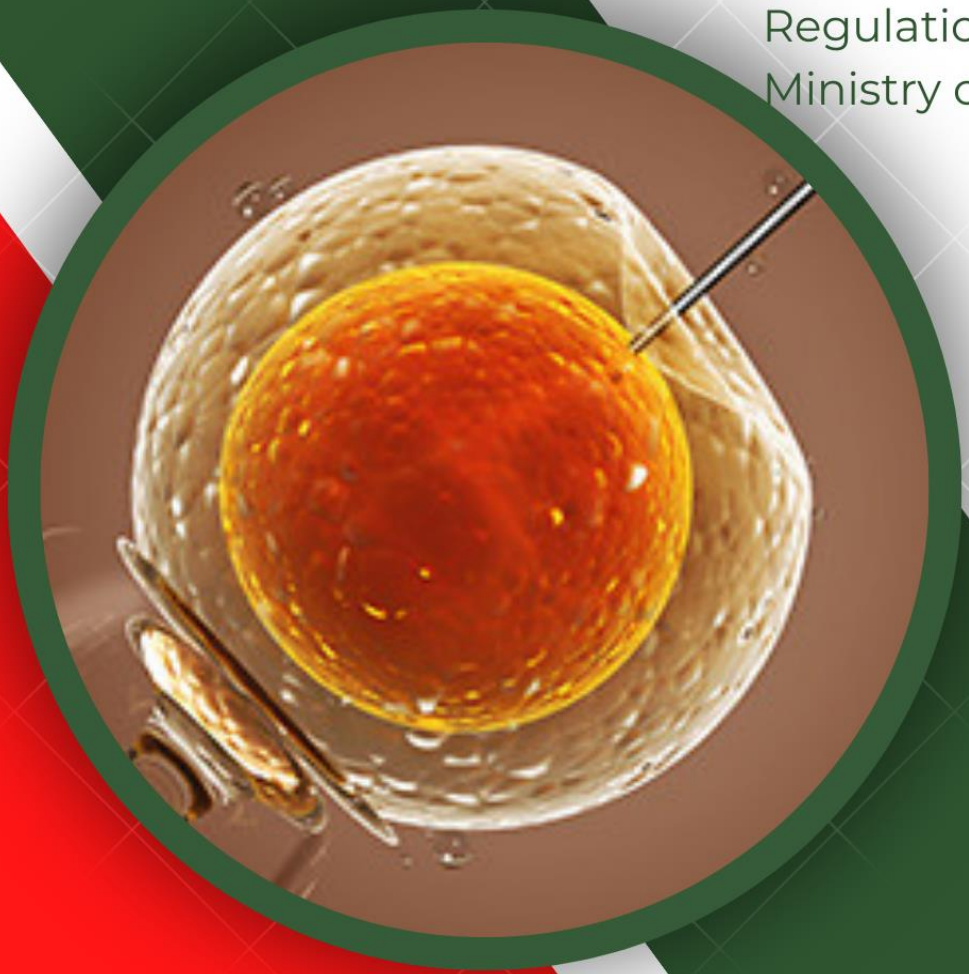
NATIONAL STANDARD FOR ASSISTED REPRODUCTIVE TECHNOLOGY IN THE MALDIVES

Quality Assurance and
Regulations Division
Ministry of Health



Republic of Maldives

National standard for

Assisted Reproductive Technology

in the Maldives

2023

Quality Assurance and Regulations Division

Ministry of Health

Male', Maldives

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Ministry of Health
Male' Republic of Maldives

1. INTRODUCTION

Assisted Reproductive Technology (ART) includes all fertility treatments in which either eggs or embryos are handled, which is used to treat infertility. It involves surgically removing eggs from the woman's ovary, combining them with sperm in the laboratory and returning them to the woman's uterus (CDC, 2019). Intra Uterine Insemination (IUI), Invitro Fertilization (IVF) and Intracytoplasmic Sperm Injection (ISCI) are types of assisted reproductive technologies. ART can alleviate the burden of infertility on individuals and families. Therefore, it is imperative for couples suffering from infertility and awaiting to conceive.

This standard outline procedure for establishment and operation of ART units in the Maldives, and it applies to all healthcare facilities operating an ART unit in the country. This standard aims to standardize ART units and its services in the Maldives, while ensuring safety, quality of services and confidentiality for the couples.

2. DEFINITIONS

For the purpose of this standard, the following terms are defined as stated below.

