

Guideline for the prevention, diagnosis and treatment of infertility

Summary of recommendations



Introduction

Infertility is a disease of the male and female reproductive system defined as the failure to achieve a pregnancy after 12 months of regular unprotected sexual intercourse.

Globally, approximately one in six people of reproductive age experience infertility at some stage in their lives. Individuals and couples have the right to decide the number, timing and spacing of their children; however, there is a gap between desired and actual fertility in many countries, implying constraints to people's ability to realize their reproductive goals because of a variety of reasons that may include infertility. Therefore, addressing infertility is an important part of enabling individuals and couples to achieve their fertility preferences.

By acting urgently, countries have an opportunity to respond to the need for services related to the prevention, diagnosis and treatment of infertility and mitigate the many inequities in the availability, accessibility, acceptability and quality of fertility care.

This policy brief summarizes recommendations to prevent, diagnose and treat infertility contained in the World Health Organization (WHO) *Guideline for the prevention, diagnosis and treatment of infertility (1)*. It is intended to serve as a tool to support infertility policy-makers and all stakeholders to understand the guideline recommendations and fulfil their respective roles to implement them.

Aim of the guideline

The WHO *Guideline for the prevention, diagnosis and treatment of infertility* aims to improve the implementation of evidence-based interventions related to infertility. The provision of high-quality services for family planning, including services to prevent, diagnose and treat infertility, is one of the core elements of reproductive health. However, access to fertility care remains a challenge in most countries. See **Figure 1** for more information on the context, burden and impact of infertility. Specific objectives are shown in the panel on the right.

Scope and intended audience

The recommendations in the guideline cover prevention of infertility, as well as diagnosis and treatment of infertility due to female, male or unexplained factors. Given that this is the first WHO infertility guideline, it does not cover all aspects of infertility and fertility care. It is anticipated that subsequent editions of the guideline will expand the scope of recommendations. The guideline is intended for a wide variety of stakeholders (**Figure 2**).

How the guideline was developed




Many systematic reviews were conducted to answer key research questions. Guideline recommendations were formulated by a multidisciplinary and regionally diverse Guidelines Development Group using methods detailed in the WHO *Handbook for guideline development, second edition (2)*. The guideline recommendations were peer-reviewed by an external review group of experts and stakeholders.



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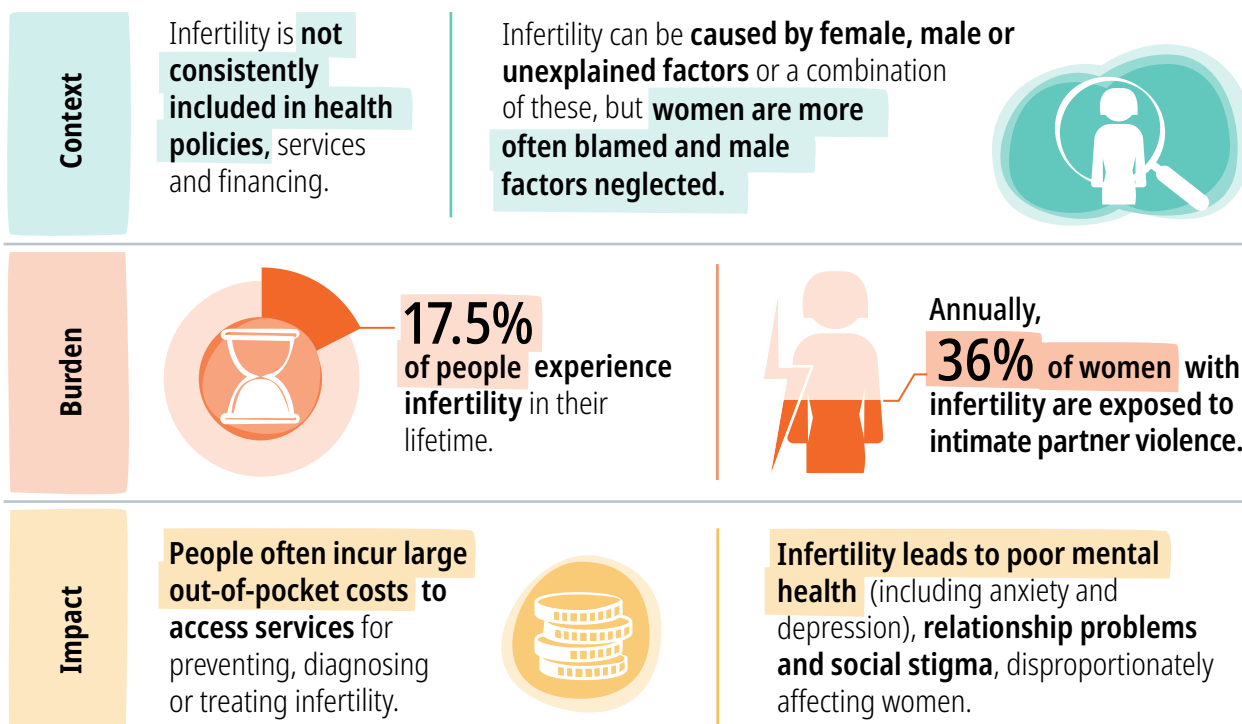


