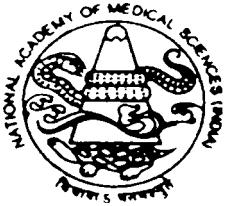
National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India

Ministry of Health and Family Welfare
Government of India



Indian Council of Medical Research
National Academy of Medical Sciences (India), New Delhi - 110029
2005

National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India

Drafting Committee

1. **Dr Baidya N Chakravorty**
2. **Dr Pushpa M Bhargava**
3. **Dr Anand Kumar T C**
4. **Dr Sulochana Gunasheela**
5. **Dr Sudarsan G Dastidar**
6. **Dr Mohinder Kochhar**
7. **Dr Kamini Rao**
8. **Dr Mehroo D Hansotia**
9. **Dr Sadhana K. Desai**
10. **Dr Chander P Puri**
11. **Dr Firuza R. Parikh**
12. **Shri Rajeev Dhavan**
13. **Dr Mira Shiva**
14. **Dr Lalrintluangi**
15. **Dr Vikram K Behal**
16. **Dr Vasantha Muthuswamy**
17. **Shri Nirakar C Saxena**
18. **Dr Radhey S Sharma**
19. **Dr Nomita Chandhiok**

Edited by

Dr Radhey S Sharma
Dr Pushpa M Bhargava
Dr Nomita Chandhiok
Shri Nirakar C Saxena

Ministry of Health and Family Welfare
Government of India

Indian Council of Medical Research
National Academy of Medical Sciences (India), New Delhi - 110029
2005

Printed at S. Narayan & Sons, B-88, Okhla Indl. Area, Phase-II, New Delhi 110 020

Contents

Forword xi - xii
Preface xiii - xv
Acknowledgement xvii
Abbreviations xix - xxi
Corrigendum xxiii-xxvi

Chapter 1 1 - 35

Introduction, Brief history of ART and Requirement of ART Clinics 1
1.0 Introduction 3
1.1 Brief History 4
1.1.1 ART – an alternative to reversal of Sterilization 5
1.2 Definitions 5
1.3 Minimal Physical Requirements for an ART Clinic 11
1.3.1 The non – sterile area 11
1.3.2 The sterile area 13
1.3.3 Ancillary laboratory facilities 15
1.4 Back-up Power Supply 17
1.5 Essential Qualifications of the ART Team 17
1.5.1 Gynaecologist 17
1.5.2 Andrologist 19
1.5.3 Clinical Embryologist 20
1.5.4 Counsellors 22
1.5.5 Programme co-ordinator/ director 23
1.6 ART Procedures 23
1.6.1 Artificial insemination with husband's semen (AIH) 24
1.6.2 Artificial insemination with donor semen (AID) 24
1.6.3 Intrauterine insemination with husband's or donor semen (IUI-H or IUI-D) 25
1.6.4 *In vitro* fertilization and embryo transfer (IVF-ET) 26

1.6.5 IVF- associated techniques 27
1.6.6 Intracytoplasmic sperm injection (ICSI) with ejaculated, epididymal or testicular spermatozoa 27
1.6.7 Oocyte donation (OD) or embryo donation (ED) 28
1.6.8 Cryopreservation 30
1.6.9 *In vitro* culture media 31
1.6.10 The future ART technologies 32
1.6.11 Caution, precautions and concerns about ART practice 32

Chapter 2 37-53

Screening of Patients for ART: Selection Criteria and Possible Complications 37
2.1 Patient Selection 39
2.1.1 Husband 39
2.1.2 Wife 39
2.2 Patient Selection for Treatment in Different Infertility Care Units 40
2.2.1 Single defect in one of the partner 40
2.2.2 Multiple defects in one or both partners 41
2.2.3 No detectable defect in either partner (Unexplained or idiopathic infertility) 41
2.3 Selection Criteria for ART 43
2.3.1 Selection criteria for *in vitro* fertilization and embryo transfer (IVF-ET) 43
2.3.2 Selection criteria for gamete intra-fallopian transfer (GIFT) 45
2.3.3 Choosing between IVF-ET and GIFT 45
2.3.4 Micro-assisted fertilization (SUZI and ICSI) 46
2.4 Complications 46
2.4.1 Multiple gestation 46

