted reproductive technology (ART).⁷ Medication and intrauterine insemination are often used at the same time. Doctors will recommend treatments for infertility based on the evaluation of specific factors contributing to infertility, including duration of infertility, age of the female, success rates, risks, and benefits of each treatment option.⁷

However, medical treatments for fertility problems are costly in the United States. The average cost of an IVF cycle is \$12,400.¹³ Hormone therapy can range from \$200 for one use of ovarian stimulatory drugs such as Clomid to \$3,000 per cycle.^{14,15} Tubal surgery can range from \$10,000 to \$15,000, which requires a hospital stay.¹³ Thus, the cost per successful delivery through IVF ranges from \$44,000 to \$211,940, depending on the cause of infertility, the mother's age, and other factors.¹⁵ Despite the high financial costs of infertility treatments, health insurance coverage for such treatments is limited. Only 19 states have passed insurance mandates to cover ART and other infertility treatments.

The lack of affordable treatment options may have significant detrimental effects on the quality of life of millions of Americans. Because of the current lack and variations of insurance coverage mandates, infertility is implicitly designated as a disease undeserving of financial support, leaving many patients unable to fulfill their reproductive goals.

This paper summarizes the current status of infertility in the United States; introduces available approaches and options for infertility treatments, and reviews the effects of insurance mandates and other legislations, aiming to feature the latest advances and critical challenges and propose future strategies for infertility insurance mandates.

2.0 Methods

Starting with a PubMed search for “infertility insurance mandates,” this paper firstly reviews the burden of infertility in the United States, including its causes, treatment options, corresponding costs, and insurance coverage, as well as the trends over time, by summarizing and comparing relevant enacted and implemented national- and state-level laws and policies. In addition, this paper also reviews the current status of infertility insurance mandates in several countries and compares those with the United States.

Sources of this paper mainly include peer-reviewed journal articles indexed in PubMed and information published on official websites of various federal and state governmental agencies, the International Agency for Research on Cancer, and national organizations such as the American Society for Reproductive Medicine, Kaiser Family Foundation and RESOLVE.

Based on the findings of the policy review and further analysis, this paper discusses the benefits and deficiencies of current infertility insurance coverage and mandates in the United States, and provides policy strategies and recommendations appropriate to the American context.

3.0 Literature Review

3.1 The Burden and Trends of Infertility in the United States

Currently, no population-based statistics are available to accurately evaluate the burden and trends of infertility. There is a lack of nationwide collection of the exact number of infertility cases and specific infertility services used in the United States, especially for trends over time. A published report presents national estimates and trends based on the National Survey of Family Growth (NSFG).¹⁶ According to this report, the percentage of women aged 15–44 who had ever used infertility services increased from 12% in 1982 to 15% in 1995, then declined to 12% in 2002 and remained at that level from 2006 to 2010. About 12% of women aged 15–44 in 2006–2010 (7.3 million), or their partners, had ever used infertility services. Among women aged 25–44, 17% (6.9 million) had ever used any infertility service, a significant decrease from 20% in 1995. When controlling for confounding factors, such as age, race, marital status, and education, the odds of ever using medical help to get pregnant increased in 2006–2010 relative to 1995.¹⁶

According to the NSFG data, in all survey years, the ever-use of specific types of infertility services was highest among older and nulliparous women and women with higher education and household income levels.¹⁶ Among women aged 25–44 with fertility problems who tried to find medical help to get pregnant, 27% of those have less than a bachelor's degree and 56% of these are college graduates, suggesting that sociodemographic factors are also significantly associated with higher use of any infertility services. This may be due to earlier detection of infertility problems and a greater willingness to seek help in higher-income and highly educated groups. In addition, the more important reason may be that higher education often leads to delayed marriage

and childbearing, and age is the most important factor for female infertility. As noted above, after the age of 30, women's ovarian function begins to decline, and after the age of 35, the decline in function is more prominent, making it more difficult to conceive.

Among men aged 25–44 interviewed in 2006–2010, about one in ten (9.4%) had ever used infertility services, which is lower than the 17% among women aged 25–44. Regardless of the lower percentages of infertility service use among men, similar associations were seen with age, marital status, and other demographic characteristics as seen among women.¹⁶

Although nationwide survey data like NSFG have provided population-based estimates of infertility service use, the exact number of infertile people may be underestimated. Inaccurate numbers may be caused by many reasons, including failure to seek infertility services, especially for male infertility, limited type of infertility treatments included, limited population and age covered by the survey, and failure to exclude confounding factors in the analysis. Therefore, a national registry covering all infertility treatments is needed to monitor potential infertility problems in the United States.

3.2 The Causes of Infertility and Trends over Time

The causes of infertility are complex, including female and male reproductive disorders. In addition to the disease itself, the following factors also contribute to infertility: women delaying marriage and childbearing, life and mental stress, and the increased proportion of male infertility (Table 1).

Table 1 Causes of Infertility for Female and Male

Causes	Definition	Description
<i>Female Factors</i>		
Fallopian tubes factors	Pelvic inflammatory disease and tuberculosis, causing tubal inflammation, damage, and scarring.	<ul style="list-style-type: none"> ♦ Chlamydia trachomatis and Neisseria gonorrhoeae as pathogenic bacteria ♦ Tuberculosis
PCOS	Polycystic Ovarian Syndrome	A common hormonal disorder among women that affects women's menstrual cycle.
POI	Premature Ovarian Insufficiency	Defined as amenorrhea with hypoestrogenism and elevated gonadotrophins occurring before the age of 40.
Endometriosis	The presence of uterine lining in other pelvic organs, especially the ovaries, characterized by cyst formation, adhesions, and menstrual pains.	The cause of endometriosis is unknown, which occurs most often between the ages of 25 and 40.
Other female factors	Physical characteristics and environment of the uterus	Including fibroids, intrauterine adhesions, endometrial polyps, and adenomyosis.
Mixed female factors	More than one factor	All the above reasons could be involved
<i>Male Factors</i>		
Oligospermia	Low sperm concentration as less than 15 million sperm per ml	Caused by varicocele, cryptorchidism, reproductive tract infection, autoimmunity, and chromosomal abnormalities.
Asthenospermia	The loss or reduction of spermatozoan motility	Caused by varicocele, cryptorchidism, reproductive tract infection, autoimmunity, and chromosomal abnormalities.
Other male factors	Disruption of testicular or ejaculatory function	Including anabolic steroid use, certain types of cancer treatment, and other medical conditions.
	Hormonal disorders	Improper function of the hypothalamus or pituitary glands and genetic disorders
<i>Lifestyle-related Causes for Female and Male</i>		
Age	Over 35 for female	Women's fertility will decline
Tobacco and excessive alcohol consumption	Affects fertility in both male and female	Affects basic reproductive activities and functions
Obesity	Affects fertility in both male and female	Abnormal metabolism of sugar, lipid, and protein; affecting sexual function and sperm quality
High pressure	Affects fertility in both male and female	Leading to anxiety, depression, and even infertility

Historically, the leading causes of infertility were infectious factors, including pelvic inflammatory disease and tuberculosis, significantly associated with tubal factor infertility.¹⁷ Most cases of tubal factor infertility are attributable to untreated sexually transmitted diseases capable of causing tubal inflammation, damage, and scarring. Evidence demonstrated the effects of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* as pathogenic bacteria involved in reproductive tract morbidities, including tubal factor infertility and pelvic inflammatory disease.¹⁷ Limited evidence points to other sexually transmitted organisms, including *Mycoplasma genitalium*, *Trichomonas vaginalis*, and other microorganisms within the vaginal microbiome, as important factors involved in the pathology of infertility.¹⁷ Further investigation into the vaginal microbiome and other potential pathogens is necessary.

Compared with the past, the current causes of infertility may be more related to life stress, social problems, and male infertility. Reasons for this transition may be the following. First, with the progress of society and the improvement in economic level, the pace of life is accelerated, the pressure of employment is increased, and the requirements for applicants such as education are higher. These may cause mental stress on both men and women, leading to anxiety, depression, and even infertility, which again will increase mental stress and cause an irreversible cycle. Secondly, due to the increasing pressure of employment, more and more women choose to pursue higher education and to delay the age of marriage and childbearing. Thirdly, unbalanced diet, lack of exercise, obesity, excessive drinking, and other lifestyle problems are gradually increasing. In addition, the problem of male infertility is becoming more and more prominent. As mentioned above, among infertile couples, about 33% of infertility cases are attributed to male factors. However, this number may be underestimated. In some situations and specific cultures, a diagnosis

of male infertility may be so stigmatized that it prevents the male partner from seeking further medical care.

