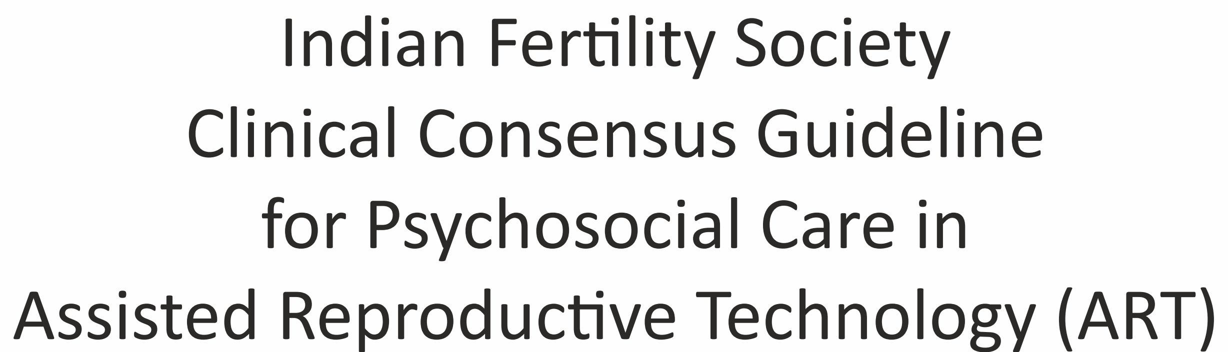

Indian Fertility Society Clinical Consensus Guideline for Psychosocial Care in Assisted Reproductive Technology (ART)

July 2024

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Clinical Consensus Guideline

The Indian Fertility Society's Executive Committee recognized the need to develop a comprehensive psychosocial consensus statement tailored to the unique social context of India. In response, they commissioned a consensus document group to review and adapt the European Society of Human Reproduction and Embryology (ESHRE) guidelines, Routine Psychosocial Care in Infertility and Medically Assisted Reproduction -A guide for the fertility care staff (2015).

This initiative aimed to address the specific challenges and considerations pertinent to the Indian population undergoing Assisted Reproductive Techniques (ART).

The primary aim of this clinical consensus guideline is to provide a comprehensive guide to enhance psychosocial care delivered to sub fertile couples by the practicing fertility team. By offering 78 evidence-based recommendations, information and best practices, the consensus guideline endeavours to establish a framework considering the dynamics of the Indian family system, social norms, and cultural values and practices. Through a synthesis of clinical expertise and cultural sensitivity, the guideline aims to furnish tailored support that resonates with the diverse fabric of Indian society.

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Foreword

I am both honored and delighted to pen the foreword for the "Clinical Consensus Guideline for Psychosocial care in Assisted Reproduction Technology (ART)". Counseling emerges as a pivotal element throughout the fertility treatment and is mandatory requirement in every Assisted Reproduction technology clinic as per the new law in India.

This consensus is first of its kind in the field of subfertility in India. It thoroughly looks into the various aspects of counselling by the Counselors and health care providers of the Assisted Reproduction Technology clinic. The recommendations are based on the scientific evidences and good practice points by the experts of this field. Each subsection of the consensus reflects the meticulous attention to detail and a compassionate approach to patient care.

This Consensus Guidelines serves as a valuable resource for Psychologists, Gynecologists, General Physicians, devoted Nurses, Embryologists, IVF coordinators, and other supportive staff in ART clinics Addressing fertility treatment challenges.

I am thankful to our International experts Dr. Sofia Gamerio, Dr. Ana Galhardo and Ms. Karen Kirchheiner Jensen for giving their valuable inputs and gratitude for their unwavering commitment to advancing the field of Counselling in reproductive medicine. Heartfelt congratulations to the Indian Fertility Society authors, Dr. Poonam Nayar and her team who have put together an excellent compilation of topics and I commend them for their invaluable expertise and dedication.

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Foreword

I am delighted to write this forward for the Indian Fertility Society and introduce the Clinical Consensus Guideline for Psychosocial Care in patients undergoing Assisted Reproductive Technology (ART).

As chair of the Routine psychosocial care in infertility and medically assisted reproduction – A guide for fertility staff, sponsored by the European Society for Human Reproduction and Embryology (ESHRE), I am often invited by scientific societies and other organisations, to discuss provision of psychosocial care at fertility clinics. It was in this context that I had the pleasure to engage with the Indian Fertility Society, specifically with their Psychology and Counselling Special Interest Group.

Led by Dr. Poonam Nayar, this is an extremely active group that has been consistently advancing the quality standards of psychosocial care provision in India and widening training in these issues across the country. Our collaboration culminated in my involvement in their work to produce the Consensus Guidelines.

Everyone who works at fertility clinic in India under any capacity or role should get acquainted with the Consensus Guideline for the management of psychosocial conditions in Patients undergoing Assisted Reproductive Technology (ART). In this document, the group compiled a set of research informed best practice recommendations to support care provision for people undergoing fertility treatment in India. The Consensus Guidelines departs from the ESHRE Routine psychosocial care in infertility and medically assisted reproduction – A guide for fertility staff, and therefore targets the whole clinic team (not only for psychologists, counsellors, or other mental health professionals). It significantly extends the scope of the ESHRE guidelines to take into account the Indian family system, social norms, and cultural values and practices. One example of this is the use of mental health screening questionnaires that are validated for the Indian population, instead of those recommended in the ESHRE guidelines. Another example is the addition of a section on psychosocial care for couples undertaking third-party reproduction.

The Consensus Guidelines results from the application of a systematic and rigorous methodology that included setting a multi-disciplinary working team of experts and international advisors, training provision for the team, multiple evidence synthesis and critical appraisal exercises, development of evidence based recommendations, consensus building about recommendations, and peer review.

It has been an absolute privilege to collaborate with such a team of committed and enthusiastic experts and see this amazing document come to light. I am confident in saying that the Consensus Guidelines will act as a reference framework and standards setting document for the work done in India for many years to come. I am certain that the Indian Psychology and Counselling Special Interest Group will support its implementation across the country via awareness raising, training, and advisory support, so that every single fertility patient in India can receive the absolute best care.

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Legal Disclaimer:

This Clinical Consensus Guideline for Psychosocial care of patients undertaking Assisted Reproductive Technology (ART) has been developed by a committee of experts established by the Indian Fertility Society ("Committee"). The statements and recommendations contained within this Guideline are provided for informational purposes only and are not intended to serve as legal advice or directives for healthcare professionals.

The Committee acknowledges that the statements and recommendations presented in this Guideline are based on a review of evidence-based practices, as well as the opinions and expertise of the participating experts. However, it is important to note that the content of this Guideline is not exhaustive and may not encompass all possible scenarios or considerations relevant to the management of psychosocial conditions in patients undergoing assisted reproduction.

Furthermore, healthcare professionals are reminded that the information provided in this Guideline is not intended to supersede their clinical judgment or override established medical protocols or standards of care. Each patient's unique circumstances and individual needs should be carefully considered when making clinical decisions, and healthcare professionals are encouraged to exercise their discretion and professional judgment in accordance with prevailing norms and guidelines.

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By accessing or utilizing this Guideline, healthcare professionals acknowledge and accept the terms of this disclaimer.

