

# **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**

**Indian Council of Medical Research  
National Academy of Medical Sciences (India), New Delhi - 110029  
2004**

© 2004 Indian Council of Medical Research, New Delhi

---

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

# Contents

<b>Preface</b>	<b>ix - x</b>
<b>Acknowledgement</b>	<b>xi</b>
<b>Abbreviations</b>	<b>xiii - xv</b>
<b>Chapter 1</b>	<b>1 - 36</b>
<b>Introduction, Brief history of ART and Requirement of ART Clinics</b>	<b>1</b>
<b>1.0 Introduction</b>	<b>3</b>
<b>1.1 Brief History</b>	<b>4</b>
1.1.1 ART – an alternative to reversal of Sterilization	5
<b>1.2 Definitions</b>	<b>5</b>
<b>1.3 Minimal Physical Requirements for an ART Clinic</b>	<b>11</b>
1.3.1 The non – sterile area	11
1.3.2 The sterile area	13
1.3.3 Ancillary laboratory facilities	15
<b>1.4 Back-up Power Supply</b>	<b>17</b>
<b>1.5 Essential Qualifications of the ART Team</b>	<b>17</b>
1.5.1 Gynaecologist	17
1.5.2 Andrologist	18
1.5.3 Clinical Embryologist	20
1.5.4 Counsellors	22
1.5.5 Programme co-ordinator/ director	22
<b>1.6 ART Procedures</b>	<b>23</b>
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 <i>In vitro</i> fertilization and embryo transfer (IVF-ET)	25
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	29
1.6.9	<i>In vitro</i> culture media	31
1.6.10	The future ART technologies	32
1.6.11	Caution, precautions and concerns about ART practice	32

**Chapter 2** **37-54**

**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 41

2.2.2 Multiple defects in one or both partners 41

2.2.3 No detectable defect in either partner  
(Unexplained or idiopathic infertility) 42

**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 46

2.4.3	Spontaneous abortion	47
2.4.4	Preterm birth	47
2.4.5	Ovarian hyperstimulation syndrome	47
<b>2.5</b>	<b>Categories of Infertility Care Units</b>	<b>48</b>
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
<b>Chapter 3</b>		<b>55-78</b>
	<b>Code of Practice, Ethical Considerations and Legal Issues</b>	<b>55</b>
<b>3.1</b>	<b>Clinics which should be Licensed</b>	<b>57</b>
<b>3.2</b>	<b>Code of Practice</b>	<b>57</b>
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	59
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	60
<b>3.3</b>	<b>Responsibilities of the clinic</b>	<b>60</b>
<b>3.4</b>	<b>Information and Counselling to be given to Patients</b>	<b>61</b>
<b>3.5</b>	<b>Desirable Practices/Prohibited Scenarios</b>	<b>63</b>
<b>3.6</b>	<b>Requirements for a Sperm Donor</b>	<b>66</b>
<b>3.7</b>	<b>Requirements for an Oocyte Donor</b>	<b>66</b>
<b>3.8</b>	<b>Requirements for a Surrogate Mother</b>	<b>67</b>