The COVID-19 pandemic is another reason to be concerned. Some studies have shown that the new coronavirus can increase male infertility.¹⁸ This needs to be confirmed by large-scale and long-term follow-up studies, and more studies focusing on the specific mechanism need to be carried out.

3.3 The Treatment Options and Costs of Treatments

Treatment options for infertility include advice on the timing and frequency of intercourse, medications to stimulate ovulation, surgery, intrauterine insemination (IUI), and assisted reproductive technology (ART). IUI, also called artificial insemination, requires specially prepared sperms to be inserted into a woman's uterus. Sometimes the woman is also treated with medicines that stimulate ovulation before IUI. ART includes all fertility treatments in which either eggs or embryos are handled outside of the body. In general, ART procedures involve removing mature eggs from a woman's ovaries using a needle, combining the eggs with sperm in the laboratory, and returning the embryos to the woman's body. The primary type of ART is in vitro fertilization (IVF). As shown in Table 2, other types include intracytoplasmic sperm injection (ICSI), zygote intrafallopian transfer (ZIFT), and gamete intrafallopian transfer (GIFT).

Table 2 Types of Infertility Treatments

Types	Definition	Description
<i>Non-ART (Assisted Reproductive Technology)</i>		
IUI	Intrauterine insemination	IUI is also called artificial insemination. Specially prepared sperm are inserted into the woman's uterus.
<i>Assisted Reproductive Technology</i>		
IVF	In vitro fertilization	IVF is the joining of a woman's egg and a man's sperm in a laboratory dish. In vitro means outside the body.
ICSI	Intracytoplasmic sperm injection	It is used when a male factor affects fertility. Through ICSI, a single sperm is injected directly into the egg.
ZIFT	Zygote intrafallopian transfer	In which eggs are fertilized in vitro, and some of the resulting fertilized eggs are inserted into a fallopian tube.
GIFT	Gamete intrafallopian transfer	GIFT involves the placement of a donor's oocyte into a surrogate's oviduct.
<i>Assisted Drugs and Technology</i>		
OI	Ovulation induction	The most common procedure in the treatment of infertility. Medicaments for ovulation induction are used in two groups. The first group consists of women who don't have ovulation. The second group consists of women who mainly have ovulation and treat infertility with assisted reproduction methods.
AH	Assisted hatching	To breaking or thinning the zona pellucida to encourage the embryo to escape.

In general, the first stage of treatment is a diagnostic workup, involving a thorough examination of each partner's reproductive organs and their circulatory and endocrine function. Further treatment includes three levels. Level I involves ovarian stimulation for up to six cycles. Level II involves the use of exogenous gonadotropins for up to six cycles. Level III involves assisted reproductive technologies such as IVF for up to four or more cycles.

All infertility treatments are exceedingly costly. Findings from one study indicated that median out-of-pocket expenses for an 18-month period were \$912 for couples using medications only, \$2,623 for those using IUI, and \$19,324 for those using IVF.¹⁹

The cost per successful delivery through IVF ranges from \$44,000 to \$211,940.¹⁵ The 2015 American Society of Reproductive Medicine (ASRM) reported that the average cost of one IVF cycle was \$12,400.¹³ Additional fees for genetic or chromosomal testing of embryos range from \$2,000 to \$5,000, and yearly fees for egg and embryo storage are around \$1,000. Many patients may require multiple treatment cycles in order to achieve a pregnancy.² The costs of infertility treatments are listed in Table 3.

A large number of people would benefit from access to ART in the United States. According to the National Assisted Reproductive Technology Surveillance System (NASS), the number of ART cycles started per year in the United States increased steadily from more than 50,000 in 1997 to about 200,000 in 2013, although some cases are repeated. The total cost of such a large number of procedures is staggering and will cause a tremendous financial burden on individuals, families, and society.²⁰

Infertility treatments can help millions of people have a child, while the disparities in access to health care persist. Various financial, social, demographic, and psychological reasons contribute to these disparities. Among them, financial accessibility plays a vital role in selecting infertility treatments. Generally, people with higher income are more likely to seek medical care for infertility and use advanced treatments. Besides income, a reduction in out-of-pocket expenses with mandated infertility insurance is associated with increased utilization of infertility treatments in the United States.

Table 3 Costs of Infertility Treatments

Types	Definition	Costs
<i>Non-ART (Assisted Reproductive Technology)</i>		
IUI	Intrauterine insemination	<p>\$3,866 to \$4,299 per cycle (Truven Health MarketScan Commercial Claims and Encounters Databases).²¹</p> <p>\$2,623 per cycle, the median out-of-pocket expenses for those using IUI (A cohort study).¹⁹</p>
<i>Assisted Reproductive Technology</i>		
IVF	In vitro fertilization	<p>\$12,400 per cycle (ASRM, not clear if medications are included)¹³</p> <p>\$12,664 per cycle in the mandate states, and \$9,791 per cycle in non-mandate states, from a fully-insured health plan.</p> <p>\$12,337 per cycle in the mandate states, and \$11,422 per cycle in non-mandate states, from a self-insured health plan. (Truven Health MarketScan Commercial Claims and Encounters Databases).²¹</p> <p>\$19,200 per cycle including medications (US-based, multicenter cohort study)²²</p> <p>\$19,324, the median out-of-pocket expenses per cycle for those using IVF (A cohort study)¹⁹</p> <p>\$72,642 for a realized pregnancy (A cohort study)¹⁹</p>
<i>Assisted Drugs and Technology</i>		
OI	Ovulation induction	\$1,830 to \$2,627 (Truven Health MarketScan Commercial Claims and Encounters Databases) ²¹
TS	Tubal surgery	\$10,000 to \$15,000 (ASRM) ¹³
Testing	Genetic or chromosomal testing of embryos	\$2,000 to \$5,000 (ASRM) ¹³
Storage	Fees for egg and embryo yearly	\$1,000 (ASRM) ¹³

3.4 Public Insurance Coverage for Infertility Diagnostics and Treatments

The 2010 Patient Protection and Affordable Care Act (PPACA) is the most recent large federal law to mandate insurance policies. However, PPACA does not include infertility care in its list of essential health benefits and does not comment on whether insurance policies should cover infertility care, leaving coverage to the discretion of private insurers and individual states. For federal employees who are eligible to elect Federal Employees Health Benefits (FEHB) coverage, very few plans pay for IVF or ART procedures. Few plans pay for fertility drugs or treatments such as IUI.²³

While most Medicare beneficiaries are adults over the age of 65, Medicare also provides health insurance to approximately 2.5 million reproductive-age adults with permanent disabilities.²⁴ According to the Medicare Benefit Policy Manual, “reasonable and necessary services associated with treatment for infertility are covered under Medicare”.²⁵ However, “reasonable and necessary” are not explicitly defined, and specific covered services are not listed. In practice, a doctor must first conduct screenings to prove infertility, and further deem fertility treatments to be medically necessary.²⁶ Medicare Part B may provide coverage for some fertility treatments, but ART is not covered. Prescription drug plans available through Medicare Part D do not cover fertility drugs such as Clomid, follicle-stimulating hormone (FSH), and human menopausal gonadotropin (hMG).²⁷ Moreover, people enrolled in Medicare Supplement insurance, such as Medicare Advantage plans and stand-alone prescription drug plans (PDP), can receive more benefits than original Medicare. The specific coverage depends on the patients’ location and the insurance provider. For example, KelseyCare Advantage in the Greater Houston area provides several plans that offer more benefits, such as prescription drug coverage for necessary medical cases involving infertility.²⁸

According to a Kaiser Family Foundation (KFF) study, as of January 2020, New York is the only state that explicitly requires its Medicaid program to cover fertility treatment (limited to three cycles of fertility drugs). Some states may require Medicaid to cover treatments for conditions that impact fertility, such as thyroid medications, surgery for fibroids, endometriosis or other gynecologic abnormalities. In addition, eight states specifically cover infertility diagnostic services (Georgia, Hawaii, Massachusetts, Michigan, Minnesota, New Hampshire, New Mexico, and New York). They all offer at least one Medicaid plan with this benefit, but the covered range varies. No state Medicaid program currently covers IUI, IVF, or cryopreservation.²⁴

Among reproductive-age women, Medicaid covers 30% who are Black and 25% who are Hispanic, compared to 15% who are White. Concerning the coverage for maternity care and family planning services, the lack of coverage for fertility assistance has a disproportionate impact on women of color. Because eligibility for Medicaid is based on being low-income, people enrolled in the program likely cannot afford to pay for services without some public assistance.