Index

1	**Introduction**	**01**
1.1	Scope	01
1.2	Target Users	01
1.3	Key Outcomes	01
2.	**Introduction to Psychosocial Care During ART**	**02**
3.	**Tabular Summary of Recommendations:**	**17**
4.	**Key Questions and Recommendations**	**18**
4.1	What is the psychosocial impact of subfertility and ART on the couples?	28
4.1.1	What is the psychosocial impact of subfertility and ART on women?	28
4.1.2	What is the psychosocial impact of subfertility and ART on men?	33
4.1.3	What are the differences in response of men and women to subfertility and ART	37
4.1.4	What is the impact of subfertility and ART on sexual function in couples?	42
4.2	What are psycho-social causes of distress in fertility care?	50
4.3	How can fertility care teams do risk prediction and psychosocial assessment?	60
4.3.1	What tests can screen out couples at risk for significant psychological distress?	61
4.3.2	How can fertility counselors make a comprehensive assessment of high-risk cases during ART?	72
4.4	What are the changing psychosocial needs of the patients during ART?	90
4.4.1	What are the psychosocial needs of a patient before treatment?	91
4.4.2	What are the psychosocial needs of a patient during treatment?	95
4.4.3	What are the psychosocial needs of patients after unsuccessful treatment?	97
4.4.4	What are the psychological needs of patients after successful treatment?	101
4.5	What causes the patient to drop out prematurely from the treatment?	103
4.6	What is the role of the fertility team in delivering psychosocial care to couples?	109
4.6.1	Which psychosocial care components can be delivered routinely and continuously by the entire fertility team from the start to the endpoint of the fertility treatment?	109
4.6.2	How can fertility staff address the needs of patients during treatment?	113
4.6.3	How can fertility staff address the needs of patients after unsuccessful treatment and breaking bad news in infertility treatment?	135
4.6.4	How can healthcare staff address the needs of patients after successful treatment?	140
4.7	How can the fertility care team provide psychosocial care for couples undertaking third party reproduction ?	150
4.8	What are the special cases of the patient undergoing ART?	155
4.8.1.	How is counselling for single women seeking motherhood through ART different?	155
4.8.2	What is the counselling for patients with gender preference undergoing ART?	158

ANNEXURES 159

Annexure 1 Methodology 159

Annexure 2 Abbreviations 206

Annexure 3 Glossary 207

Annexure 4 Reviewers' Comments 222

1. Introduction

1.1 Scope

The Indian Fertility Society has formulated a comprehensive scope to delineate the parameters and objectives of the Clinical Consensus Guideline for Psychosocial Care in patients undergoing Assisted Reproductive Technology or ART.

This document seeks to elucidate the core objectives and guiding principles of the consensus, aimed at Addressing the multifaceted psychosocial challenges encountered by individuals and couples embarking on the journey of assisted reproduction.

Integral to the ethos of this consensus is the identification and prioritization of knowledge gaps within the domain of psychosocial care in Assisted Reproductive Technology or ART. By identifying, acknowledging, and Addressing these gaps, the guideline aspires to foster continuous improvement and innovation in care provision, ensuring that patients receive the highest standard of support throughout their treatment journey.

Moreover, the applicability of existing guidelines for psychosocial care by the European Society of Human Reproduction and Embryology (ESHRE 2015) in the Indian social and cultural context has been critically evaluated, enabling the adaptation and contextualization of best practices to suit the specific needs and preferences of Indian patients and healthcare providers.

The needs of specialized care required for major psychiatric disorders, financial counselling for patients undergoing treatments for infertility, and procedural counselling as mandated by regulations are excluded from the scope of this document. These aspects necessitate specialized attention and may involve collaboration with relevant professionals and regulatory bodies.

1.2 Target Users of the Guideline:

The Clinical Consensus Guideline on psychosocial care of patient's undergoing Assisted Reproductive Technology is tailored to serve as a resource for the entire infertility team, encompassing a diverse array of healthcare professionals and administrative staff. Target users include doctors specializing in reproductive medicine, nurses proficient in patient care, embryologists involved in laboratory procedures, counsellor's adept at providing emotional support, administrative staff such as clinic coordinators facilitating smooth operations, and financial counsellors offering guidance on financial aspects. This guideline equips these professionals with evidence-based information and best practices to enhance psychosocial care provision, fostering a collaborative approach to support patients through the intricate journey of assisted reproduction within the Indian socio-cultural context

1.3 Key Outcomes

In the Clinical Consensus Guideline for psychosocial care in patients undergoing Assisted Reproductive Technology, key outcomes are evaluated considering behavioural, relationship, emotional and cognitive needs. Such outcomes include improvements in patient satisfaction and psychological well-being throughout the treatment journey. Additionally, the guideline assesses the adoption of recommended practices by healthcare professionals within the infertility unit, ensuring adherence to evidence-based strategies for Addressing psychological distress and promoting resilience among patients. Furthermore, the guideline aims to identify and adDr.ess knowledge gaps within the domain of psychosocial care in assisted reproduction, fostering continuous improvement and innovation in care provision. By evaluating these key outcomes, the guideline endeavours to optimize patient-centred care, ultimately enhancing the overall experience and outcomes for individuals undergoing medically assisted reproduction.

2. An Introduction to Psychosocial Care During ART:

An overview of the ESHRE guidelines (2015) is essential as it provides an important foundational framework for routine psychosocial care during ART. The evidence-based insights are simple and clear, throwing light on the needs and preferences of the couple during different stages of fertility care as well as the ways and means by which these needs may be addressed. It provides an invaluable road map into the process of client-centred care for patients during ART. Hence a summary is given below. However, keeping in view the culture, language, and social context, a survey of the key recommendations of ESHRE was conducted to find out areas of agreement (Annexure 1) On the basis of the report of the survey as well as expert group discussion, some changes are recommended for better adaptation to our patient population. Also, the review and recommendations reported below have attempted to incorporate studies done after ESHRE 2015 guideline.

First important change is in the domain of identification of couples at risk using the best available tools in India. The tests which have been developed and standardised on the Indian population have been recommended for use during initial screening for distress levels. These have been described in detail in later sections. Though these are generic tools for measuring severity of distress and general well being, these are very useful for screening purposes. The suitable adaptations of fertility specific tools such as SCREEN IVF or FERTIQOL are yet to be standardised in the local languages. Screen IVF and FERTIQOL are recommended by ESHRE (2015) as they give valuable information about what the patients are struggling with while experiencing infertility or ART. Hence it is recommended that suitable translations and standardisation be done for the fertility-specific tools for more precise psychometric data.

Second is the in-depth collation of data available on yoga based techniques (YBT) of physical exercises, breath regulation and meditation. These are culturally consonant methods of self-regulation which are widely accepted in India and thus may be integrated into the routine psychosocial care for ART. If the practices are initiated during the pretreatment period as group interventions that focus on education and skills training, they may be very useful during subsequent treatment and post-treatment phases to buffer high emotional distress.

The third aspect which has been discussed is the practice of psychological care after successful ART pregnancy, Along with the yoga-based techniques YBT i.e. yogic exercises, regulated breathing, and meditation for self, there is a unique added feature i.e. meditative focus on the baby with positive affirmations, visualizing and bonding with the baby. This can be integrated along with the standard antenatal care as recommended by the obstetricians (Neel et al 2018; Pragya et.al. 2023) to enhance the positive psychological state of the mother which influences the birth parameters as well as the early childhood development. The totally new research section covers the role of yoga based techniques for the male factor infertility

Fourthly, the social fabric and value system are rapidly changing due to heterogeneity in education, western values shaped by the media and the global exchange of information and ideas. The deeply held traditional values intermingle with the individualistic Western orientation. Unfortunately, practices like gender preference for male children persist in some families. The consensus group has made recommendations as to how such a situation may be dealt with. The family dynamics in a joint family system will also require more work for us to develop clear-cut guidelines about how the much needed support system for the patient can be developed.