<b>3.9</b>	<b>How may Sperm and Oocyte Donors and Surrogate Mothers be Sourced?</b>	<b>67</b>
3.9.1	Semen banks	67
3.9.2	Sourcing of oocytes and surrogate mothers	68
3.9.3	Oocyte sharing	69
<b>3.10</b>	<b>Surrogacy: General Considerations</b>	<b>69</b>
<b>3.11</b>	<b>Preservation, Utilization and Destruction of Embryos</b>	<b>70</b>
<b>3.12</b>	<b>Rights of a Child Born through various ART Technologies</b>	<b>71</b>
<b>3.13</b>	<b>Responsibility of the Drug Industry</b>	<b>72</b>
<b>3.14</b>	<b>General Considerations</b>	<b>72</b>
<b>3.15</b>	<b>Responsibilities of the Accreditation Authority</b>	<b>75</b>
<b>3.16</b>	<b>Legal Issues</b>	<b>76</b>
3.16.1	Legitimacy of the child born through ART	76
3.16.2	Adultery in case of ART	76
3.16.3	Consummation of marriage in case of AIH	77
3.16.4	Rights of an unmarried woman to AID	77
3.16.5	Posthumous AIH through a sperm bank	77
<b>3.17</b>	<b>Institutional Ethics Committees</b>	<b>77</b>
<b>Chapter 4</b>		<b>79-100</b>
<b>Sample Consent Forms :</b>		<b>79</b>
<b>4.1</b>	<b>For the Couple</b>	<b>81</b>
<b>4.2</b>	<b>For Artificial Insemination with Husband's Semen</b>	<b>83</b>
<b>4.3</b>	<b>For Artificial Insemination with Donor Semen</b>	<b>84</b>
<b>4.4</b>	<b>For Freezing of Embryos</b>	<b>86</b>
<b>4.5</b>	<b>For the Procedure of PESA &amp; TESA</b>	<b>88</b>
<b>4.6</b>	<b>Oocyte Retrieval/ Embryo Transfer</b>	<b>90</b>
<b>4.7</b>	<b>Agreement for Surrogacy</b>	<b>93</b>
<b>4.8</b>	<b>For the Donor of Eggs</b>	<b>97</b>
<b>4.9</b>	<b>For the Donor of Sperm</b>	<b>99</b>

<b>Chapter 5</b>	<b>101-104</b>
<b>Training</b>	<b>101</b>
<b>5.0 Training</b>	<b>103</b>
<b>Chapter 6</b>	<b>105-108</b>
<b>Future Research Prospects</b>	<b>105</b>
<b>6.0 Future Research Prospects</b>	<b>107</b>
<b>6.1 Preimplantation Genetic Diagnosis and Chromosomal         and Single-Gene Defects</b>	<b>108</b>
<b>Chapter 7</b>	<b>109-112</b>
<b>Providing ART Services to the Economically Weaker Sections     of the Society</b>	<b>109</b>
<b>7.0 Providing ART Services to the Economically Weaker         Sections of the Society</b>	<b>111</b>
<b>Chapter 8</b>	<b>113-116</b>
<b>Establishing a National Database for Human Infertility</b>	<b>113</b>
<b>8.0 Establishing a National Database for Human Infertility</b>	<b>115</b>
<b>Chapter 9</b>	<b>117-120</b>
<b>Composition of the National Accreditation Committee</b>	<b>117</b>
<b>9.0 Composition of the National Accreditation Committee</b>	<b>119</b>
<b>Bibliography</b>	<b>121-124</b>
<b>Members of the Expert Group for Formulating the National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India</b>	<b>125-128</b>

## Preface

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 numerous reports in the press of malpractices carried out by some ART clinics and legal action having been taken against some of them.

Such malpractices are not unique to India but are a global phenomenon. Many countries have taken steps to prevent such aberrant



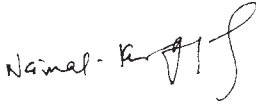
occurrences. Austria, Australia, Brazil, Canada, the Czech Republic, Denmark, France, Germany, Greece, Hungary, Iceland, Israel, Italy, Japan, Korea, Mexico, the Netherlands, Norway, Saudi Arabia, Singapore, South Africa, Spain, Sweden, Switzerland, Taiwan and Turkey have legislations for the practice 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.

New Delhi  
March 2004

  
**Prof. N. K. Ganguly**  
**Director General**

## 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 16<sup>th</sup> 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 <sub>2</sub>	-	Carbon Dioxide
CC	-	Clomiphene Citrate
CASA	-	Computer-Aided Sperm Analysis
CBAVD	-	Congenital Bilateral Absence of Vas Deferens
CMV	-	Cytomegalo Virus
DHEA	-	Dehydro-epiandrosterone
DNA	-	Deoxyribonucleic Acid
DMSO	-	Dimethylsulfoxide
ED	-	Embryo Donation
ELSNI	-	Elongated Spermatid Nuclear injection
ESHRE	-	European Society for Human Reproduction and Embryology
FISH	-	Fluorescent <i>in situ</i> 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	-	<i>In vitro</i> Fertilization–Embryo Transfer
IVMTS	-	<i>In vitro</i> 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