The insurance program for military families, TRICARE, covers some types of assisted reproductive services if deemed “medically necessary,” and pregnancy is achieved through “natural conception,” meaning fertilization occurs through heterosexual intercourse. Covered services include diagnosis and treatment for an illness or injury of the male or female reproductive system, care for erectile dysfunction if it has a physical cause, and diagnostic services (semen analysis, hormone evaluation, chromosomal studies). However, IUI, IVF, costs related to donor eggs/sperm, and cryopreservation are not usually covered.²⁹ If service members have sustained severe illness or injury while on active duty that led to the loss of their natural reproductive ability, sperm/egg retrieval, IVF, artificial insemination, blastocyst implantation, and cryopreservation may be covered for them.³⁰

Another program offered by Veterans Affairs (VA) for Veterans, Women Veterans Health Care, may cover a wide range of fertility treatments, procedures, and services. This includes infertility assessments and counseling, laboratory tests, genetic counseling, ultrasound imaging, hormone therapies, surgical correction, medications, and intrauterine insemination. However, donor eggs/sperm/embryos, surrogacy, and experimental treatments are not VA-covered services.³¹

3.5 Private Insurance Coverage for Infertility Diagnostics and Treatments

West Virginia enacted the first state-level infertility insurance mandate in 1977. As of April 2021, 19 states (Arkansas, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Louisiana, Maryland, Massachusetts, Montana, New Jersey, New Hampshire, New York, Ohio, Rhode Island, Texas, Utah, and West Virginia) have passed fertility insurance coverage laws that require insurers to either cover (17 states) or offer (two states, California and Texas) coverage for infertility diagnosis and treatment. Thirteen of those states include IVF coverage, and 11 states have fertility preservation laws for iatrogenic (medically-induced) infertility.

A “mandate to cover” is a law requiring that health insurance companies provide coverage of infertility treatment as a benefit included in every policy. A “mandate to offer” is a law requiring that health insurance companies make available for purchase a policy that offers coverage of infertility treatment. Among states that do not have a “mandate to cover,” nine states (Arizona, Iowa, Michigan, Missouri, Nevada, North Carolina, Pennsylvania, Tennessee, and Virginia) and Washington, D.C. have a benchmark plan that includes coverage for at least some infertility services for most individual and small group plans sold in that state.

However, these laws apply only to certain insurers, for certain treatment services, and for certain patients, and some states have monetary caps on costs. In addition, state laws do not apply to self-funded or self-insured employer plans regulated by federal law. Moreover, many states provide exemptions for small employers (<50 employees) or religious employers (see Table 4 and Table 5).

The use of infertility services is higher in states with an infertility insurance mandate compared with states without a mandate. Infertility expenditures for women enrolled in self-insured plans were 1.2 times higher for those living in states with this mandate versus those without a mandate. In contrast, there was a threefold difference for women enrolled in fully-insured plans, suggesting that these plans incur more significant expenditures in the context of an insurance mandate.²¹ In addition, infertility insurance mandates have been shown to increase the use of infertility services in studies using the Society for Assisted Reproductive Technologies (SART) clinical data reported to the CDC and the National Survey of Family Growth.^{32,33}

Table 4 States with Laws Mandating Insurance Coverage for both Female and Male Factors

State	Start Year Revise Year	Group Insurers	Employers	Age Limit	Coverage	IVF	HMO Treatment	Religious Organization	Fertility Preservation Services
California	1989	To offer	Employers who self-insure are exempt	Not	Diagnosis, diagnostic testing, medication, surgery, GIFT	Not include	All plans covered	Not require	Not detailed
Connecticut	1989 2005 2017	To cover	Employers who self-insure are exempt	Not	4 cycles for OI 3 cycles for IUI 2 cycles for IVF, GIFT, ZIFT Low tubal ovum transfer (≤ 2 embryo)	Include	HMOs excluded	Not require	Yes
Delaware	2018	To cover	Employers who self-insure or fewer than 50 employees are exempt	Yes For IVF, retrieval ≤ 45 transfers ≤ 50	diagnostic testing, medication, surgery, IUI, AH, ICSI, OI, IVF	Include	All plans covered	Not require	Yes
Illinois	1991 1997 2019	To cover	Employers who self-insure or fewer than 25 employees are exempt	Not	diagnostic testing, medication, surgery, Low tubal ovum transfer IVF, GIFT, ZIFT	Include	All plans covered	Not require	Yes

Maryland	1985 2000 2018 2020	To cover	Employers who self-insure or fewer than 50 employees are exempt	Not	Three IVFs per live birth, Maximum \$100,000	Include	All plans covered	Not require	Not
Massachusetts	1987 2010	To cover	Employers who self-insure are exempt	Yes Female ≤ 35 (1 year period) Female ≥ 35 (6-month period)	Diagnosis, diagnostic testing, medication, surgery, IVF, GIFT, ICSI, ZIFT	Include	All plans covered	Not detailed	Not detailed
Montana	1987	To cover	Employers who self-insure are exempt	Not	Requires HMOs to cover infertility services as part of basic healthcare services. (Not detailed)	Not include	HMOs only	Not detailed	Not detailed
New Hampshire	2020	To cover	Not detailed	Not	Diagnosis, diagnostic testing, medication, surgery	Not include	All plans covered	Not detailed	Yes
New Jersey	2001 2017	To cover	Employers who self-insure or fewer than 50 employees are exempt	Yes Female ≤ 35 (1 year period) Female ≥ 35 (6-month period)	Diagnosis, diagnostic testing, medication, surgery AH, IVF, ICSI, GIFT, ZIFT, OI	Include	All plans covered	Not require	Not detailed

New York	1990 2002 2020	To cover	Employers who self-insure are exempt	Not	Diagnosis, diagnostic testing, medication, surgery 3 cycles for IVF	Include (100 or more employees)	All plans covered	Not detailed	Yes But not defined by law
Ohio	1991	To cover	Employers who self-insure are exempt	Not	Requires HMOs to cover infertility services as part of basic healthcare services. IVF, GIFT, ZIFT are not required by the law	Include (not required by the law)	HMOs only	Not detailed	Not detailed
West Virginia	1995	To cover	Employers who self-insure are exempt	Not	Requires HMOs to cover infertility services as part of basic healthcare services.	Not detailed	HMOs only	Not detailed	Not detailed

Table 5 States with Laws Mandating Insurance Coverage for Female Factors Only

State	Start Year Revise Year	Group Insurers	Employers	Age Limit	Coverage	IVF	HMO Treatment	Religious Organization	Fertility Preservation Services
Arkansas	1987	To cover	Employers who self-insure are exempt	Not	IVF Maximum \$15,000 Procedures and treatment under IVF benefit	Include	HMOs excluded	Not detailed	Not detailed
Colorado	2020	To cover	Employers who self-insure are exempt	Not	Oocyte retrievals (3 completed, using single- embryo transfer)	Not include	All plans covered	Not require	Yes
Hawaii	1989 2003	To cover	Employers who self-insure are exempt	Not	1 cycle for IVF diagnostic testing under IVF benefits	Include	All plans covered	Not detailed	Not detailed
Louisiana	2001	To cover	Employers who self-insure are exempt	Not	Not detailed, Not required to cover IVF or other ART	Not include	All plans covered	Not detailed	Not detailed
Rhode Island	1989 2006 2017	To cover	Employers who self-insure are exempt	Yes Female between 25	Diagnosis, diagnostic testing, medication,	Not include	All plans covered	Not detailed	Yes

				and 42	surgery Maximum \$100,000, up to 20% copayment				
Texas	1987	To offer	Employers who self- insure are exempt	Not	No coverage is required. Only required to offer IVF	Include	All plans covered	Not require	Not detailed
Utah	2018 2020	To cover	Not detailed	Not	Diagnosis, diagnostic testing, medication, indemnity \$4,000 to treatment	Not include	All plans covered	Not detailed	Not detailed

4.0 Discussion

Currently, infertility affects about seven million individuals in the United States, causing a substantial economic burden and a serious socio-psychological burden. Infertility can be caused by various reasons, including infertility-related disease, and psychological and lifestyle-associated reasons. This section will discuss the challenges of infertility treatments, the benefits of infertility insurance mandates, the impact of employer-provided infertility benefits on employers and workers, and insurance coverage and mandates for male factor infertility. The current status of infertility insurance mandates in the United States and comparison with other countries will be addressed. Recommendations tailored to state infertility insurance laws are also provided.