We sincerely hope that the consensus statements will provide a starting point for subsequent explorations and research on improving as well as opening ever-growing new perspectives to enhance the psychosocial care during ART within our socio-cultural settings.

A Summary Overview

Eshre Guidelines (2015) Routine Psychosocial Care During Medically Assisted Reproduction: A guide for the fertility staff

Caring for the emotional needs of the patient demands continuity of care. It means providing patient-centred care in all aspects and all stages of infertility treatment. The empathetic clientcentered approach provides the basic core context of ongoing psychological support for all patients.

The European Society of Human Reproduction and Embryology (ESHRE) guideline 2015 has differentiated patient support into two complementary levels of psychosocial care:

■ Routine Psychosocial Care, meaning that psychosocial care practices are embedded in the routine care that is offered to patients as they progress through their treatment pathway

■ Specialized Psychosocial Care which needs the attention of a mental health professional. It includes: i. Infertility Counselling (e.g., crisis intervention, grieving support, implications counselling) ii. Psychotherapy (for patients with diagnosed mental health disorders)

It is accepted that most patients (i.e 80%) report a common set of challenges to the treatment process. These can be addressed via routine psychosocial care. Routine psychosocial care is the responsibility of all fertility staff to be given continuously in an ongoing manner throughout the treatment pathway.

Specialized psychosocial care should be targeted to those 20% or so of patients who are at risk of experiencing significant emotional problems. This group needs to be identified early during the infertility treatment so that they can be referred for specialized psychosocial care to a qualified mental health practitioner.

The evidence indicates that providing routine psychosocial care can positively affect many patient outcomes, reduce emotional distress and increase compliance with treatment, decrease concerns about medical procedures, change lifestyle behaviors (i.e., nutrition, exercise), improve fertility knowledge, and improve well-being. This can enhance the treatment outcome.

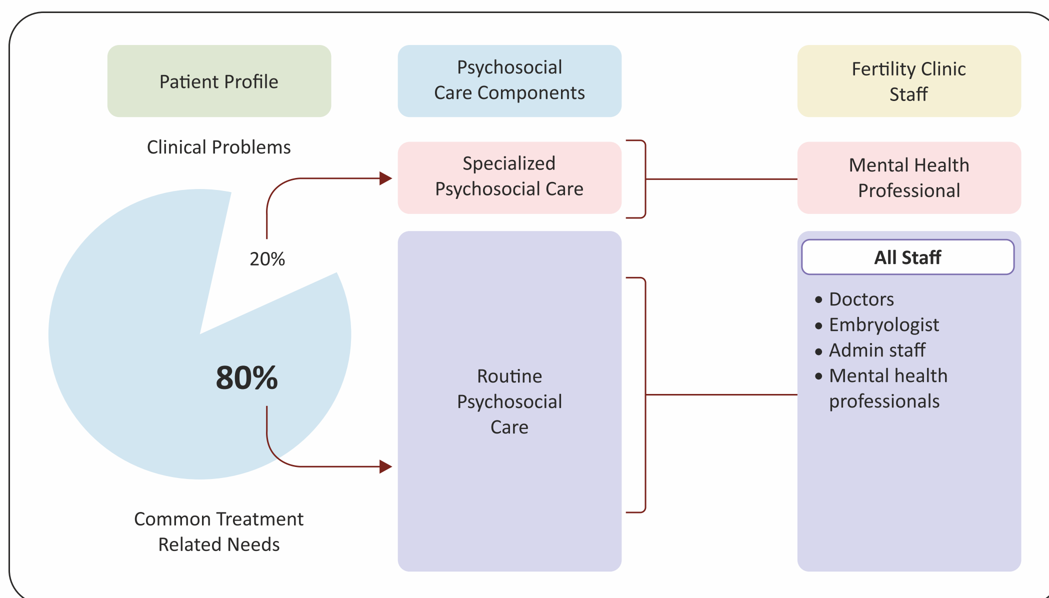

Fig. 1: Schematic representation of the clinical profile of infertility patients, the corresponding psychosocial care needs, and the staff who can address the psychological needs of the patient (ESHRE 2015)

Routine Psychosocial Care

Routine psychosocial care is a client-centred approach intended to address the changing needs of patients across different stages of fertility treatment. The four needs of the patient have been described. This differentiation addresses the WHO definition of health as holistic and multidimensional

Cognitive Needs: The patient's need to know and understand the various facets of infertility diagnosis and management to clear the doubts and concerns, to be meaningfully engaged in shared decision-making processes. This enables the patient to make informed choices and be prepared for possible unfavourable outcomes as and when they arise.

Emotional Needs: There is a need to identify and address depression, anxiety, psychopathology, and general well-being. Unresolved emotional distress is a major contributor to drop-out as well as litigations against the medical team. The coping methods used by the couple determine how they face the challenge of infertility diagnosis or treatment.

Relational and Social Needs: The relational needs refer to marital/relationship satisfaction, relational stress, sexual relationship and differing views of the partners on the need to have a child. It also includes social concerns such as sensitivity to comments, reminders of infertility, feelings of social isolation, and alienation from family, peers, and the occupation or work

Behavioral Needs: The lifestyle affects both general as well as reproductive health. Patients may need support for their weight loss program or to modify other lifestyle risk factors such as unhealthy diet, irregular sleeping-waking cycles etc. Compliance with treatment protocols is also a behaviour which can impact the treatment outcome. Hence, there is also a need to understand and address the reasons for poor compliance with the treatment protocols.

Evidence suggests that the needs of patients (behavioural, relational social, emotional and cognitive) change during the different phases of treatment, that is, before, during, and after treatments. It has been stated that if the staff are aware of the most common needs that patients experience at different stages, then implementing routine procedures to address these needs can maximize the impact of psychosocial care for patients.