The objectives of the guideline:

-  To provide evidence-based recommendations.
-  To provide explanations of all the relevant factors that guided the recommendations.
-  To provide a source for countries to adopt, adapt or update their national guidelines.

Infertility can be caused by female, male or unexplained factors, or a combination of these, but women are more often blamed and male factors neglected ”

Fig. 1. Context, burden and impact of infertility



The provision of high-quality fertility care services is one of the core elements of reproductive health ”

Fig. 2. Intended users of the guideline include:



Summary of recommendations

The following Table 1 presents all recommendations included in the guideline, including the strength of the recommendation and certainty of the evidence supporting each recommendation. These recommendations are also presented in the relevant guideline chapters, accompanied by explanations for the judgements, appropriate diagnostic flow charts and treatment algorithms.

Table 1. Summary of recommendations and key guidance

 General approach and management of infertility	
Good practice statements on the general approach and management of infertility →	<p>For males and females being evaluated and managed for infertility, it is good practice to:</p> <ul style="list-style-type: none">✓ select diagnostic tests based on the clinical findings from the medical history and physical examination to ensure that evaluation is systematic and cost-effective. <i>(Good practice statement)</i>✓ listen to individuals and couples, respect their preferences, discuss if psychological and social or peer support is needed, and if needed, provide it or refer patients for it. <i>(Good practice statement)</i>✓ base treatment decisions on benefits and harms, patient values and preferences, feasibility, costs and availability of resources. <i>(Good practice statement)</i>✓ consider the cost-effectiveness of treatment (e.g. least expensive but effective treatments should be provided initially). <i>(Good practice statement)</i>✓ discuss the plan for clinical follow-up and management of potential risks that may occur during infertility treatment. <i>(Good practice statement)</i>✓ document the outcomes of pregnancies resulting from infertility treatment. <i>(Good practice statement)</i>



Recommendations for the prevention of infertility

Recommendations for information provision on fertility and infertility →

For the general population of reproductive age, WHO suggests providing information about fertility and infertility using low-cost strategies or whenever there is opportunity. (*Conditional recommendation, very low certainty of evidence*)

Remarks:

- Low-cost strategies may include information in digital or paper format when opportunities occur in schools, at primary health care centres or at reproductive health (contraceptive, sexual health) clinics.
- Information adapted to local contexts and audiences, including how to reduce risk factors for infertility, lifestyle modification, age-related fertility decline/potential, and timely medical consultation, may increase the likelihood of information uptake and beneficial outcomes.

For individuals and couples with infertility, WHO suggests providing low-cost lifestyle advice before and during infertility treatment. (*Conditional recommendation, low certainty of evidence*)

Remark:

- Lifestyle advice may include advice to change diet, alcohol intake, smoking, physical activity and/or weight management.