4.1 Challenges for Infertility Treatments

There are many therapeutic options for infertility, such as medicine, surgery, IUI, or ART. IVF is the primary type of ART. With the continuous improvement of technologies, therapeutic options will increase. The increased therapeutic options have brought many opportunities to infertile couples. They can choose different types of treatment according to their specific situation, economic and insurance status, and the scope of insurance coverage. In the meantime, technological advancements and increased therapeutic options could decrease treatment costs, which will benefit more infertile couples, meaning that families that cannot afford the high costs can have their genetically related children.

However, infertility treatments also bring some challenges. First of all, not every technology is 100% successful. The probability of success is related to various factors, including severity of disease, the patient's age, and the function of the ovary. Therefore, some infertile couples may have to undergo multiple cycles or even different treatments, further increasing the cost and bringing a greater psychological burden to infertile couples. Second, therapeutic options also bring challenges to infertility insurance providers. Specific types and numbers of infertility treatment, including pre-treatment tests and evaluations, should be covered, which requires detailed research to develop a feasible plan. Third, the implication of ART treatment can lead to an increase in the rate of multiple births,³⁴ especially for those with limited or no insurance coverage. Because of the financial pressure associated with the ART treatment, they are more likely to ask to transfer more than one embryo to maximize their chance for success. Multiple embryo transfer can increase the rate of multiple births (twins, triplets, or more), which can lead to increased risk of gestational diabetes, hypertensive disorders of pregnancy, hemorrhage, and stillbirth.³⁵ In 2011, fertility treatments were responsible for 36% of all twin births and 77% of triplet and higher-order multiple births in the United States.³⁶ A multiple birth can be good news for women who have difficulty conceiving. For women over 35, the most common recipients of IVF, the total number of multiple births they produce has skyrocketed, associated with increased health risks to mothers and infants. According to infant mortality statistics, the infant mortality rate of multiple births is five times higher than for singleton births,³⁷ because multiple births are often accompanied by an increase in preterm birth rates. The neurological and endocrine systems of multiple preterm infants are poorly developed, and their self-regulation function is extremely low, which can lead to death at any time. Therefore, choosing single embryo transfer is very important for IVF to prevent multiple births.

4.2 Benefits of Infertility Insurance Mandates

Infertility insurance mandates for ART increase access to infertility treatment and may influence clinical practice. With the infertility mandates, the financial pressure on infertile couples has reduced significantly,³⁸ and more infertile and older women choose ART due to their higher probability of having private health insurance, resulting in increasing fertility rates and live births, especially for first birth rates for women over 35.³⁹ A study analyzed 1981-1998 Vital Statistics data on births and maternal mortality, suggesting that White women ages 35-49 lived in states with mandated insurance coverage of infertility treatment had 20% lower maternal mortality rates relative to women living in states that did not adopt mandates.⁴⁰

A study examined whether infertility insurance mandates for ART were successful in increasing fertility rates and estimated the number of new births generated by the mandates would be IVF related, suggesting that for every 88 births generated by infertility diagnosis and treatment, 24 would be likely to be IVF related.⁴¹

The effect of mandates on first birth rates might depend on the type of mandate enacted. A “mandate to cover” affects births differently than a “mandate to offer,” or a mandate that includes IVF affects births differently than one that excludes IVF. Several studies showed that a mandate is associated with increases in the use of IVF. They also established a market model for IVF to predict the utilization rate and found that the infertility insurance mandates could increase the IVF utilization rate.⁴ In some states with full IVF coverage, fewer embryos per cycle are transferred, leading to a reduced risk of multiple births per cycle. By maximizing the chance of a full-term, normal-birthweight infant, substantial benefits accrue to the patient, the infant, and even the healthcare system.

A number of scientists have also examined the effects of these mandates, using differences-in-differences approaches⁴² where they exploit variation across states, over time, and by demographic categories. Although, they found that the mandates have not reduced disparities in the use of infertility treatment by race and socio-economic status, they found that mandates are associated with an increase in reported use of infertility treatment among highly educated, older women that is larger than the effects for other groups.⁴

In addition to the benefits mentioned above, infertility insurance mandates can also increase social stability, harmony, and people's happiness. Evidence shows that a female or male factor infertility diagnosis is associated with a lower personal quality of life, and undergoing ART can positively affect the well-being of couples accessing infertility services. From a social point of view, this reduces the likelihood of divorce,⁴³ promoting social harmony. Infertility insurance mandates can also increase the cohesion of enterprises if employers provide infertility insurance coverage.

4.3 Impact of Employer-provided Infertility Benefits on Employers and Workers

Unlike typical pregnancy-related services guaranteed nationally as basic health plan benefits under the National Pregnancy Discrimination Act (PDA), coverage for infertility treatment services is not similarly ensured, especially for ART. In the United States, only one in five employers provide infertility treatment benefits to their employees, and these policies vary widely in their comprehensiveness, reimbursement limits, and eligibility requirements.⁵

Both employers and employees can achieve positive outcomes if employers provide infertility insurance coverage. A 2016 online consumer survey commissioned by RESOLVE of

more than 700 employees pursuing IVF found that those with employer-provided IVF benefits had higher satisfaction with their employer than respondents without coverage. Covered employees were less likely to miss time from work due to treatments, experience psychological stress, depression, or other conditions related to infertility. In addition, covered employees were more likely to recommend their employer as a place to work; and felt their employer listened, met their needs, and cared about their well-being. Similarly, a 2017 survey conducted by FertilityIQ of patients who had undergone IVF found that employees who had their IVF covered reported being more likely to remain in their job for a longer period (62%), were more willing to overlook the shortcomings of their employer (53%) and were more likely to work harder (22%).⁴⁴

Employers fight to attract and retain talent in the current tight labor market, and growth in infertility benefits coverage is a suitable strategy for achieving this. A review of coverage data from FertilityIQ shows a clear trend in industries such as finance, consulting, and technology toward offering fertility benefits and expanding existing coverage.⁴⁵ Another recent national survey also found that many employers are interested in expanding their infertility benefit offerings. Of the respondents who do not currently cover IVF, almost a fifth say they are likely to add this coverage in the next two years. Likewise, of the respondents who do not currently cover egg freezing, 12% are likely to do so within two years.⁴⁶

The most common reason given by employers for not providing infertility coverage is cost. Larger employers are more likely to cite cost as a barrier than smaller employers. A study shows that if employees do not value infertility mandates at cost empirically and are unwilling to take wage cuts, employers may decrease their demand for this affected and identifiable group, women between the ages of 28 and 42.¹⁴

However, the national survey also showed that 47% of respondents would be more likely to provide fertility coverage if they knew the cost of covering infertility treatment would be offset by savings from eliminating other medical plan costs, such as multiple births.⁴⁶

4.4 Insurance Coverage and Mandates for Male Factor Infertility

As mentioned above, about 33% of infertility cases are attributed to male factors. There is a possibility that this number is underestimated. Data from the National Survey of Family Growth (NSFG) demonstrates that among couples actively seeking infertility care in the United States, as many as 18%–27% of men do not complete a male evaluation,⁴⁷ indicating that male factor infertility must be given close attention and high priority. The true prevalence of male factor infertility in the United States is unknown. Based on data from the National Assisted Reproductive Technology Surveillance System (NASS), researchers mapped the geographic distribution of male factor infertility for IVF between 1999 and 2010. The prevalence varied by states during the study interval, and the overall prevalence of isolated and total male factor infertility remained stable at around 17.1% and 34.6%, respectively.⁴⁸

Infertility has traditionally been considered a female problem. In certain cultures and situations, a diagnosis of male infertility may be so negative as to prevent the male partner from seeking medical care for diagnosis and treatment.⁴⁹ Religion can also influence the attitudes toward a diagnosis and treatment for the male partner.⁴⁸ Generally, there is a lack of knowledge among policymakers and insurance providers about male factor infertility.⁵⁰ Thus, efforts must be made to recognize male factor infertility and understand its mechanism and necessary treatments.