Identifying and Addressing Patient Needs at Different Stages of Treatment

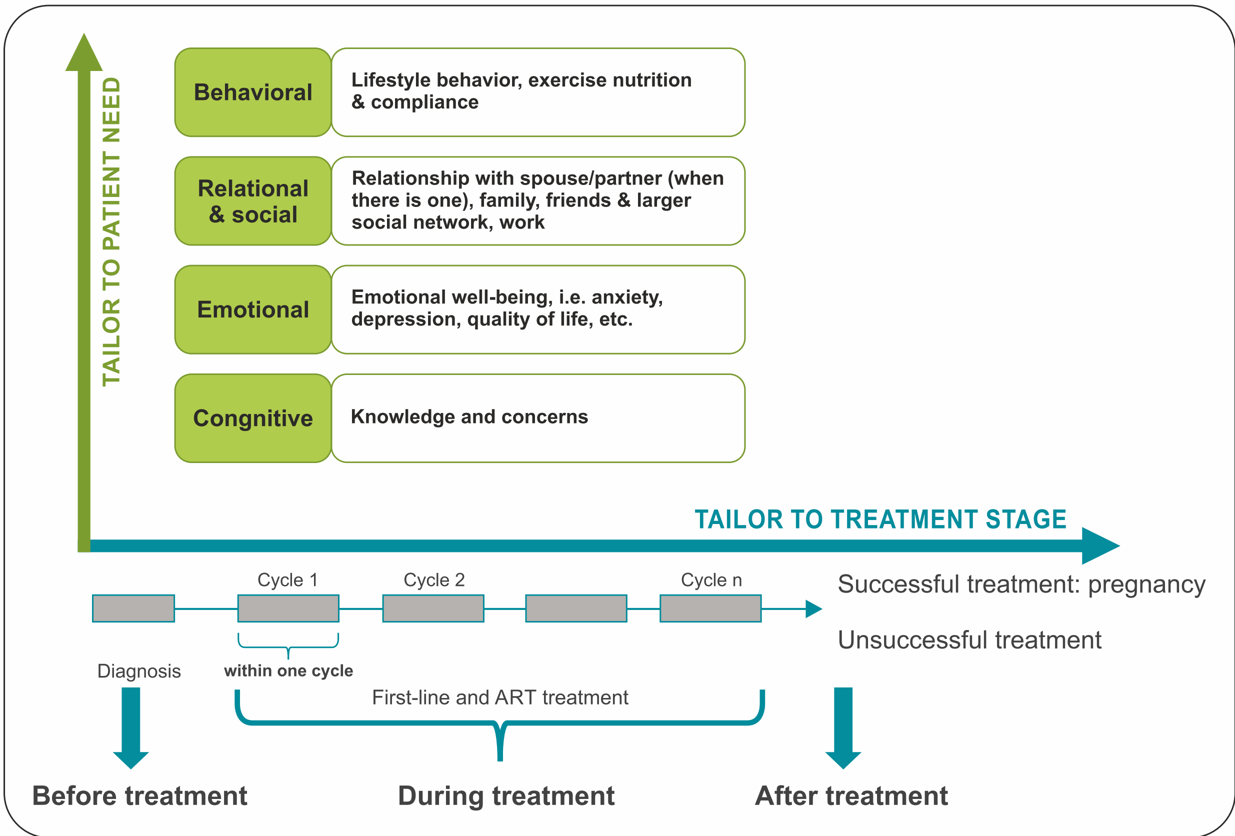

Fig. 2: Schematic representation of the guideline approach for the provision of psychosocial care tailored to specific treatment stages and patient needs (ESHRE 2015)

The Psychosocial Care Before Starting Art Treatment

Cognitive Needs

The most important need of the patient at the beginning is to understand what is going to happen, what lies ahead in the treatment processes. Knowing what is to come, helps to allay emotional distress associated with uncertainty.

Addressing cognitive needs

Providing information tailored specifically to the patient's diagnosis and management is one of the most important components of routine psychosocial care at each and every stage of the infertility treatment. Also, the manner of disseminating the information needs to be done according to the level of awareness and education of the couple. This can be kept in mind by the fertility staff, as it forms an important part of the psychosocial care at all stages of treatment.

1. The patients prefer written treatment-relevant information. They need explanations about treatment results and treatment options, understandable, customized and personally relevant. Written information in hand gives them time to read, understand, ask questions and clear doubts.

2. Verbal explanations and information is likely to be partially remembered and hence may create scope for confusion, doubt and later misgivings. The clinician, as well as other team members often use medical terms which are not understood by the patient.

3. It is important to obtain feedback from the couple about how much of the information they actually understood. It can be done by asking the patient to summarize and explain what all they understood, at various points. Doubts and misconceptions need to be addressed. This process also helps to build a sense of trust and rapport between the patient and the medical team..

   There is a need to allocate specific duty to one or more team members to ensure that information is correctly understood. At times, the patient may be hesitant to ask questions or clear doubts from the consultant. The patients then go to other ancillary staff like receptionists, nurses on duty for clarifications who may not be able to give the full information relevant for a particular patient.

Emotional Needs

Before first-line or ART treatment, the women didn't have psychopathological symptoms or psychiatric disorders (Volgsten et.al.2008;2010;Zaig 2013). A systematic review of 25 years of research (Verhaak et.al. 2007) using different measures of depression reported that women starting IVF treatment are not more depressed than the general population. Evidence about anxiety (state and trait anxiety) is inconsistent (Lykeridou et.al.2009). These inconsistencies are related to cultural issues. The study on subjective well-being of 120 Indian infertile couples showed it was the same in infertile women as in normal women. However, men were significantly lower than normal on subjective well-being (Dhaliwal et.al. 2004). It may be that patients with strong pronatalist views, i.e. those cultures or societies advocating or supporting a high birth rate, show higher depression and / or anxiety and lower general being before the start of treatment (Kumbak et.al.2010).

Risk factors or predictors of high emotional distress (ESHRE 2015)

- Presence of pre-existing psychiatric illness increases vulnerability. This needs to be identified during case history taking right at the beginning of the infertility treatment.
- Women are more susceptible to emotional maladjustment than men. They experience higher levels of depression and infertility stress than men.
- Women whose partner has male factor infertility experience higher anxiety than women with female factor, mixed, or unexplained infertility. Type of infertility diagnosis is not related to depression
- Men also find infertility treatment stressful
- The use of passive, avoidant coping (e.g., rumination, withdrawal) is associated with poor adjustment. Active coping (e.g. goal-oriented problem-solving, thinking rationally about the problem) is a protective factor. This can be ascertained with help of psychological tests.
- Patients with a lower occupational status experience higher infertility stress and anxiety than patients with a medium or high occupational status.

Screening High Risk Cases

Patients with high distress need to be identified first and foremost at the very start with the help of psychological tests. The SCREEN IVF and FERTIQOL have been recommended for use by ESHRE 2015. It has been translated in many languages world over; however, the Indian adaptation is yet to be developed. The patients obtaining scores on the psychological tests indicative of significantly elevated emotional distress, poor coping styles and /or presence of risk factors, need to be referred for specialised psychosocial care right at the outset so that they do not suffer adverse mental health consequences during the treatment cycle.

Relational and Social Needs

There are no indications of psychosexual problems at the start of the treatment. At the beginning, women starting first-line or ART treatments have the same marital satisfaction as in the general population (Verhaak et.al. 2005). This is seen from consensus i.e. playing equal roles in domestic and social decisions and cohesion i.e. the degree to which interests and experiences are shared. The prevalence of erectile dysfunction in males was as follows: 18% had mild, 4% had moderate erectile dysfunction (Shindel et.al. 2008). These were not higher than those observed in general population

Risk factors for increased relational stress are as follows:

- Couples who have different views on the importance of parenthood and social concerns show lower relationship satisfaction than those who have similar views. (Moura-Ramos et.al. 2016).
- Women report worse marital adjustment and relational stress than men. They experience higher social and sexual stress and concerns than men (Peterson et.al. 2007)
- Avoidant, emotion based or passive coping gives rise to greater fertility specific marital and social distress in the relationships as compared to meaning based, active coping.(Peterson et.al. 2008)

Addressing the relational and social needs

It is necessary to involve both partners in the diagnosis and treatment process right from the beginning This facilitates the couple's management of treatment as a team by improving communication between the couple and medical staff. The differences in motivation for having children, differences in reaction to infertility and in coping styles need to be kept in view when dealing with the couple. Individual and couple counselling by mental health professionals may be necessary if there are major differences in viewpoints regarding these issues.

Within the Indian cultural context, the role of the extended family is very important. The couple must come to a consensus regarding how much information they want to share with the whole family, especially in cases requiring third party reproduction.