Recommendation for risk reduction from tobacco smoking →

WHO recommends that brief advice (between 30 seconds and 3 minutes per encounter) be consistently provided by health care providers as a routine practice to all tobacco users accessing any health care settings. (*Strong recommendation, moderate certainty of evidence*)

Remarks:

- This is an existing WHO recommendation for the general population that also applies to individuals and couples who are planning a pregnancy, attempting to achieve a pregnancy or with infertility, given the association between infertility and current or previous history of smoking.
- Assessment of lifestyle, including the use of tobacco, is part of medical history when evaluating individuals and couples for infertility.
- Brief advice is advice to stop using tobacco – usually taking only a few minutes – given to all tobacco users, usually during a routine consultation or interaction.
- Brief advice should include informing individuals and couples that (i) use of tobacco, particularly smoking, is associated with a higher risk of infertility; (ii) the risk of infertility due to tobacco smoking is higher among women; and (iii) a range of interventions to assist in cessation of tobacco use exist.

Recommendation for risk reduction from tobacco smoking (cont.)



- Brief advice should include the 5As: *asking* about tobacco use; *advising* to make a quit attempt; *assessing* readiness to quit; *assisting* in making a quit plan; and *arranging* a follow-up. Advice should be tailored or personalized based on individual circumstances.
- All adults interested in quitting smoking should be offered or referred to interventions to assist in tobacco cessation as recommended by existing WHO guidelines for preventing tobacco use uptake, promoting tobacco cessation or diagnosing and treating tobacco dependence.

Recommendation for risk reduction from sexually transmitted infections



Couples and individuals planning or attempting to achieve pregnancy who are accessing any health care settings should be routinely informed about sexually transmitted infections (STIs), including the risk of infertility when STIs are untreated. Couples and individuals should be encouraged to seek prompt care and treatment if they have symptoms of STIs. (*Good practice statement*)

Remark:

- If symptoms of an STI are present, or if infection is confirmed, WHO guideline recommendations on the management of STIs are available.



Recommendations for the diagnosis of female-factor infertility

Recommendations for the diagnosis of infertility due to ovulatory dysfunction



For females with infertility but normal findings on history-taking (including regular menstrual cycles) and physical examination, WHO suggests presumptive confirmation of ovulation by measuring the level of mid-luteal serum progesterone rather than performing an ultrasound scan. For females in whom the initial mid-luteal serum progesterone indicates no ovulation, a repeat measurement is suggested to minimize the risk of an inaccurate diagnosis of anovulation. (*Conditional recommendation, very low certainty of evidence*)

Remarks:

- Mid-luteal serum progesterone levels are assessed approximately 7 days before the expected onset of the next menses, noting that the specific cycle day can vary based on the length of the menstrual cycle.
- A repeat mid-luteal serum progesterone measurement could be performed in a subsequent menstrual cycle, considering the turnaround time for tests and cycle-to-cycle variations.

Recommendations for the diagnosis of infertility due to ovulatory dysfunction (cont.)



For females with infertility and suspected anovulation or oligo-ovulation, it is good practice to assess reproductive hormones related to the hypothalamic-pituitary-ovarian (HPO) axis (such as follicle-stimulating hormone (FSH) and luteinizing hormone (LH), and in some clinical presentations, estradiol (E2) and testosterone [T]). Additional testing (e.g. thyroid-stimulating hormone (TSH), prolactin [PRL]) may also be indicated based on the clinical presentation. The choice of diagnostic tests should be based on clinical findings from a comprehensive medical history and physical examination, to ensure that evaluation is systematic and cost-effective. *(Good practice statement)*

For females with infertility in whom other causes of anovulation and oligo-ovulation have been ruled out, WHO suggests that a diagnosis of low ovarian reserve should be based on age rather than diagnostic tests. If ovarian reserve diagnostic testing is conducted, WHO suggests using antral follicle count (AFC), anti-Müllerian hormone (AMH) or day 2 or 3 follicle-stimulating hormone (FSH). *(Conditional recommendation, very low certainty of evidence)*

Remarks:

- Age is the most important predictor of ovarian reserve. Therefore, ordering an ovarian reserve test in addition to age assessment may not substantially improve the accuracy of diagnosing low ovarian reserve (as assessed by poor response to stimulation). Note that the ability of age to predict ovarian reserve may be limited in some clinical scenarios, such as cases of premature ovarian insufficiency.
- Selection of the test to assess ovarian reserve should be based on relative acceptability, availability and resources in local contexts.