There is an inequity between male and female coverage in state laws for the infertility insurance mandates.⁵¹ In 19 states with laws mandating insurance coverage for female factor infertility, 12 (California, Connecticut, Delaware, Illinois, Maryland, Massachusetts, Montana, New Hampshire, New Jersey, New York, Ohio, and West Virginia) have mandates for male factor infertility evaluation or treatment (Table 4), and seven (Arkansas, Colorado, Hawaii, Louisiana, Rhode Island, Texas, and Utah) have mandates for female factor only (Table 5).

Although there are recommendations that male and female partners begin infertility evaluations together, only 12 of 19 states with laws mandating infertility insurance coverage for male partners. Excluding men from infertility coverage has several risks, such as reducing male access to necessary care, inducing a higher burden on female partners, and missing opportunities to diagnose severe male health problems. Therefore, future laws should promote equal attention to male and female partners.

4.5 Impact of Assisted Reproductive Technology on Fertility Preservation

Fertility Preservation (FP) is a fundamental issue for males and females whose future fertility may be compromised. Reproductive capacity may be seriously affected by age, different medical conditions, and treatments, especially those with gonadal toxicity.⁵² Although patients diagnosed with benign diseases, including benign hematological diseases, autoimmune diseases, and gynecological or genetic disorders, account for 8% - 13% of the demand for fertility preservation, the main population at risk consists of young oncology patients treated with chemotherapy, radiotherapy, or ovarian surgery.⁵³

Cancer can affect reproductive organs, or the damage to the ovaries and testis can be caused by the type and dose of chemotherapy or radiotherapy.⁵⁴ So infertility is a known complication of cancer treatment, and fertility preservation is one of the top concerns for most cancer survivors.^{55,56} Advancing cancer therapies and high survival rates associated with these treatments have resulted in the need for female patients to have the option to preserve fertility through embryo or oocyte preservation.⁵⁷

The Alliance for Fertility Preservation (AFP) estimates that in the United States, approximately 160,000 people between the ages of 0-44 are diagnosed with cancer each year.⁵⁸ According to the WHO-International Agency for Research on Cancer (IARC) database,⁵⁹ the estimated number of new cancer cases in 2020, aged 25-44 years, in the United States for both sexes is 115,532 (Figure 1A), and 77,247 for female only (Figure 1B). Moreover, the estimated number of prevalent cancer cases (three-year) in 2020 in the United States for both sexes is 270,306 (Figure 1C), and 180,103 for female only (Figure 1D).

The American Society of Clinical Oncology, American Society of Reproductive Medicine (ASRM), Society for Assisted Reproductive Technology (SART), and the American Medical Association (AMA) maintain that fertility preservation should be offered in certain instances. These circumstances include fertility preservation for women receiving gonadotoxic therapies for cancer or other medical diseases and certain genetic disorders such as BRCA mutations.⁶⁰ The primary care community is in a critical position to provide information about the possibility of fertility preservation, providing referrals to a reproductive endocrinology and infertility specialist, or a gynecologist, in order to incorporate reproductive goals into the patient's overall survivorship and overall quality-of-life plan.⁶¹ In addition, the knowledge that efforts have been made to preserve future fertility can serve as a stimulus of hope.

An anonymous online survey of SART membership shows that the large majority of SART members favored insurance for fertility preservation for cancer patients and the avoidance of genetic disorders.⁶² Federal legislation has been introduced for fertility preservation in the Department of Defense.⁶³ Moreover, 11 states have current fertility preservation laws for iatrogenic (medically-induced) infertility.⁶⁴

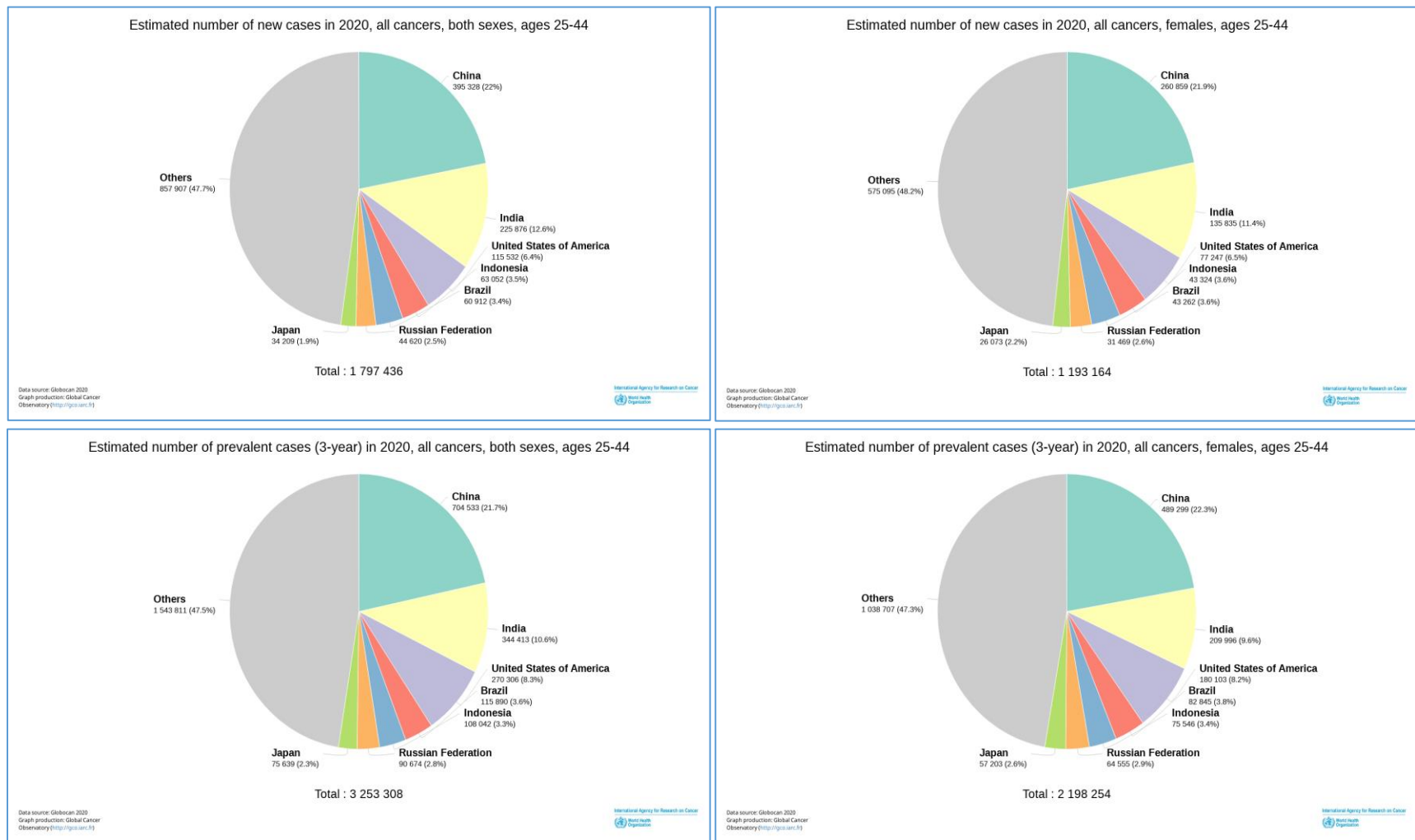


Figure 1 Estimated Number of New and Prevalent Cases (3-year) Worldwide in 2020, ages 25-44

4.6 Current Status of Infertility Insurance Mandates in the United States and Other Countries with Social Health Insurance System

There are differences between states to access general infertility insurance in the United States, dependent on the state of underwriting and the median disposable income of the locals in question. Therefore, improved access to and utilization of infertility insurance is crucial and may have broader implications for public health.