The provision of information about social support options e.g contact details of support groups, online support options, access to infertility counselling, or psychotherapy has been found to be useful. (Gameiro et.al. 2012)

Behavioral Needs

Treatment Compliance

As per the international estimates, about one-tenth of patients planning for treatments discontinue during diagnosis, before starting treatment. dropout occurred also while on waitlist to start ART Research on treatment compliance, shows that only about 55% of people seek fertility treatment and of those that do, 22% discontinue IVF treatment before completing a course of recommended treatment. Patients refer to specific psychological needs not being met as important reasons for having discontinued treatment prematurely. (Gameiro et.al. 2012)

Treatment compliance is improved by providing personally relevant treatment information. Studies have shown that providing information leaflet explaining what would happen during appointment, content and sequence of components of fertility workup, detailed description of the medical examinations, reassurance regarding procedures, description of sperm sample preparation improved compliance significantly more than those not receiving the information (Pook et.al. 2005)

Lifestyle Behaviours:

A significant proportion of patients have lifestyle behaviours that are not optimal for conception i.e. smoking, alcohol use, excessive exercise, unhealthy diet affecting BMI, use of anabolic steroids (Schilling et.al. 2012) These lifestyle behaviours negatively affect their general and reproductive health.

Addressing lifestyle risk

- Infertile women coming for treatment are not well informed about the detrimental effect of lifestyle risk factors. Providing patients with information about unhealthy lifestyle behaviours. They need to be made aware of the importance of health optimization before and during pregnancy, infectious disease screening, risks of smoking, recreational drug abuse.

- Fertility treatment can start with preconception care. We have unique access to patients in the preconception period. RCTs show that even short interventions work. Weight loss programs offered pre-ART can be effective in reducing weight and BMI (Moran et.al. 2011), however their impact on live birth rates needs to be ascertained due to low quality of existing research, which remains inconclusive (Boedt et.al. 2021)

Psychosocial Care of The Patient During The Treatment

The treatment period refers to the time when the treatment is started. It includes ovarian stimulation, oocyte retrieval, embryo transfer, the waiting period until the first measurement of pregnancy outcome and reactions to treatment outcome.

The couple's distress i.e. depression, anxiety, stress, negative affect i.e. anger, tension, grief begins to increase during IVF/ICSI cycle (Verhaak et.al.2010). Patients' experience high emotional distress when they are informed that the treatment was unsuccessful. After treatment failure, 10-20% women experience clinically significant levels of depressive symptoms. There is a marked increase in psychiatric disorders; 10-25% women and 10% men have a depressive disorder and about 14% women and 5% men have an anxiety disorder. This is much higher than global norms (WHO, 2017) of anxiety disorders (i.e. 4.6% in females and 2.6% in males) and depression (i.e. 5.1% in females and 3.6% in males); thus there is three to fourfold increase in women and men who develop common mental disorders like anxiety and depressive disorders. It highlights the urgent need as well as the ethical responsibility of the infertility team, to mitigate the negative impact of infertility treatment especially failed treatment which will be inevitable in 60-70% cases.

Social and Relational Needs

In a dyad, the way one partner reacts to the subfertility condition/diagnosis is associated with how the other partner reacts; each partner's depressive symptoms are associated with their own and their partner's infertility-specific distress.(Peterson et.al. 2014)

Addressing social and relational needs

The two partners can have varying attitudes towards childlessness and conflicting opinions on how infertility influences their relationship and sexual life (Lalos et.al. 1999). It is not always that the couple receives the information as a unit; one needs to deal with two separate individuals with different reactions and behaviour. Thus, there is a need for individual supportive counselling parallel to the psychological treatment of the couple. In order to manage the relational stress, there is a need to address decision conflict and encourage active participation in decision making, helping the couple to identify alternatives and new life perspectives.

Patients may need help in dealing with strains on the relationship related to subfertility or its treatment through support for grief work. The marital and or individual counselling may be carried out by the mental health professional if the distress is high as reflected in psychological tests and clinical observations.

Cognitive Needs

The patient's biggest concern is achieving desired results, which remains high from beginning of treatment to ET stage. Other concerns regarding side effects of hormones, finances, undergoing surgery, work related concerns decreased as the treatment progresses. There is persistent preoccupation and obsessive rumination about a possible pregnancy or lack of it. These ideations are related to infertility-specific distress in women, after controlling for depression and anxiety. The uncertainty leads to worry as various possible outcomes are considered. Although the objective probability of achieving pregnancy during IVF is low, women may disregard or downplay factual information about IVF pregnancy rates and hold beliefs such as having embryo transfer on a 'lucky' day, or on optimistic feedback from medical staff (Boivin et.al. 2010). Their expectations may therefore be more optimistic or pessimistic than actual probabilities.

The couple also need to decide whether to continue in the treatment after failure of one cycle, how many cycles to try, when to end the treatment and turn to adoption, surrogacy. Other difficult decisions during treatment include multifetal pregnancy reduction, embryo disposition and single Vs multiple embryo transfer.

Addressing cognitive needs

It is necessary to give patients the opportunity to discuss and clarify their treatment related concerns such as uptake or not of recommended treatment by the process of shared decision making. In shared decision making, physicians and patients take decisions together using the best available evidence. Patients are helped to make informed choices by considering the options, and the likely benefits and disadvantages of each option.

However, the way the clinician provides information may strongly affect people's preferences, prompting the need for standardized information to be used as patient decision aids. (International Patient Decision Aids Standards (IPDAS) (Stacy et.al, 2021) Many decision aids are based on a conceptual model or theoretical framework. Patient decision aids supplement, rather than replace, clinicians' counselling about options. The decision aids describe the options in enough detail that the couple can imagine what it is like to experience the physical, emotional, and social effects, or they guide them to consider which benefits and harms are most important to them. They have been used in helping patients make decisions about single vs double embryo transfer and in the cases of fertility preservation. (Stacey et.al. 2017)

The decision aids are different from health education materials which help couples to understand the diagnosis, treatment, and management in general terms. Educational materials are not focused on decision points which occur during the treatment hence the educational material do not help patients to participate in decision making. The latest foci of research are on developing decision support tools to help patients deliberate their choices, and to have less decisional regret.

Emotional Needs

The women have consistently reported heightened anxiety during following points in the treatment i.e.

1. Before any invasive procedure
2. At the time of Oocyte pickup
3. Embryo transfer
4. Waiting period
5. Breaking bad news.

Addressing emotional needs

There are several meta-analyses of psychological interventions. The psychotherapeutic approach with emphasis on emotional expression and support and/or discussion about thoughts and feelings related to infertility are comparatively less effective. The body of effectiveness research showed that the most effective interventions are group interventions that focus on education and skills training e.g., relaxation training, mindfulness, selfregulation with help of Yoga based techniques and developing coping skills. Hence, it is recommended to focus on specific needs which have been clearly and consistently identified. There is a need to develop a protocol for the five clearly demarcated points of exacerbated distress listed above. (ESHRE, 2015)

Many women undergoing IVF procedures are employed (Landcastle et al 2008) extra attendance at clinics for counselling is inconvenient. Also, such interventions are of doubtful efficacy. Delivered by trained professionals, the financial costs are also there. As a consequence, only 10– 15% of infertile patients used the

counselling provided (Boivin et.al. 1999). Moreover, there is typically no requirement to attend a clinic for medical procedures or tests during the waiting period. The sources of informal expert support (e.g. patients undergoing the same procedures and medical staff) are not as easily available as they were at earlier stages of the IVF treatment cycle. Due to these practical issues, a home-based intervention which women can use without supervision is needed for the IVF waiting period.