2.4.2	Ectopic pregnancy	47
2.4.3	Spontaneous abortion	47
2.4.4	Preterm birth	47
2.4.5	Ovarian hyperstimulation syndrome	47
2.5	**Categories of Infertility Care Units**	**48**
2.5.1	Primary (Level 1A) infertility care units	48
2.5.2	Primary (Level 1B) infertility care units engaging in IUI	50
2.5.3	Secondary (Level 2) infertility care units	51
2.5.4	Tertiary (Level 3) infertility care units	52
Chapter 3		**55-76**
Code of Practice, Ethical Considerations and Legal Issues		**55**
3.1	**Clinics which should be Licensed**	**57**
3.2	**Code of Practice**	**57**
3.2.1	Staff	57
3.2.2	Facilities	58
3.2.3	Confidentiality	58
3.2.4	Information to patient	58
3.2.5	Consent	58
3.2.6	Counselling	58
3.2.7	Use of gametes and embryos	59
3.2.8	Storage and handling of gametes and embryos	59
3.2.9	Research	59
3.2.10	Complaints	59
3.3	**Responsibilities of the clinic**	**60**
3.4	**Information and Counselling to be given to Patients**	**61**
3.5	**Desirable Practices/Prohibited Scenarios**	**62**
3.6	**Requirements for a Sperm Donor**	**65**
3.7	**Requirements for an Oocyte Donor**	**66**

3.8 Requirements for a Surrogate Mother 66
3.9 How may Sperm and Oocyte Donors and Surrogate Mothers be Sourced? 66
3.9.1 Semen banks 66
3.9.2 Sourcing of oocytes and surrogate mothers 68
3.9.3 Oocyte sharing 68
3.10 Surrogacy: General Considerations 68
3.11 Preservation, Utilization and Destruction of Embryos 70
3.12 Rights of a Child Born through various ART Technologies 70
3.13 Responsibility of the Drug Industry 71
3.14 General Considerations 71
3.15 Responsibilities of the Accreditation Authority 73
3.16 Legal Issues 74
3.16.1 Legitimacy of the child born through ART 74
3.16.2 Adultery in case of ART 75
3.16.3 Consummation of marriage in case of AIH 75
3.16.4 Rights of an unmarried woman to AID 75
3.16.5 Posthumous AIH through a sperm bank 75
3.17 Institutional Ethics Committees 76

Chapter 4 77-97

Sample Consent Forms : 77
4.1 For the Couple 79
4.2 For Artificial Insemination with Husband's Semen 81
4.3 For Artificial Insemination with Donor Semen 82
4.4 For Freezing of Embryos 84
4.5 For the Procedure of PESA & TESA 86
4.6 Oocyte Retrieval/ Embryo Transfer 88
4.7 Agreement for Surrogacy 91
4.8 For the Donor of Eggs 95

4.9 For the Donor of Sperm 97

Chapter 5 99-101

Training 99

5.0 Training 101

Chapter 6 103-106

Future Research Prospects 103

6.0 Future Research Prospects 105

6.1 Preimplantation Genetic Diagnosis and Chromosomal and Single-Gene Defects 106

Chapter 7 107-109

Providing ART Services to the Economically Weaker Sections of the Society 107

7.0 Providing ART Services to the Economically Weaker Sections of the Society 109

Chapter 8 111-113

Establishing a National Database for Human Infertility 111

8.0 Establishing a National Database for Human Infertility 113

Chapter 9 115-118

Composition of the National Accreditation Committee 115

9.0 Composition of the National Accreditation Committee 117

Bibliography 119-122

Members of the Expert Group for Formulating the National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India 123-126

Foreword

Shri Prasanna Hota
Secretary
Ministry of Health and Family Welfare
Government of India

Infertility, though not life threatening, can cause intense agony and trauma to the infertile couples. No data on the extent of infertility prevalent in India is available; but the multinational study carried out by WHO (Diagnosis and Treatment of Infertility, ed. P. Rowe and E.N. Vikhlyaeva, 1988) that included India, places the incidence of infertility between 10 and 15%. Out of the population of 1020 million Indians, an estimated 25% (about 250 million individuals) may be conservatively estimated to be attempting parenthood at any given time. By extrapolating the WHO estimates, approximately 13 to 19 million couples are likely to be infertile in the country at any given time. These couples approach ART Clinics.

The increasing demand for ART has resulted in mushrooming of infertility clinics in India. The Assisted Reproductive Technology (ART) in India is being provided by private sector only. Many of these technologies require enormous technical expertise and infrastructure. However, the success rate is below 30% under the best of circumstances. Moreover, it taxes the couple's endurance physically, emotionally and monetarily. Many of these clinics do not have adequate trained manpower and infrastructure facilities to deliver these highly sophisticated technologies and even services provided by some of these clinics are highly questionable. In some cases, the infertile couple are being cheated by providing relatively simple procedure and charged for complicated and expensive procedures. The procedures, wherein Round Spermatid Nuclear Injection and Pre-implantation

Genetic Diagnosis in gender selection of the embryo are used, have not been universally accepted. These issues are of great concern to the society.