About 30 states in the United States have not enacted infertility insurance mandates. The possible reasons are as follows. First, there is a lack of a population-based database that could accurately define the burden of infertility and difficulties in access to infertility services. Secondly, patient, public, and provider awareness of infertility is limited, due to education level, scientific biases, and conflicts of interest. Thirdly, there is a lack of health insurance coverage and limited funding for clinical care. Finally, cultural, religious, and societal perceptions of infertility diagnosis and acceptance are important to consider. Altogether, infertility needs to be recognized as a disease and a public health issue. Further evaluation of the effects of these mandated benefits is essential to inform this policy debate.

In several countries with social health insurance systems, the mandated insurance coverage for infertility testing and treatment is quite different. In Germany, before 2004, all financial costs of maximally four IVF treatment cycles were fully reimbursed by the public health insurance system without restriction by a lower age limit. In 2004, following the implementation of the German healthcare modernization law, only women covered by the social healthcare system, between the ages 25 and 40 years, with a male partner younger than 51 years, qualified for 50% reimbursement of maximally three IVF cycles, resulting in a dramatic reduction of ART treatment in Germany.⁶⁵

Australia has a tradition of supportive public funding of ART treatment through its publicly financed health insurance scheme, Medicare. Since 2001, women have been eligible for partial reimbursement of almost all ART and IUI cycles with no funding limits to factors such as the number of previous cycles, maternal age, and duration of infertility.⁶⁶

In Korea, the government enacted health insurance coverage for infertility treatment procedures in October 2017. Furthermore, in July 2019, the government abolished the restriction on the age of women so that women aged 45 years or older could benefit from health insurance for infertility treatment if considered necessary by a physician. The co-pay rate for IVF and IUI procedures also increased from 30% to 50%.⁶⁷

In Japan, with its universal health insurance coverage, people can receive medical tests for fertility problems, including hormonal tests, hysterosalpingography, and early-phase fertility treatments, including ovulation induction with timed intercourse using transvaginal ultrasonography with 30% copayments. However, public health insurance does not cover IUI and ART treatments. Alternatively, the government offers partial reimbursement of 300,000 Japanese Yen (JPY) per ART cycle for up to six cycles for women younger than 43. In February 2022, Japan plans to expand the scope of universal health insurance coverage for infertility.⁶⁸ As a result, treatments such as artificial insemination that were not covered by medical insurance will be included for the first time.

To control overpopulation, severe poverty, and resource shortages, China implemented the family planning of encouraging one-child policy (abbreviated as one-child policy) in the early 1980s. Since 2013, this policy started to be relaxed to ameliorate the stagnant population growth, aging population, and shrinking workforce. Currently, there is no national-level infertility insurance coverage in China.⁶⁹ In March 2022, the Beijing Municipal Medical Insurance Bureau,

together with the Municipal Health Commission and the Municipal Human Resources and Social Security Bureau, announced that 16 safe and reliable assisted reproductive technologies such as common intrauterine insemination, embryo transfer, and sperm optimal treatment will be included in residents medical insurance.⁷⁰ This municipal policy change in Beijing is an important step toward a more supportive environment in society to encourage childbearing in women.

5.0 Proposed Strategies

At present, 19 states in the United States have passed insurance mandates to cover infertility treatments, yet other states have no infertility insurance mandates. The main reasons have been analyzed above. In order to improve access to and utilization of infertility insurance, proposed strategies are recommended at the national and state levels based on the three categories, including no insurance mandate, insurance mandates for women only, and insurance mandates for both men and women.

5.1 Proposed Strategies at the National Level

5.1.1 Health Education

1. To conduct nationwide health education to raise public awareness of infertility, especially for insurance providers, political leadership, and many medical societies and practitioners.

2. To popularize public health knowledge related to infertility, improving the awareness of early diagnosis and treatment.

5.1.2 Infertility Insurance Mandates

1. To establish a national population-based database that can accurately analyze the burden of infertility and collect all data on access and utilization of infertility care and insurance.

2. To evaluate the possibility of passing national-level infertility insurance mandates and then make legislative advocacy efforts.

At the national level, infertility insurance can be promoted in three stages (such as for women)

- ♦ Stage I: covering diagnosis and related tests for fertility problems, such as hormonal tests and early-phase fertility treatments, including ovulation induction, can be required of insurance providers. According to the costs listed in Table 3, the estimated maximum cost is \$7,600 per person (including ovulation induction, \$2,600, and testing, \$5,000). Based on the data from CDC, 13% of the approximately 72 million reproductive-aged American women need infertility services, and the total costs are \$71 billion for those women.
- ♦ Stage II: IUI can be required to be covered. According to the costs listed in Table 3, the estimated maximum cost is \$4,299 per cycle for IUI. Based on the NASS data, the number of ART cycles performed per year in the United States is 200,000, with costs of about \$860 million. Generally, infertility insurance covers three cycles for IUI, and total costs are \$7,100 million per year (including \$1,520 million for stage I, \$3,000 million for surgery, and \$2,580 million for IUI).
- ♦ Stage III: IVF, GIFT, and ZIFT can be required to be covered. Take IVF as an example: according to the costs listed in Table 3, the estimated cost is \$12,400 per cycle. Based on the NASS data, the number of ART cycles performed per year in the United States is 200,000, with costs of about \$2,480 million per cycle. Generally, infertility insurance covers three cycles for IVF, and total costs are about \$12 billion

per year (including \$1,520 million for stage I, \$3,000 million for surgery, and \$7,440 million for IVF).

The government can decide the age limit, number of cycles for IUI and IVF, and maximum payment (such as infertility insurance mandates in Delaware, Massachusetts, Connecticut, Maryland, New Jersey, New York), or offer partial reimbursements or copayments with a percentage for those infertility treatments (such as infertility insurance mandates in Germany, South Korea, and Japan).

5.2 Proposed Strategies at the State Level

For the states have passed infertility insurance mandates for both men and women, including 12 states (California, Connecticut, Delaware, Illinois, Maryland, Massachusetts, Montana, New Hampshire, New Jersey, New York, Ohio, and West Virginia):

- ♦ Collect related information on infertility insurance, including the number of the insured population, treatment options, costs, and other effects, conduct a systematic evaluation.
- ♦ Increase infertility insurance coverage based on treatment options, especially for male factor infertility.

For the states have passed infertility insurance mandates only for women, including seven states (Arkansas, Colorado, Hawaii, Louisiana, Rhode Island, Texas, and Utah):

- ♦ Collect related information on infertility insurance for women, including the number of the insured population, treatment options, costs, and other effects, conduct a systematic evaluation.

- ♦ Increase infertility insurance coverage for women based on treatment options.
- ♦ Collect population-based data on the male factor infertility in the state and estimate the possibility of passing male infertility insurance mandates dependent on the state of underwriting and median disposable income of the locals, then make legislative advocacy efforts.

For the states that have no infertility insurance mandates for women and men (other 31 states):

- ♦ Collect population-based data related to infertility of women and men in the state, and estimate the possibility of passing infertility insurance mandate dependent on the state of underwriting and median disposable income of the locals, then make legislative advocacy efforts.
- ♦ Enact infertility insurance mandates for women firstly based on treatment options.
- ♦ Estimate the possibility of passing male infertility insurance mandates dependent on the state of underwriting and median disposable income of the locals, then make legislative advocacy efforts.

6.0 Limitations

This paper has several limitations. Although all the referenced documents and information were obtained from credible sources online, this paper does not include data analysis using the original database from the Society for Assisted Reproductive Technology (SART) or the National Survey of Family Growth (NSFG). Also, most published data examine only the use of assisted reproductive technologies (ART) like in vitro fertilization (IVF), which compose only a small fraction of infertility treatments. The effects of non-ART infertility treatments such as ovulation-inducing drugs and artificial insemination are relatively unclear.