Some Therapeutic Methods Which May Be Used During The Treatment Cycle:

The following can be taught to women during the treatment, so that they can continue the practice on their own during the days when they do not visit the infertility clinic (Stanton et.al.1999)

1. Relaxation Techniques

There are a wide variety of relaxation techniques that have been useful in inducing the relaxation response. This inhibits the negative physiological responses to stress (e.g., increased heart rate, blood pressure, respiratory rate, and muscle tension). Relaxation techniques include diaphragmatic breathing; progressive muscle relaxation (PMR); autogenic relaxation training; imagery (e.g., guided imagery and covert sensitization); meditation, chanting, biofeedback; systematic desensitization. Whether relaxation training is a specific goal of psychotherapy or a patient 'homework' assignment, men and women were found to benefit equally. (Dumbala et.al.2020)

2. Positive Reappraisal Coping Strategy

One meaning-based coping strategy that is easy to learn is positive reappraisal coping, which is based on cognitive efforts or as cognitive manoeuvre to redefine the experience that changes the meaning of the situation. Positive reappraisal coping involves effortful derivation of benefit from a difficult situation, individuals start focussing on the positive aspects of a situation rather than ruminating distressing and negative aspects. Such efforts in the IVF context may involve focusing on the fact that a partner is especially loving and supportive and the most advanced fertility treatment is being used. The positive reappraisal strategies are associated with increased positive affect and sustained ability to cope in unpredictable and uncontrollable stressor situations. It has beneficial effects in difficult health-related circumstances such as the failed fertility treatment (Landcastle et.al. 2008)

Following items are part of the Positive Reappraisal Coping Inventory (Ockhuijese 2014). It is a small convenient pocket-sized card containing statements to promote positive reappraisal coping efforts. It is easy to use and can be used whenever patients feel the need. It is costeffective and can be freely available to all patients. It is generic enough to be used by any patient waiting for the results of medical tests and procedures. Patients are asked to read these daily, at least twice a day. To illustrate, some of the items from Positive Reappraisal Coping Inventory (PRCI) are given below:

During this experience I will:

- Try something that makes me feel positive
- Focus on the positive aspects of the complex circumstances
- Highlight something good in what is happening
- Make the best of the situation with positivity
- Try something meaningful and productive
- Focus on the benefits and not just the difficulties

Breaking Bad News

In the ART context bad news is a frequent occurrence: the infertility diagnosis, the repeated failures in the treatment, low rates of success and the clinical ineffectiveness of medical treatments are all bad news that professionals need to communicate. From the couple's point of view, involuntary childlessness is not a question of once receiving bad news but repeatedly receiving bad news during the infertility investigation and treatment. Clinicians are usually not prepared to manage this kind of communication, as literature on assisted reproductive technology (ART) lacks specific guidelines for breaking bad news. (Neighbour, 2005)

Consequences of bad communication between patients and healthcare professionals include patients' poor satisfaction with care, lower treatment compliance, reduced quality of care, physician burn-out and increased medico-legal litigation. Since the supreme court brought the patient–doctor relationship and medical treatment under the in the ambit of consumer protection act in 1995, number of medico legal cases have increased in India

A variety of reactions can occur in the patient. These symptoms follow the pattern observed in a crisis situation, in which four main phases have been identified: 1. shock (e.g. denial), 2. reaction (e.g. anger, depression), 3. adaptation (e.g. acceptance) and 4. resolution (planning of solution).

However, the crisis of infertility differs from that of a general traumatic crisis, in which the duration of the reactive phase is usually 6 weeks. New events, new hopes and new forms of bad news prevent the adaptation to and resolution of the previous trauma, e.g. an ectopic pregnancy, a miscarriage or an acute laparotomy. As a consequence, there can be a state of prolonged chronic crisis during infertility treatment. This is further exacerbated due to the tendency of infertile couples to be isolated with their problems and experiences; they vacillate between hope and despair around the menstrual period perhaps until menopause.

Needless to say, this is a very important area of infertility counselling which needs the intervention of the mental health professional

Psychosocial Care of Patients After Treatment

Successful treatment: Pregnancy

When the mother's own egg and father's self-sperm are used in IVF the parents have both a genetic and gestational link to the child in the same way as parents of naturally conceived children. The women have similar self-esteem and mental health to women who conceive spontaneously. The way they relate to their fetus is similar whether the fetus is conceived with ART treatment or spontaneously. Hence, they require routine antenatal care. However, women who experienced multiple failed ART cycles or high stress during treatment may be more likely to experience pregnancy specific anxiety during pregnancy. They may need extra psychosocial support during pregnancy.

Unsuccessful Treatment

It's difficult for the patients to decide when to stop seeking treatment. Frequently one partner wants to end treatment before another. Acceptance of childlessness is hampered by denial or the persistent hope for a miracle (Edelmann et.al. 2000)

The treatment failure and subsequent inability to accept non-biological parenthood have long term consequences. Patients who remain childless 5 years after unsuccessful IVF/ICSI treatment may use more sleeping pills, smoke more often, and consume more alcohol than former patients that become parents via adoption, or spontaneously. They are three times more likely to separate than patients that become parents via adoption, or spontaneously. Women with a persistent desire for pregnancy 3 to 5 years after unsuccessful treatment may experience more anxiety and depression than women who find new life goals or women who become mothers. Long term studies show that those couples who are able to get a child through adoption or otherwise are able to adjust back. Those who remain childless but are able to find alternate meaningful life goals also remain normal. (ESHRE 2015)

The ability to disengage from the goal of biological parenthood is critical to long-term wellbeing rather than the specific absence of a child. Counselling or specialized care by a mental health professional is necessary. The transition from wanting biological children to accepting non–biological parenthood or coming to terms with being childless is possible with help from mental health professional. It is very important to offer patients the opportunity to discuss the implications of ending unsuccessful treatment. They need to redefine the success of infertility treatment. The couples are enabled to see their childlessness from another perspective. They redefine it as a child free state where they are free to pursue other goals This allows them to reshape their lives and achieve life satisfaction.

Implication counseling in third party reproduction

Many patients achieve parenthood through adoption, surrogacy, donor gametes or embryos. Even after the birth of the baby, they continue to think about how the child was conceived (Mahlstedt et.al. 1989). A growing number of children are being born by the donation of sperm, eggs or embryos, resulting in the absence of a genetic link with the mother or father or both. In surrogacy there is an absence of gestational link with women. The absence of a genetic and/or gestational connection between one or both parents and the child and the secrecy about the child's biological origin affects the parent/ child bond and subsequently the welfare of the child (Richards et.al. 2012). Other family types in which social parenthood is dissociated from biological parenthood are adoptive families in which both parents are biologically unrelated to the child. It is an important aspect of infertility counseling which requires the presence of a mental health professional and the in-depth psychological exploration of the couple to ensure that they understand the implications of having such a child. There is a need to redefine the concept of parenthood.

Summary

1. The treatment for infertility requires ongoing psychosocial care. Majority i.e. 80% couples can be managed by routine psychosocial care. Patients have clear preferences about the psychosocial care they want. The staff should be aware of these preferences and consider Addressing them. These include a sensitive, empathetic staff, who are aware of the emotional impact of infertility. The couple needs to be involved in decision making right from the beginning. The clinic environment with professional competence, continuity of care, ability to connect with other patients and physical comfort is important. Cross-sectional research showed that the different staff and clinic characteristics that patients value are indeed associated with higher emotional wellbeing.

2. The patients value information, especially written customized information about treatment options and explanations of results, as well as available psychosocial support options. Information provision, in particular the provision of preparatory information, decreases patient infertility-specific anxiety and stress. In addition, tailored psycho-educational interventions also improve the emotional well-being of patients, especially when they are highly distressed during specific points in the course of treatment. Pre-treatment preparation with stress management techniques like yoga, relaxation, and positive reappraisal coping is simple, easy to learn by the patient and can be administered in groups.