Recommendation for the diagnosis of infertility due to tubal disease



For females with infertility and suspected tubal disease, WHO suggests using either hysterosalpingogram (HSG) or hysterosalpingo contrast sonography (HyCoSy) to assess tubal patency. *(Conditional recommendation, low certainty of evidence)*

Remark:

- When selecting whether to use HSG or HyCoSy to assess tubal patency, consider feasibility, the availability of trained health care providers and the potential for allergy.

Recommendation for the diagnosis of infertility due to uterine cavity disorder →

For females with infertility who are suspected to have a uterine cavity disorder, WHO suggests assessing the uterine cavity with saline infusion sonohysterography (SIS) rather than three-dimensional ultrasound (3D US). *(Conditional recommendation, low certainty of evidence)*

Remark:

- In settings where 3D US is already available within the existing resources, 3D US may be the preferred option.

For females with infertility who are suspected to have a uterine cavity disorder, WHO suggests assessing the uterine cavity with three-dimensional ultrasound (3D US) rather than two-dimensional ultrasound (2D US) where resources are available. *(Conditional recommendation, low certainty of evidence)*

For females with infertility who are suspected to have a uterine cavity disorder, WHO suggests assessing the uterine cavity with saline infusion sonohysterography (SIS) rather than two-dimensional ultrasound (2D US). *(Conditional recommendation, low certainty of evidence)*

For females with infertility due to suspected uterine cavity disorder, WHO suggests assessing the uterine cavity with saline infusion sonohysterography (SIS) rather than hysterosalpingogram (HSG). *(Conditional recommendation, very low certainty of evidence)*

Remark:

- Health care providers may choose to use 2D US rather than HSG when resources are limited. Follow-up would be required for women who are negative on 2D US but still suspected of uterine cavity disorder because of high rates of false negatives.



Recommendations for the diagnosis of male-factor infertility

Recommendation for semen analysis



For males (in couples with infertility) with one or more semen parameters outside the WHO reference ranges, WHO suggests repeating the semen analysis after a minimum of 11 weeks. *(Conditional recommendation, very low certainty of evidence)*

For males (in couples with infertility) with all semen parameters within the WHO reference ranges, WHO suggests not repeating the semen analysis. *(Conditional recommendation, very low certainty of evidence)*

Remark:

- The latest edition of the WHO laboratory manual for the examination and processing of human semen provides WHO reference ranges for semen parameters and details about the standardized procedures for semen collection and analysis.



Recommendations for the diagnosis of unexplained-factor infertility

WHO suggests making a diagnosis of unexplained infertility in a couple when all the following have occurred:

- failure to achieve pregnancy after 12 months of regular unprotected sexual intercourse;
- normal physical examination and medical history in both the male and female;
- presumptive confirmation of ovulation *and* patent tubes in the female partner; and
- semen parameters that are within the WHO reference ranges in the male partner.

(Conditional recommendation, very low certainty of evidence)



Recommendations for the treatment of female-factor infertility

Recommendations for the treatment of infertility due to ovulatory dysfunction



For females with infertility due to ovulatory dysfunction caused by polycystic ovary syndrome (PCOS), WHO suggests using letrozole over clomiphene citrate or metformin. Using letrozole alone rather than with metformin is suggested. *(Conditional recommendation, low certainty of evidence for letrozole compared to clomiphene citrate, low certainty evidence for letrozole compared with metformin alone and very low certainty of evidence for letrozole compared to letrozole with metformin)*

Where off-label use of letrozole is not permitted, use of clomiphene citrate with metformin rather than clomiphene citrate alone or metformin alone is suggested. *(Conditional recommendation, moderate certainty of evidence for clomiphene citrate compared to clomiphene with metformin, very low certainty of evidence for clomiphene citrate compared to metformin)*