7.0 Conclusions

Infertility is a disease with a considerable socio-psychological burden in the United States. With the progress of society and economic development, the causes of infertility have also changed, from mainly infectious factors to be more related to life stress and male infertility. Infertility can be treated with many therapeutic options, including medicine, surgery, intrauterine insemination (IUI), or assisted reproductive technology (ART). While infertility treatments are quite expensive, many health insurance plans do not cover infertility diagnoses or treatments. The lack of affordable treatment options affects the quality of life of millions of Americans. Therefore, infertility insurance mandates are necessary and have many benefits for infertile couples. Currently, 19 states have passed insurance mandates to cover ART and other infertility treatments. The reason why some states have not enacted mandates might be the common misperception that infertility-related care is an elective option rather than a medical necessity, especially for male infertility. Therefore, infertility needs to be recognized as a public health issue by raising public awareness to be accepted by insurance providers, political leadership, and many medical societies and practitioners. Recommendations tailored to state infertility insurance policies to improve access to and utilization of infertility insurance are provided. In addition, a national registry covering all infertility treatments is needed to monitor potential infertility problems in the United States.

Bibliography

1. Deshpande PS, Gupta AS. Causes and prevalence of factors causing infertility in a public health facility. *J Hum Reprod Sci.* 2019;12(4):287-293. doi:10.4103/jhrs.JHRS_140_18
2. Insogna IG, Ginsburg ES. Infertility, inequality, and how lack of insurance coverage compromises reproductive autonomy. *AMA J Ethics.* 2018;20(12):E1152-1159. doi:10.1001/amajethics.2018.1152
3. Zegers-Hochschild F, Adamson GD, de Mouzon J, et al. International Committee for Monitoring Assisted Reproductive Technology (ICMART) and the World Health Organization (WHO) revised glossary of ART terminology, 2009. *Fertil Steril.* 2009;92(5):1520-1524. doi:10.1016/j.fertnstert.2009.09.009
4. Kawwass JF, Penzias AS, Adashi EY. Fertility-a human right worthy of mandated insurance coverage: the evolution, limitations, and future of access to care. *Fertil Steril.* 2021;115(1):29-42. doi:10.1016/j.fertnstert.2020.09.155
5. How common is infertility? - NICHD. Accessed January 14, 2022. <https://www.nichd.nih.gov/health/topics/infertility/conditioninfo/common>
6. Health Insurance 101 - RESOLVE: The National Infertility Association. Accessed January 14, 2022. <https://resolve.org/learn/financial-resources-for-family-building/insurance-coverage/health-insurance-101/>
7. Infertility - Reproductive Health - CDC. Accessed January 14, 2022. <https://www.cdc.gov/reproductivehealth/infertility/index.htm>
8. Cena H, Chiovato L, Nappi RE. Obesity, Polycystic Ovary Syndrome, and Infertility: A New Avenue for GLP-1 Receptor Agonists. *J Clin Endocrinol Metab.* 2020;105(8). doi:10.1210/clinem/dgaa285
9. Having a Baby After Age 35: How Aging Affects Fertility and Pregnancy | ACOG. Accessed April 23, 2022. <https://www.acog.org/womens-health/faqs/having-a-baby-after-age-35-how-aging-affects-fertility-and-pregnancy>
10. Sharma R, Biedenharn KR, Fedor JM, Agarwal A. Lifestyle factors and reproductive health: taking control of your fertility. *Reprod Biol Endocrinol.* 2013;11:66. doi:10.1186/1477-7827-11-66
11. Farhi J, Ben-Haroush A. Distribution of causes of infertility in patients attending primary fertility clinics in Israel. *Isr Med Assoc J.* 2011;13(1):51-54.

12. Infertility - Diagnosis and treatment - Mayo Clinic. Accessed June 3, 2022. <https://www.mayoclinic.org/diseases-conditions/infertility/diagnosis-treatment/drc-20354322>
13. Is In Vitro Fertilization Expensive? Accessed April 10, 2022. <https://www.reproductivefacts.org/faqs/frequently-asked-questions-about-infertility/q06-is-in-vitro-fertilization-expensive/>
14. Lahey JN. The Efficiency of a Group-Specific Mandated Benefit Revisited: The Effect of Infertility Mandates. W.E. Upjohn Institute; 2011. doi:10.17848/wp11-175
15. Bitler MP, Schmidt L. Utilization of infertility treatments: the effects of insurance mandates. *Demography*. 2012;49(1):125-149. doi:10.1007/s13524-011-0078-4
16. Chandra A, Copen CE, Stephen EH. Infertility service use in the United States: data from the National Survey of Family Growth, 1982-2010. *Natl Health Stat Report*. 2014;(73):1-21.
17. Tsevat DG, Wiesenfeld HC, Parks C, Peipert JF. Sexually transmitted diseases and infertility. *Am J Obstet Gynecol*. 2017;216(1):1-9. doi:10.1016/j.ajog.2016.08.008
18. Khalili MA, Leisegang K, Majzoub A, et al. Male Fertility and the COVID-19 Pandemic: Systematic Review of the Literature. *World J Mens Health*. 2020;38(4):506-520. doi:10.5534/wjmh.200134
19. Katz P, Showstack J, Smith JF, et al. Costs of infertility treatment: results from an 18-month prospective cohort study. *Fertil Steril*. 2011;95(3):915-921. doi:10.1016/j.fertnstert.2010.11.026
20. Adashi EY, Dean LA. Access to and use of infertility services in the United States: framing the challenges. *Fertil Steril*. 2016;105(5):1113-1118. doi:10.1016/j.fertnstert.2016.01.017
21. Boulet SL, Kawwass J, Session D, Jamieson DJ, Kissin DM, Grosse SD. US State-Level Infertility Insurance Mandates and Health Plan Expenditures on Infertility Treatments. *Matern Child Health J*. 2019;23(5):623-632. doi:10.1007/s10995-018-2675-y
22. Wu AK, Odisho AY, Washington SL, Katz PP, Smith JF. Out-of-pocket fertility patient expense: data from a multicenter prospective infertility cohort. *J Urol*. 2014;191(2):427-432. doi:10.1016/j.juro.2013.08.083
23. Will My FEHB Plan Pay for That? - Guide to Health Plans for Federal Employees. Accessed January 19, 2022. <https://help.checkbook.org/article/51-will-my-fehb-plan-pay-for-that>
24. Coverage and Use of Fertility Services in the U.S. - KFF. Accessed September 4, 2021. <https://www.kff.org/womens-health-policy/issue-brief/coverage-and-use-of-fertility-services-in-the-u-s/>

25. Medicare Benefit Policy Manual. Medicare Benefit Policy Manual Chapter 15 – Covered Medical and Other Health Services. Published online February 2, 2018.
26. Does Medicare Cover Fertility Treatments - MedicareFAQ. Accessed April 23, 2022. <https://www.medicarefaq.com/faqs/does-medicare-cover-fertility-treatments/>
27. Does Medicare Cover Fertility Treatments? | HelpAdvisor.com. Accessed April 23, 2022. <https://www.helpadvisor.com/medicare/does-medicare-cover-fertility-treatments>
28. Does Medicare Cover Fertility Treatments? Accessed June 2, 2022. <https://artcompass.io/does-medicare-cover-fertility-treatments/>
29. Assisted Reproductive Services | TRICARE. Accessed April 22, 2022. <https://www.tricare.mil/CoveredServices/IsItCovered/AssistedReproductiveServices>
30. Artificial Insemination | TRICARE. Accessed April 22, 2022. <https://www.tricare.mil/CoveredServices/IsItCovered/ArtificialInsemination>
31. Infertility and IVF - Women Veterans Health Care. Accessed April 22, 2022. <https://www.womenshealth.va.gov/WOMENSHEALTH/topics/infertility-and-ivf.asp>
32. Henne MB, Bundorf MK. Insurance mandates and trends in infertility treatments. *Fertil Steril*. 2008;89(1):66-73. doi:10.1016/j.fertnstert.2007.01.167
33. Hamilton BH, McManus B. The effects of insurance mandates on choices and outcomes in infertility treatment markets. *Health Econ*. 2012;21(8):994-1016. doi:10.1002/hecl.1776
34. Rebar RW. What are the risks of the assisted reproductive technologies (ART) and how can they be minimized? *Reprod Med Biol*. 2013;12(4):151-158. doi:10.1007/s12522-013-0156-y
35. Peipert BJ, Chung EH, Harris BS, Jain T. Impact of comprehensive state insurance mandates on in vitro fertilization utilization, embryo transfer practices, and outcomes in the United States. *Am J Obstet Gynecol*. Published online March 11, 2022. doi:10.1016/j.ajog.2022.03.003
36. Kulkarni AD, Jamieson DJ, Jones HW, et al. Fertility treatments and multiple births in the United States. *N Engl J Med*. 2013;369(23):2218-2225. doi:10.1056/NEJMoal301467
37. Matthews TJ, MacDorman MF, Thoma ME. Infant mortality statistics from the 2013 period linked birth/infant death data set. *Natl Vital Stat Rep*. 2015;64(9):1-30.
38. Lai JD, Fantus RJ, Cohen AJ, et al. Unmet financial burden of infertility care and the impact of state insurance mandates in the United States: analysis from a popular crowdfunding platform. *Fertil Steril*. 2021;116(4):1119-1125. doi:10.1016/j.fertnstert.2021.05.111
39. State Insurance Mandates Have A Positive Impact On Infertility Treatment Success | ASRM. Accessed April 15, 2022. <https://www.asrm.org/news-and-publications/news-and->

research/press-releases-and-bulletins/state-insurance-mandates-have-a-positive-impact-on-infertility-treatment-success/