Terms	Definitions
Ministry	Ministry of health
ART	Assisted Reproductive technology using IUI, IVF and ICSI.
ART Unit(s)	A stand-alone unit or a dedicated unit within a government healthcare centre, or a private healthcare centre providing Assisted Reproductive Technology (ART) in the Maldives.
Couple	A married man and a woman, and the marriage registered at family court/magistrate court of the Maldives
Infertility	In general, infertility is defined as not being able to get pregnant (conceive) after one year (or longer) of regular unprotected sex (CDC, 2022)
Sperm	A sperm is the male "gamete" or sex cell.
Zygote	The egg when it is fertilized by the husband's sperm
Embryo	The fertilized egg (the zygote) undergoes cell division in pre-organogenesis stage, that is during the first two weeks.
Intra Uterine Insemination (IUI)	Intra-uterine insemination (IUI) is a procedure for placing washed/ rinsed semen in a uterus during ovulation period.
Invitro fertilization (IVF)	The technique in which eggs (oocytes) are retrieved from wife's ovary fertilized by the husband's sperm in the laboratory, preserved under certain conditions, and then returned to the wife's uterus, after ensuring proper cell division.
Intracytoplasmic Sperm Injection (ICSI)	Procedure where a tiny needle, called a micropipette, is used to inject a single sperm into the center of the egg.
Fatwa	A formal and authoritative ruling or interpretation on a point of Islamic law given by the Supreme Council for Islamic Affairs. For the purposes of this Standard, any religious ruling on matters pertaining to this Standard, issued by the Ministry of Islamic Affairs, under its general

	mandate to oversee religious affairs and advice the State and public on religious matters, will be considered to have the same status.
Supreme Council for Islamic Affairs	The Council formed pursuant to S. 5 of the Act No. 6/94 (Religious Unity Act) with the authority to explore issues related to Islamic jurisprudence (Fiqh) and issue Fatwas to guide the State and the public on matters that cause religious conflicts in the country.
Ministry of Islamic Affairs	Government Ministry mandated to advice the State on religious matters and oversee religious affairs in the Maldives.
Maldives Medical and Dental Council (MMDC)	The council formed under S.29 of the Act No. 13/2015 (Health Professionals Act) to regulate the practice, registration and licensure of medical practitioners and dental practitioners in the Maldives.
Maldives Allied Health Council	The council formed under S.41 of the Act No. 13/2015 (Health Professionals Act) to regulate the practice, registration ad licensure of allied health professionals of the Maldives.
Allied Health Professionals	Health Professionals besides medical and dental practitioners, nurses, and midwives, who fall into any of the categories stated in S. 45 (b) of the Act No. 13/2015 (Healthcare Professionals Act).

For the purpose of this standard, the auxiliary verb:

“must” means that compliance with requirements are mandatory for compliance with this standard and the unit cannot omit or use part of those points;

“shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

“may” is used to describe a permissible way to achieve compliance with a requirement or test.

3. SERVICES

The following services which may be provided from ART units

3.1 Couple consultation

3.2 Pre-treatment assessment and counseling

3.3 Blood collection and investigations

3.4 Ultrasound examination

3.5 Ovarian stimulation therapy

3.6 Intra Uterine Insemination (IUI)

3.7 Oocyte (egg) collection

3.8 Semen collection and examination TESA (Testicular Sperm Aspiration), PESA (Percutaneous Epididymal Sperm Aspiration) and micro TESA (Microscopic Testicular Sperm Aspiration)

3.9 Semen preparation for Intra Uterine Insemination (IUI) and In-vitro Fertilization (IVF)

3.10 Embryo culture and transfer

3.11 Invitro Fertilization (IVF)

3.12 Cryopreservation and thawing of sperm/ oocyte/ embryo

3.13 Intra Cytoplasmic Sperm Injection (ICSI) fertilization

3.14 Intracytoplasmic Morphologically selected Sperm Injection (IMSI)

Note: Services addition requires request to Quality Assurance and Regulations Authority (QARD).

4. INFRASTRUCTURE, FUNCTIONAL REQUIREMENTS AND GRADING LEVEL

4.1 Infrastructure

4.1.1 Any ART unit providing services in the Maldives shall observe mandatory infrastructure requirements in chapter 3 of the Regulation No. 2021/R-28 (Regulations on Operating Healthcare Centres). They are:

S. 10 -Structural standards of healthcare centres

S. 11- Hygiene maintenance standard

S. 12- Safety standard

S. 13- Reception or waiting area

S. 14- Consultation room

S. 15- Procedure room

S. 16- Laboratory, x-ray and other examination rooms

S. 18- Sterilization and disinfection

4.1.2 All ART units shall follow the design and functional requirements stipulated in annex 1 of this standard.

4.1.3 Reproduction techniques that require laparoscopy or general anaesthesia are only permissible for in-hospital fertility treatment units

4.2 Laboratories

The ART units shall:

4.2.1 Use appropriate building materials and furniture for the nature of its work. The same applies for air and ventilation. The construction shall ensure aseptic and optimal handling of reproductive tissue during all stages of the process.

4.2.2 Have air conditioning and ventilation with High Efficiency Particulate Air (HEPA) filters, controlled humidity (20%) and controlled temperature (22-24 degree centigrade).

4.2.3 Have temperature regulation mechanism to assist in maintaining room temperature at 36-37 degrees centigrade to prevent deterioration of oocytes in lamina flow and incubators where gametes are handled.

4.2.4 Have 24hours CCTV surveillance and fully functional alarm system.

4.2.5 Have separate office space for record keeping, data entry and other administrative tasks shall be available.

4.2.6 Use laboratory equipments that fulfill specifications by the Ministry of Health where required.

4.2.7 Provide safe working environment for the staff and allow easy movements and material pass through hatches available.