3. Some patients are more vulnerable than others to demands of treatment. They need to be identified early so that appropriate psychosocial support with the help of a mental health practitioner can be given.

4. The needs of patients vary across treatment stages and therefore psychosocial support should be provided accordingly. Before treatment, patients' needs are related to behaviours that do not optimize their chances of pregnancy, namely non-compliance with recommended treatment and unhealthy lifestyle behaviour. Pre-treatment programs to improve lifestyle have been found beneficial for enhancing general as well as reproductive health. During treatment, patients have multiple needs. At the behavioural level, 1 in 5 patients do not comply with recommended treatment. At the relational level, women may lack adequate support from significant others and are absent from work due to treatment. Emotional and cognitive needs are related to the uncertainty about the outcome of treatment, and tend to peak just before the oocyte retrieval, embryo transfer, and the pregnancy test. The escalating distress during the treatment can be addressed using skill based, psycho-educational self-help stress reduction programs which can be taught as part of routine psychosocial care and practiced by women at home. Ability to regulate and manage stress with help of relaxation, yoga, and positive appraisal helps them throughout the treatment cycles. The use of decision aids and shared decision making processes helps in educating and improving awareness of the couple regarding various treatment options. Finally, patients experience intense distress when treatment is unsuccessful. Protocols have been suggested for breaking bad news.

5. After treatment, infertile patients who achieve successful pregnancy do not differ from couples who conceived spontaneously. The women who had experienced repeated treatment failure are more anxious about their pregnancy and need psychosocial care and support during this phase also. The women who experienced unsuccessful fertility treatment and remained childless after treatment present worse emotional well-being than women with children. They need specialized psychosocial care to accept non-biological parenthood or redefine their life goals without children. Otherwise they are at risk of psychological disorders, maladjustment and impaired quality of life, long after the treatment has ended.

6. The options of use of donor gamete, or donor embryo surrogacy are all challenging decisions. They need to be well thought out with implications for the future of the child, its effect on the family and the donor. The counsellor and the psychosocial support becomes an essential part of the treatment process. Hence it is of utmost importance to prepare the couple for the end, right from the beginning

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3. Tabular Summary of Recommendations

4.1 What is the Psychosocial Impact of Subfertility and ART on the Patients?

4.1.1 What is the psychosocial impact of subfertility and ART on women?

Recommendations **The fertility care team should be aware that:**	**GRADE**
There is a significant association between subfertility, psychological distress and depression.	A
Women with female factor infertility show a significantly higher prevalence of anxiety, The association of sub fertility with anxiety is inconsistent	A
Before ovum pick up, and embryo transfer and in the subsequent waiting period, there is a marked increase in anxiety.	A
Threat to self-esteem, identity and purpose, deterioration of the couple and weakened support network is experienced by women.	C

4. Key Questions and Recommendations

4.1.2 What is the psychosocial impact of subfertility and ART on men?

Recommendations The fertility care team should be aware that:	GRADE
Men also experience either depression or anxiety or both during infertility	C
Men also experience adverse psychosocial effects if unsuccessful ART occurs during the first year. which subsequently, decreases after 2-5 years.	C
The diagnosis male factor infertility is accompanied by lowered selfesteem, socially avoidant behaviour and negative dyadic coping which decreases if the sperm is detected in testicular aspiration.	C
The new onset of erectile dysfunction, reduced intercourse satisfaction, and orgasmic function may occur after unsuccessful TESE.	C
The fertility care staff should be aware of the fact that men value information regarding the treatment, possible outcomes, success rates, complications, and recovery, a clear, long-term treatment plan, with alternatives, such as donor sperm or adoption.	C
The men in fertility settings feel marginalized and need direct communication and support from the clinicians, highlighting their need for inclusion and involvement in fertility treatment.	C

4.1.3 What are the differences in the response of men and women to subfertility and ART?

Recommendations

The fertility care team should be aware that:	GRADE
Although both women and men suffer from significantly raised levels of either depression or anxiety or both, the levels in women are much higher, with a poorer quality of life than men.	B
In women, anxiety levels increased before oocyte retrieval, embryo transfer, and the waiting period for a pregnancy test, but men experience increase in depression before treatment	C
Both men and women undergoing fertility treatment experience relationship and sexual concerns, which have the strongest connections to depression and suicidal ideation.	C
The adverse effects of unsuccessful ART is more intense and prolonged in women than men.	C

4.1.4 What is the impact of subfertility and ART on sexual function in couples?

Recommendations

The fertility care team should be aware that:	GRADE
The psychosocial strain of subfertility and ART can induce, worsen or maintain sexual disturbances and disorders in both partners.	A
Identifying sexual disorders during the entire course of diagnosis and treatment is necessary for the psychosocial well- being of the couple.	GPP

4.2 What Are The Psycho-social Causes of Distress in Fertility Care?

Recommendations

The fertility care team should be aware that:	GRADE
Unemployed, uneducated and older women have a higher risk of psychosocial distress.	C
Patients with prolonged duration of sub-infertility, repeated fertility treatments and miscarriage are at higher risk of psychosocial stress and may need specialised care.	B
Positive attitude, optimism, and resilience protect the couple against anxiety.	C
Encouraging the partners to work together as a team can be a valuable resource to moderate the stress of subfertility and ART	C
Fertility care staff should be aware that the better the belief of the couple in the ability to control events, the more use they make of adaptive coping, the less are the anxiety and depressive symptoms.	C

4.3 How Can Fertility Care Teams Do Risk Prediction and Psychosocial Assessment?

4.3.1 What tests can screen out couples at risk for significant psychological distress?

Recommendations

The fertility care team should be aware that:	GRADE
The PGI Health Questionnaire N2 can be a generic measure for screening out couples with high distress.	GPP
PGI Well-being scale can be used as a generic measure of overall well-being.	GPP
The fertility specific tests like SCREEN IVF, FERTIQOL must be translated and standardised for the Indian patient	GPP

4.3.2 How can fertility counsellors make a comprehensive assessment of high risk cases during ART?

Recommendations

The fertility care team should be aware that:	GRADE
Fertility counsellors can use the in-depth interview schedule as well as one or more of the available psychological tools for in-depth assessment.	GPP
There is a need to take into account the complex family dynamics of extended family system in Indian settings	GPP
Lifestyle factors influencing general as well as reproductive health need to be fully explored with emphasis on sleep hygiene as a stress modulator	GPP

4.4 What are the changing psychosocial needs of the couple during ART?

4.4.1 What are the psychosocial needs of the patient BEFORE starting treatment?

Recommendations

The fertility care team should be aware that:	GRADE
There is a need to provide personalised information about the treatment processes, prognosis, side effects of medications, stress, lifestyle and address concerns of the couple.	A
There is a need to give information about lifestyle behaviours that negatively affect reproductive health and support patients in changing them.	A
It is recommended to involve both partners in the diagnosis and treatment process.	A
There is a need to identify at-risk couples (risk factors and screening) and refer them to specialised psychosocial care.	A

4.4.2 What are the psychosocial needs of a couple DURING treatment?

Recommendations

The fertility care team should be aware that:	GRADE
There is a need for psychosocial care during the five clearly demarcated points of exacerbated distress during treatment, i.e. before any invasive procedure; at the time of oocyte pickup; embryo transfer; during the waiting period; before the outcome of ART procedures and after receiving bad news.	A
The high-risk cases identified during the earlier stage, i.e. before treatment and new cases showing a significant increase in psychosocial distress levels need referral to specialised psychosocial care for individual and /or couple counselling	A

4.4.3 What are the psychosocial needs of patients AFTER unsuccessful treatment?

Recommendations

The fertility care team should be aware that:	GRADE
There is a need to provide special psychosocial care to those who end the treatment but are unable to give up the wish to be a parent.	B
Special psychosocial care is needed for couples with treatment failures who are not ready to accept the end of treatment or adopt.	B
The men need to be specifically counselled and given psychosocial support in the form of informative discussions leading to acceptance and inclusion of coping skill mechanisms when treatment fails.	GPP
There should be specialised psychosocial care tailored to the needs of pre-adoptive couples, focusing on coping skills, decision-making support, and emotional processing.	GPP

4.4. 4 What are the psychosocial needs of patients AFTER successful treatment?