40. Abramowitz J. Infertility insurance mandates and maternal mortality - Fertility and Sterility. February 17, 2020. Accessed April 15, 2022. <https://www.fertstertdialog.com/posts/59742-abramowitz-consider-this>
41. Schmidt L. Effects of infertility insurance mandates on fertility. J Health Econ. 2007;26(3):431-446. doi:10.1016/j.jhealeco.2006.10.012
42. Galic I, Negriz O, Warren C, Brown D, Bozen A, Jain T. Disparities in access to fertility care: who's in and who's out. F S Rep. 2021;2(1):109-117. doi:10.1016/j.xfre.2020.11.001
43. Cintina I, Wu B. How do state infertility insurance mandates affect divorce? Contemp Econ Policy. 2019;37(3):560-570. doi:10.1111/coep.12416
44. Fertility Insurance Coverage Myths and Facts - RESOLVE: The National Infertility Association. Accessed January 14, 2022. <https://resolve.org/learn/financial-resources-for-family-building/insurance-coverage/fertility-insurance-coverage-myths-and-facts/>
45. Is It Time to Rethink Fertility Benefits? Accessed January 15, 2022. <https://www.shrm.org/resourcesandtools/hr-topics/benefits/pages/time-to-rethink-fertility-benefits.aspx>
46. The 2021 Survey On Fertility Benefits Encourages Companies To Offer Family-Building Coverage. Accessed May 19, 2022. <https://resolve.org/the-2021-survey-on-fertility-benefits-encourages-companies-to-offer-family-building-coverage/>
47. Eisenberg ML, Lathi RB, Baker VL, Westphal LM, Milki AA, Nangia AK. Frequency of the male infertility evaluation: data from the national survey of family growth. J Urol. 2013;189(3):1030-1034. doi:10.1016/j.juro.2012.08.239
48. Mehta A, Nangia AK, Dupree JM, Smith JF. Limitations and barriers in access to care for male factor infertility. Fertil Steril. 2016;105(5):1128-1137. doi:10.1016/j.fertnstert.2016.03.023
49. Galic I, Swanson A, Warren C, et al. Infertility in the Midwest: perceptions and attitudes of current treatment. Am J Obstet Gynecol. 2021;225(1):61.e1-61.e11. doi:10.1016/j.ajog.2021.02.015
50. Ethics Committee of the American Society for Reproductive Medicine. Disparities in access to effective treatment for infertility in the United States: an Ethics Committee opinion. Fertil Steril. 2021;116(1):54-63. doi:10.1016/j.fertnstert.2021.02.019
51. Dupree JM, Dickey RM, Lipshultz LI. Inequity between male and female coverage in state infertility laws. Fertil Steril. 2016;105(6):1519-1522. doi:10.1016/j.fertnstert.2016.02.025

52. Martinez F, International Society for Fertility Preservation–ESHRE–ASRM Expert Working Group. Update on fertility preservation from the Barcelona International Society for Fertility Preservation-ESHRE-ASRM 2015 expert meeting: indications, results and future perspectives. *Fertil Steril*. 2017;108(3):407-415.e11. doi:10.1016/j.fertnstert.2017.05.024
53. Condorelli M, Demeestere I. Challenges of fertility preservation in non-oncological diseases. *Acta Obstet Gynecol Scand*. 2019;98(5):638-646. doi:10.1111/aogs.13577
54. Fertility Preservation > Fact Sheets > Yale Medicine. Accessed June 6, 2022. <https://www.yalemedicine.org/conditions/fertility-preservation>
55. Sax MR, Pavlovic Z, DeCherney AH. Inconsistent mandated access to fertility preservation: A review of relevant state legislation. *Obstet Gynecol*. 2020;135(4):848-851. doi:10.1097/AOG.0000000000003758
56. Loren AW, Senapati S. Fertility preservation in patients with hematologic malignancies and recipients of hematopoietic cell transplants. *Blood*. 2019;134(9):746-760. doi:10.1182/blood.2018846790
57. Basco D, Campo-Engelstein L, Rodriguez S. Insuring against infertility: expanding state infertility mandates to include fertility preservation technology for cancer patients. *J Law Med Ethics*. 2010;38(4):832-839. doi:10.1111/j.1748-720X.2010.00536.x
58. FEHB FERTILITY PRESERVATION COVERAGE | Alliance for Fertility Preservation. Accessed May 9, 2022. <https://www.allianceforfertilitypreservation.org/options-for-women/fertility-sparing-surgeries/fehb-fertility-preservation-coverage/>
59. Ferlay J, Ervik M, Lam F, Colombet M, Mery L, Piñeros M, Znaor A, Soerjomataram I, Bray F (2020). *Global Cancer Observatory: Cancer Today*. Lyon, France: International Agency for Research on Cancer. Available from: <https://gco.iarc.fr/today>, accessed [15 April 2022]
60. Infertility treatment as a covered health insurance benefit. *J Obstet Gynecol Neonatal Nurs*. 2014;43(2):264-265. doi:10.1111/1552-6909.12293
61. Waimey KE, Smith BM, Confino R, Jeruss JS, Pavone ME. Understanding fertility in young female cancer patients. *J Womens Health (Larchmt)*. 2015;24(10):812-818. doi:10.1089/jwh.2015.5194
62. Seifer DB, Wantman E, Sparks AE, et al. National survey of the Society for Assisted Reproductive Technology membership regarding insurance coverage for assisted reproductive technologies. *Fertil Steril*. 2018;110(6):1081-1088.e1. doi:10.1016/j.fertnstert.2018.07.016
63. Strasser MO, Dupree JM. Care delivery for male infertility: the present and future. *Urol Clin North Am*. 2020;47(2):193-204. doi:10.1016/j.ucl.2019.12.006

64. Insurance Coverage by State - RESOLVE: The National Infertility Association. Accessed January 14, 2022. <https://resolve.org/learn/financial-resources-for-family-building/insurance-coverage/insurance-coverage-by-state/>
65. Griesinger G, Diedrich K, Altgassen C. Stronger reduction of assisted reproduction technique treatment cycle numbers in economically weak geographical regions following the German healthcare modernization law in 2004. *Hum Reprod.* 2007;22(11):3027-3030. doi:10.1093/humrep/dem293
66. Chambers GM, Hoang VP, Illingworth PJ. Socioeconomic disparities in access to ART treatment and the differential impact of a policy that increased consumer costs. *Hum Reprod.* 2013;28(11):3111-3117. doi:10.1093/humrep/det302
67. Kim M. National policies for infertility support and nursing strategies for patients affected by infertility in South Korea. *Korean J Women Health Nurs.* 2021;27(1):1-5. doi:10.4069/kjwhn.2021.03.12.1
68. Iba A, Maeda E, Jwa SC, et al. Household income and medical help-seeking for fertility problems among a representative population in Japan. *Reprod Health.* 2021;18(1):165. doi:10.1186/s12978-021-01212-w
69. Qiao J, Wang Y, Li X, et al. A Lancet Commission on 70 years of women's reproductive, maternal, newborn, child, and adolescent health in China. *Lancet.* 2021;397(10293):2497-2536. doi:10.1016/S0140-6736(20)32708-2
70. Beijing's Assisted Reproduction is Covered by Medical Insurance (Chinese). Accessed March 1, 2022. <https://www.163.com/dy/article/H167HJ5J0534A4SB.html>