As part of management of polycystic ovary syndrome (PCOS), it is good practice to advise patients on lifestyle interventions such as a healthy diet, regular physical activity and/or weight management. *(Good practice statement)*

For females with infertility due to ovulatory dysfunction caused by polycystic ovary syndrome (PCOS) who have been unsuccessful with oral pharmacological therapies such as letrozole or clomiphene citrate with metformin, WHO suggests using gonadotrophins over laparoscopic ovarian drilling (LOD). *(Conditional recommendation, low certainty of evidence)*

Recommendations for the treatment of infertility due to ovulatory dysfunction (cont.)



For females with infertility due to ovulatory dysfunction caused by polycystic ovary syndrome (PCOS) who have been unsuccessful with pharmacological therapies such as letrozole, clomiphene citrate with metformin or gonadotrophins, WHO suggests in vitro fertilization (IVF) rather than expectant management. *(Conditional recommendation, very low certainty of evidence)*

For females with infertility due to ovulatory dysfunction caused by hyperprolactinaemia, WHO suggests using cabergoline over bromocriptine. *(Conditional recommendation, low certainty of evidence)*

Recommendations for the treatment of infertility due to tubal disease



For females aged <35 years with mild-to-moderate tubal disease (Hull and Rutherford grades I and II), WHO suggests surgery rather than in vitro fertilization (IVF). *(Conditional recommendation, very low certainty of evidence)*

Remarks:

- After surgery, a reasonable minimum time to wait to achieve pregnancy before pursuing other interventions, such as IVF, is 1 year.
- This recommendation does not apply to females who have had previous tubal sterilization.

For females aged <35 years with severe tubal disease (Hull and Rutherford grade III), WHO suggests in vitro fertilization (IVF) rather than surgery. *(Conditional recommendation, very low certainty of evidence)*

Remark:

- This recommendation does not apply to females who have had previous tubal sterilization.

For females aged ≥ 35 years with any tubal disease, WHO suggests in vitro fertilization (IVF) rather than surgery. *(Conditional recommendation, very low certainty of evidence)*

For females with tubal factor infertility due to hydrosalpinx, WHO suggests either salpingectomy or tubal occlusion before provision of in vitro fertilization (IVF). *(Conditional recommendation, very low certainty evidence)*

Remark:

- When selecting whether to use salpingectomy or tubal occlusion, consider feasibility, availability of trained health care providers and presence of adhesions.

For females with tubal factor infertility caused by hydrosalpinx, WHO suggests either salpingectomy or tubal occlusion rather than transvaginal aspiration of hydrosalpingeal fluid before provision of in vitro fertilization (IVF). *(Conditional recommendation, very low certainty of evidence)*

Remark:

- In settings where salpingectomy and tubal occlusion are not available or feasible, transvaginal aspiration may be offered.

Recommendations for the treatment of infertility due to uterine cavity disorder →

For females with infertility and uterine septum who have no history of recurrent pregnancy loss, WHO suggests that hysteroscopic septum resection (septoplasty) not be performed. (*Conditional recommendation, low certainty of evidence*)



Recommendations for the treatment of male-factor infertility

Recommendation on the use of antioxidants →

For males with infertility and one or more semen parameters that are outside the WHO reference ranges who are attempting to achieve pregnancy with or without medically assisted reproduction, the WHO infertility Guideline Development Group (GDG) did not make a recommendation for or against the use of antioxidant supplements.

Remark:

- Optimal nutrition is important during the pre-pregnancy period for the couple; however, the effects of antioxidant supplements for males with specific male-factor pathologies in couples with infertility are currently not known.

Recommendations for the treatment of varicocele →

For males with infertility and clinical varicocele, WHO suggests surgical or radiological treatment over expectant management. (*Conditional recommendation, low certainty of evidence*)

Remarks:

- Males with clinical varicocele and semen parameters that are outside the WHO reference ranges are more likely to benefit from receiving treatment for varicocele, compared to men with semen parameters within the WHO reference ranges.
- This recommendation applies to males with varicocele in couples with infertility who are not undergoing treatment with assisted reproductive technology (ART).