Recommendations

The fertility care team should be aware that:	GRADE
Psychosocial care should be ongoing in couples with ART pregnancy to address their concerns.	GPP
Couples with ART pregnancy, and more so twin pregnancy, are more prone to anxiety and depression with higher chances of postpartum depression not resolving with time	GPP
Women should be continuously supported in the postpartum period in ART pregnancies, more so with multiple pregnancy	GPP

4.5 What Causes the Patient to Drop Out from the Treatment?

Recommendations

The fertility care team should be aware that couple may drop out due to:	GRADE
Financial reasons like inability to pay out of pocket and depletion of financial resources. Lack of social support, communication breakdown or noncooperation of spouse in treatment. Factors related to treatment like insufficient response to stimulation, poor prognosis, unsuccessful treatment cycle, and unacceptable treatment options. Factors related to the clinic, like lack of organised and continuous care, and absence of facilities. Factors related to pregnancy, like biochemical pregnancy, missed abortion, ectopic pregnancy and spontaneous pregnancy.	C

4.6 What is the Role of the Fertility Care Team in Delivering Psychosocial Care to Couples?

4.6.1 Which psychosocial care components can be delivered routinely and continuously by the entire fertility team from the start to the endpoint of the fertility treatment?

Recommendations

The fertility care team should be aware that:	GRADE
A client-centred approach with sensitivity, respectful communication and empathy are important for the couple's well-being.	A
The couple values the individualised treatment-specific information, which is shared in a continuous manner.	A
The couple value both partners being involved in the treatment and decision-making process.	C
The couple's well-being is linked to satisfaction with care and better compliance, resulting in improved ART outcomes.	C
It is recommended that fertility staff be trained to detect high-risk individuals right at the beginning of treatment as well as during the phases of treatment.	GPP

4.6.2 How can fertility staff address the needs of patients during treatment?

Recommendations The fertility care team should be aware that:	GRADE
It is recommended that psychosocial interventions should be offered to couples undergoing fertility treatment.	A
Cognitive Behavioural Therapy (CBT) can be recommended as a psychological intervention in women undergoing ART	A
It is recommended that Acceptance and Commitment Therapy (ACT)be offered to couples undergoing fertility treatment to improve psychological wellbeing.	B
Mind Body Therapy (MBT) can be recommended as a psychological intervention in women undergoing IVF	A
It is recommended that the fertility care team must integrate the Mindfulness-Based Program, including meditation, into standard treatment protocols for couples facing infertility to help deal with infertility-related stress considering that no adverse effect of this therapy has been found.	A
It is recommended that the fertility care team should utilize a group format for MBPI sessions, allowing participants to share experiences.	B
It is recommended that the fertility care team must advise patients to incorporate yoga into fertility treatment plans, before and during treatment, to alleviate stress, anxiety, or depression related to ART treatment and potentially lead to increased treatment success.	A
It is recommended that yoga must be used as an adjunct in the management of male infertility.	A

4.6.3 How can fertility staff address the needs of patients after unsuccessful treatment?

Recommendations

The fertility care team should be aware that:	GRADE
Short-term and long-term psychosocial care is recommended for couples with unsuccessful treatment.	A
The concept 'SPIKES' should be used to manage imparting bad news in fertility care	B
Couples who make decisions both to leave treatment or continue after an unsuccessful cycle need referral for special psychosocial care	A
Follow-up with psychosocial support beyond one year is recommended in couples who have had an unsuccessful cycle, specialised grief counselling being directed at helping individuals relinquish their parenthood goals.	B
Acceptance, making meaning and pursuing alternative goals should be the target when giving psychotherapeutic guidance for long-term management of the couples after unsuccessful treatment	A
Specialized psychosocial care is needed for couples with unsuccessful treatment who are planning adoption, focusing on coping skills, decision-making support, and emotional processing.	A
Men should be specifically counselled and given psychosocial support in the form of informative discussions leading to acceptance and inclusion of coping skill mechanisms when treatment fails.	A

4.6.4 How can healthcare staff address the needs of patients after successful treatment?

Recommendations

The fertility care team should be aware that:	GRADE
It is recommended that prenatal yoga-based techniques (YBT) be part of routine antenatal care as these have an effect on reducing anxiety, depression, and perceived stress and increasing normal vaginal birth with a shorter duration of labour.	A
It is recommended to implement prenatal interventions such as cognitive defusion, generative meditation, mindfulness, positive affirmations, visualisations, and emotional bonding, which enhances the psychological well-being of the mother, birth outcomes and child development	C

4.7 How can the fertility care team provide psychosocial care for couples undertaking third party reproduction ?

Recommendations	GRADE
It is recommended that the fertility care staff should impart appropriate pretreatment counselling to all persons involved in the third party reproduction process i.e. donors, recipients, surrogates, with the aim of maintaining the psychological and emotional well-being of all parties involved.	C
Fertility care team should be aware that specialised psychosocial care is needed during the process of treatment with donated oocytes as the experience of distressing psychological symptoms, social stigmatisation and negative coping mechanisms in the recipient women, such as denial of pregnancy and complexity may follow it.	C
Fertility care staff should be aware that surrogacy may present moral, ethical, legal, cultural, religious, socioeconomic and neuropsychiatric concerns.	C
The couples who conceive with oocyte/sperm donation should be offered special psychosocial support from a mental health professional. This is important so that they can make an informed decision about acceptance of non-biological parenthood.	GPP
The healthcare worker must stress the commitment to legal contract to the donor and the recipient of the gamete.	GPP

4.8 What Are The Special Cases Of Couples Undergoing ART?

4.8.1 How is counselling for single women seeking motherhood through ART different?

Recommendations

The fertility care team should be aware that:	GRADE
Fertility staff should offer pre-treatment counselling on various aspects like ART with donor sperm, implications for pregnancy care, child raising, and financial and legal long-term consequences to all women wanting to become solo mothers to help them to make informed decisions before embarking on fertility treatment.	GPP
Mental health professionals should carefully assess the mental health status of single women to ensure that it is not an emotional and ambivalent decision.	C

4.8.2 What is the Counselling for couples with gender preference undergoing ART?

Recommendations

The fertility care team should be aware that:	GRADE
Counselling by healthcare staff should be consistently and continuously gender-neutral throughout the treatment cycle, stressing the need for delivery of healthy children without any gender preference. All fertility Staff must reinforce the same concept to the couple who desire to have a boy. All staff must be aware of the laws which prohibit sex determination. The Preconception and Prenatal Diagnostic Techniques (Prohibition of Sex Determination) Act (PC-PNDT which prohibits sex determination. The couple needs to be well informed about the same and the reason for making the law.	GPP