In order to regulate and supervise the ART clinics, the Indian Council of Medical Research (ICMR) and National Academy of Medical Sciences (NAMS) have come out with National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India. These Guidelines have been evolved after detailed discussion and debate by experts, practitioners of ART and public.

I take immense pleasure in presenting these Guidelines, which I strongly feel, would be very useful in regulating and supervising the functioning of ART Clinics and would be helping the ART Clinics in providing safe and ethical services to the needy infertile couples. I also place on record our appreciation of the efforts of the experts of ICMR & NAMS in bringing out these Guidelines.

(Prasanna Hota)
Secretary
Ministry of Health and Family Welfare
Government of India
New Delhi-110011

Preface

Prof. N. K. Ganguly
Director General
Indian Council of Medical Research

The successful birth of the world's first baby conceived by *in vitro* fertilization (IVF) and embryo transfer occurred on July 25, 1978, in the UK. The world's second IVF baby was born 67 days later on October 3, 1978 in Kolkata. India's first scientifically documented IVF baby was, however, born on August 6, 1986 in Mumbai through the support of the Indian Council of Medical Research. Since then, over one and half million babies conceived by Assisted Reproductive Technologies (ART) have reportedly been born throughout the world.

The advent of any new technology that affects mankind raises several technical and moral dilemmas and poses many ethical and technical challenges. ART is no exception. In the Indian context where barrenness is looked down upon, infertile patients look up to ART as the last resort to parenthood. Some of them are prepared to go to any extent to achieve their life's ambition. Unfortunately, ART has not reached a stage where all forms of infertility can be treated, nor can any clinic offer a 100% success if the couples were to undergo any of the assisted reproductive technologies. The ART practitioner is often faced with a technical challenge of trying to select the right treatment for a particular type of infertility, knowing fully well that none of the available techniques offer 100% success. The practitioner also faces moral responsibility of trying to convince the infertile couple of this fact and let them know the chances of success and failure by the particular treatment that is being offered.

The increasing demand for ART has resulted in mushrooming of infertility clinics in India. There is no reliable information on the number of ART clinics in India in the absence of a national registry of ART clinics. There is no information on the follow-up of babies born after the use of ART to know the incidence of congenital malformation in them. There have been reports in the press of malpractices carried out by some ART clinics.

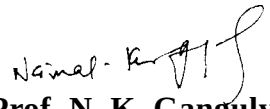
Such malpractices are not unique to India but are a global phenomenon. Many countries have taken steps to prevent such aberrant occurrences. Austria, Australia, Brazil, Canada, the Czech Republic, Denmark, France, Germany, Greece, Hungary, Iceland, Israel, Italy, Japan, Korea, Mexico, the Netherlands, Norway, Saudi Arabia, Singapore, South Africa, Spain, Sweden, Switzerland, Taiwan and Turkey have legislations for the practice of ART. Scientific societies in Finland, Poland, Portugal and the USA have drawn up guidelines for the practices of ART. Argentina, Egypt and the UK have both guidelines and legislation. Guidelines and/or legislation in these countries have been shown to improve the process of patient care and procedure outcomes.

There are no guidelines for the practice of ART, accreditation of infertility clinics and supervision of their performance in India. This document aims to fill this lacuna and also provide a means of maintaining a national registry of ART clinics in India. The document has been widely publicized, discussed and debated by expert groups of the ICMR and the National Academy of Medical Sciences and then by practitioners of ART and the public in Chennai, Jodhpur, Kolkata, Bangalore, Hyderabad and Mumbai. These discussions involved over 4000 participants including doctors, scientists, bureaucrats, legal experts, infertile couples and the general public. This document was also put on the Council's website and elicited many comments and responses.

All attempts have been diligently made to encompass all points of view and bring out a document that conveys the views of the vast majority of participants in the above mentioned discussions and debates.

This document should be useful to the infertility clinics as well as to those who seek the services of such clinics. However, as ART is an evolving field, this

document will need to be periodically reviewed. This will be a challenging task both for the practitioners of ART and the regulatory authority that is yet to be established.



(Prof. N. K. Ganguly)
Director General
Indian Council of Medical Research
New Delhi-110029

Acknowledgements

The Council gratefully acknowledges the valuable contribution of all the members of the Expert Committee responsible for formulating these guidelines, for providing continued guidance in drafting and finalizing the guidelines. We are extremely grateful to the Chairpersons of the subcommittees of the Expert Committee for conducting regional discussions and preparing the draft document on the respective topics assigned to them.