For males with infertility undergoing treatment of varicocele, WHO suggests using either surgical or radiological treatment. (*Conditional recommendation, very low certainty of evidence*)

Remarks:

- When selecting whether to use surgical or radiological treatment, consider feasibility, the availability of trained health care providers and patient preferences regarding the type of treatment procedure.
- This recommendation applies to males with varicocele in couples with infertility who are not undergoing treatment with assisted reproductive technology (ART).

Recommendations for the treatment of varicocele (cont.)



For males with infertility undergoing surgical treatment of varicocele, WHO suggests using microscopic surgery rather than other surgical procedures. *(Conditional recommendation, very low certainty of evidence)*

Remarks:

- Subinguinal microsurgery is a common surgical varicocelectomy procedure, while other surgical procedures include non-microscopic open approaches (such as inguinal and retroperitoneal) and laparoscopic methods.
- In settings where the expertise to perform microscopic surgery is not available, other surgical techniques may be used.
- This recommendation applies to males with varicocele in couples with infertility who are not undergoing treatment with assisted reproductive technology (ART).

For males with infertility undergoing non-microscopic surgical treatment of varicocele, WHO suggests using either inguinal or retroperitoneal surgical procedures. *(Conditional recommendation, very low certainty of evidence)*

Remarks:

- When selecting whether to use an inguinal or retroperitoneal surgical procedure, consider feasibility and the availability of trained health care providers.
- This recommendation applies to males with varicocele in couples with infertility who are not undergoing treatment with assisted reproductive technology (ART).



Recommendations for the treatment of unexplained infertility

Recommendations for first-line management of couples with unexplained infertility →

For couples with unexplained infertility, WHO suggests expectant management rather than unstimulated intrauterine insemination (U-IUI). *(Conditional recommendation, low certainty of evidence)*

Remarks:

- Expectant management refers to monitoring the couple with the expectation that pregnancy will be achieved without medical intervention. It includes providing advice on lifestyle and the most fertile days of the menstrual cycle, and monitoring if pregnancy will occur; however, no medical intervention is provided.
- The duration of expectant management was typically 3–6 months in studies informing this recommendation.

Recommendations for first-line management of couples with unexplained infertility (cont.)



For couples with unexplained infertility, WHO suggests expectant management rather than ovarian stimulation with timed intercourse. *(Conditional recommendation, low certainty of evidence)*

Remarks:

- Expectant management refers to monitoring the couple with the expectation that pregnancy will be achieved without medical intervention. It includes providing advice on lifestyle and the most fertile days of the menstrual cycle, and monitoring if pregnancy will occur; however, no medical intervention is provided.
- The duration of expectant management was typically 3–6 months in studies informing this recommendation.

Recommendations for second-line management of couples with unexplained infertility



For couples with unexplained infertility, where expectant management has been unsuccessful, WHO suggests stimulated intrauterine insemination (S-IUI) with either clomiphene citrate or letrozole. *(Conditional recommendation, low certainty of evidence)*

Remarks:

- When selecting whether to use clomiphene citrate or letrozole, consider the applicable national laws and regulations related to off-label use of letrozole.
- The optimal number of S-IUI cycles is unknown; in the studies used to inform this recommendation, different numbers of cycles were provided, ranging from one to six, with more recent studies providing three to six cycles.

For couples with unexplained infertility, where expectant management has been unsuccessful, WHO suggests stimulated intrauterine insemination (S-IUI) with either clomiphene citrate or letrozole rather than with gonadotrophins. *(Conditional recommendation, very low certainty of evidence)*

Remark:

- The optimal number of S-IUI cycles is unknown; in the studies used to inform this recommendation, different numbers of cycles were provided, ranging from one to six, with more recent studies providing three to six cycles.