This document is a concerted effort made possible by the advice, assistance and co-operation of many individuals, institutions and government and non-governmental organizations, specially the National Academy of Medical Sciences (NAMS), The Medically Aware and Responsible Citizens of Hyderabad (The MARCH), Indian Society for the Study of Reproduction and Fertility (ISSRF) and Federation of Obstetrics and Gynaecology Society of India (FOGSI).

The suggestions and advice emerging from the workshop sponsored by the National Academy of Medical Sciences held on 16th September 2001 at Bangalore were of great significance. Therefore, the Council is particularly grateful to the participants of the NAMS workshop (i.e. Manohar, Aruna Sivakami, J Mehta, S. Narang, M. S. Sreenivas, M. Gourie Devi, B. Kalyan, N. Krishnan, N. Pandiyan, K. S. Jayaraman, P. B. Seshagiri, R. H. Mehta, Seema Singh, P. V. Kulkarni, Lalitha, P. Sarkar, M. Sarkar, M. Priya, K. Nath, M. Nirad, D. Raghunath, Gopinathan, R. S. Sharma, N. C. Saxena, V. Muthuswamy, B. N. Chakravarthy, C. S. Bhaskaran, M. Rajalakshmi and T. C. Anand Kumar).

Special thanks are due to Dr. P. M. Bhargava not only for his initiative, professional and editorial inputs and consistent interest in and enthusiasm for the guidelines, but also doing everything in good humour, inspite of continual office interruptions and information overload on the various topics of the guidelines.

We are also grateful to the National Commission for Women and the National Human Rights Commission for their valuable advise.

Secretarial assistance provided by Mr. Mahesh Kumar is gratefully acknowledged.

Abbreviations

AIDS	-	Acquired Immune Deficiency Syndrome
ASRM	-	American Society for Reproductive Medicine
AI	-	Artificial Insemination
AID	-	Artificial Insemination with Donor Semen
AIH	-	Artificial Insemination with Husband's Semen
ART	-	Assisted Reproductive Technology
BBT	-	Basal Body Temperature
CO_2	-	Carbon Dioxide
CC	-	Clomiphene Citrate
CASA	-	Computer-Aided Sperm Analysis
CBAVD	-	Congenital Bilateral Absence of Vas Deferens
CMV	-	Cytomegalo Virus
DHEA	-	Dehydro-epiandrostendione
DNA	-	Deoxyribonucleic Acid
DMSO	-	Dimethylsulfoxide
ED	-	Embryo Donation
ELSNI	-	Elongated Spermatid Nuclear injection
ESHRE	-	European Society for Human Reproduction and Embryology
FISH	-	Fluorescent *in situ* Hybridization

FSH - Follicle Stimulating Hormone

GIFT - Gamete Intrafallopian Transfer

GnRH - Gonadotropin Releasing Hormone

GLP - Good Laboratory Practices

HBV - Hepatitis B Virus

HCV - Hepatitis C Virus

hCG - Human Chorionic Gonadotropin

hMG - Human Menopausal Gonadotropin

HIV - Human Immunodeficiency Virus

HOST - Hypo-Osmotic Swelling Test

ICMR - Indian Council of Medical Research

ICPD - International Conference for Population and Development

IFFS - International Federation of Fertility Societies

ICSI - Intracytoplasmic Sperm Injection

IUI - Intra-uterine Insemination

IRR - Institute for Research in Reproduction, (now National Institute for Research in Reproductive Health, NIRRH)

IVF-ET - *In vitro* Fertilization–Embryo Transfer

IVMTS - *In vitro* Maturation of Testicular Sperm

LH - Luteinizing Hormone

OD	-	Oocyte Donation
OT	-	Operation Theatre
OHS	-	Ovarian Hyperstimulation Syndrome
PESA	-	Percutaneous Epididymal Sperm Aspiration
PGD	-	Pre–implantation Genetic Diagnosis
PCOS	-	Polycystic Ovarian Syndrome
PCR	-	Polymerase Chain Reaction
RNA	-	Ribonucleic Acid
SCMPT	-	Sperm Cervical Mucous Penetration Test
SOP	-	Standard Operating Procedure
TESA	-	Testicular Sperm Aspiration
TESE	-	Testicular Sperm Extraction
TSH	-	Thyroid Stimulating Hormone
TVS	-	Transvaginal Sonography
UPS	-	Uninterrupted Power Supply
WHO	-	World Health Organization
WMA	-	World Medical Assembly