Recommendations for third-line management of unexplained infertility



For couples with unexplained infertility, where stimulated intrauterine insemination (S-IUI) has been unsuccessful, WHO suggests in vitro fertilization (IVF) rather than expectant management. *(Conditional recommendation, low certainty of evidence)*

For couples with unexplained infertility undergoing in vitro fertilization (IVF) after S-IUI has been unsuccessful, WHO recommends using IVF alone rather than IVF with intracytoplasmic sperm injection (ICSI). *(Strong recommendation, low certainty of evidence)*



Prevent infertility by providing early information on fertility and infertility, including age-related fertility decline/potential, and lifestyle and other factors that increase the risk of infertility.

Diagnose promptly the cause of infertility in females and males.

Treat people with infertility, and assess, provide or refer for psychosocial support if needed.



Adaptation of guideline recommendations

It is expected that countries will adapt the recommendations to suit their national needs, based on local contexts, through inclusive engagement of all local partners, including national and subnational governments, civil society, patient organizations and professional societies of various health care providers involved in fertility care. It is anticipated that national adaptation will be based on the epidemiological profile related to the burden of infertility and needs assessments and will consider the organization and capacity of the health care system, required resources, as well as the local health, social, cultural and economic contexts.



Implementation of guideline recommendations

Successful implementation of the recommendations in the guideline will require endorsement by multiple stakeholders at the country level, including ministries of health, local professional societies, nongovernmental organizations, civil society and patient groups. For effective use of these recommendations, it is essential that the health systems at the country level create an enabling environment for the prevention, diagnosis and treatment of infertility. This may include, for example, ensuring that infertility is included in relevant government departments, health and other (e.g. educational or social) policies, strategic plans, services and financing, as well as ensuring that fertility care medications are included in essential medicines lists, training health care providers on infertility, modifying health information systems to incorporate data on infertility and developing national clinical guidelines on infertility.



Monitoring and evaluation of guideline recommendations

Monitoring and evaluation should be built into the implementation process to provide important lessons to continually improve implementation. The implementation of the guideline recommendations should involve national programmes (and relevant partners) collecting and reporting data on services provided to prevent, diagnose or treat infertility. This may require review of existing health information systems, including ART registries, medical electronic records and other patient electronic reporting and vital registration systems, to ensure that service provision data are

adequately captured and reported. Some indicators that can be used to monitor progress may already be available in the existing health management information systems, national surveillance systems or ART registries; for others, periodic surveys or evaluations may be required. Political support is essential, as is the need to embed a reproductive rights-based approach to implementation. Provision of fertility care should not be based on total fertility rates. Implementation research should be encouraged to inform guideline adaptation, implementation and continuous quality improvement.



Future scope and updating of the guideline recommendations

The WHO *Guideline for the prevention, diagnosis and treatment of infertility* does not cover all aspects of infertility. It is anticipated that subsequent editions of the guideline will have an expanded scope, allowing future recommendations to address topics that are not currently included. These include management of other personal risk factors (such as obesity, low body weight, excessive intake of alcohol and other substances, including the use of cannabis vapes and e-cigarettes or non-smoked/smokeless tobacco products, among others), as well as non-personal risk factors (e.g. environmental and workplace factors), sexual dysfunction, fertility preservation in the context of gonadotoxic

therapy, third-party reproduction (donor gametes, surrogacy), fertility care for individuals with pre-existing medical conditions that affect fertility (such as endometriosis and fibroids), or with obstructive, congenital, accessory gland, genital or hormonal abnormalities associated with male infertility, and psychosocial support for people with infertility. An expanded guidance on advanced diagnosis and treatment modalities for male-factor infertility is also needed. New and experimental interventions in infertility are emerging, including use of artificial intelligence, equipment technology, and medical treatments. WHO will track these and other developments for potential consideration in subsequent updates of the guideline.

References

1. Guideline for the prevention, diagnosis and treatment of infertility. Geneva: World Health Organization; 2025. [Forthcoming]
2. World Health Organization. WHO Handbook for Guideline Development. 2nd ed. Geneva: World Health Organization; 2014 (<https://apps.who.int/iris/handle/10665/145714>).

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