4.2.8 Have access control to prevent unauthorized entry, particularly to the laboratory areas, cryopreservation and record keeping rooms.

4.2.9 Have an Uninterrupted Power Supply (UPS) with adequate number of power outlets. Special consideration shall be given to critical equipments such as incubators, refrigerators, biosafety cabinets that they shall have emergency backup generator.

4.2.10 Meet criteria set out in Chapter 3 section 16 of the Regulation 2021/R-28 (Regulation on operating healthcare centres).

4.2.11 Strictly observe the laboratory requirements stipulated in this standard. See annex 2 for standards for different types of laboratories.

4.2.12 Have a storage location system that minimizes the amount of handling required to retrieve gametes.

4.2.13 Ensure that gametes are packed for storage in a way that it prevents any adverse effects and minimizes risk of contamination.

4.2.14 Ensure cryopreservation tanks are fitted with alarm system and be linked with auto dial or similar facility to alert the staff on malfunctioning in non-working hours.

4.2.15 Have Operation Theatres (OT) adjacent to laboratories.

4.2.16 There shall be at least 2 (two) qualified embryologists with a valid license from MMDC.

4.3 **Grading**

ART units shall be graded as:

Level 1: Treatment of infertility with injectable ovulation drugs and IUI

Level 2: Treatment with IVF

Level 3: Treatment of infertility with ICSI and micromanipulation

5. REQUIREMENTS FOR REGISTRATION AND LICENSING

5.1 No ART unit may be established or operated except after obtaining registration and license from Ministry of Health.

5.2 Registration and licensing are required for ART units requesting to establish healthcare services for the first time. Existing healthcare centres/hospitals with a valid operating license requires new service approval.

5.3 Service approval shall be granted by QARD upon meeting requirements set out in this standard and chapter 4 of Regulation no. 2021/R-28 (Regulation on registration and licensing of healthcare Centres) and other relevant laws and regulations.

5.4 All licensed health facilities shall pay the prescribed annual fees as stipulated in Regulation no. 2021/R-28 (Regulation on registration and licensing of healthcare Centres).

5.5 The ART unit may be registered as a stand-alone or a dedicated unit within a government or a private healthcare centre and graded as 3 (three) levels.

5.6 Level 1 ART unit

5.6.1 level 1 ART unit with injectable ovulation drugs and IUI, the following conditions must be satisfied:

a) The supervisor in-charge at the unit must be an Obstetrician and Gynecologist registered at MMDC;

b) The supervisor in-charge shall be experienced in infertility treatment and use of vaginal ultrasound devices, if not, a radiologist is required to closely monitor ovulation induction.

c) Level 1 ART unit shall have the following equipments

i. Basic equipments of a clinic as per the specifications of Ministry of Health.

ii. Ultrasound device, equipped with a vaginal probe, to measure the size and number of follicles.

iii. Basic equipments such as small procedure room, a laboratory area with laminar flow, equipments needed for semen separation, and a trained assistant shall be available.

5.7 Level 2 ART unit

5.7.1 For level 2 ART unit for infertility with IVF, the following conditions must be satisfied.

a) The supervisor in-charge must be a consultant in Obstetrics and Gynecology who is registered at MMDC.

b) The consultant shall have credentials and minimum of 1 (one) year of experience in the area of infertility treatment, and no less than 1 (one) year of experience in using vaginal ultrasound device.

c) Where the supervisor in-charge does not have credentials and experience, a radiologist is required to closely monitor ovulation induction.

d) The assistant must have a degree in Obstetrics and Gynecology.

e) Andrologist, Urologist or who is trained for male infertility shall be available in the unit who is registered at MMDC.

f) Embryologist must have a bachelor's degree from a recognized university by Maldives Qualification Authority (MQA). They must possess documented training experience in IVF laboratories for a period of 1 (one) year.

g) The laboratory assistant may be employed to assist in administrative activities.

h) For level 2 ART unit, the following equipments must be available.

i. Complete equipment for a clinic as per the specification of QARD

ii. An ultrasound device, equipped with vaginal probe.

iii. A laboratory that contains a centrifuge, CO2/trigas/dry incubators, oocyte/ovum aspiration pumps, cryocans. Embryoscopes and laser hatching system are optional.

iv. A clear and accurate system and procedure for collecting and analyzing samples, and for confirming the name and identity of the sample owner.

v. System for keeping records and information and entering data in an accurate, clear and auditable way.

5.8 Level 3 ART units

5.8.1 For level 3 ART units with ICSI and micromanipulations, the following conditions must be satisfied.

a) The supervisor in-charge must be a consultant in Obstetrics and Gynecology who is registered at MMDC. The consultant shall have credentials and minimum of 1 (one) years of experience in the area of infertility treatment.

b) The supervisor in-charge shall be experienced in infertility treatment and the use of vaginal ultrasound devices and shall work in the unit on full-time basis.

c) The assistant Obstetrician and Gynecologist must have a degree in obstetrics and gynecology.

d) Andrologist and Urologist shall be trained in male infertility who is registered at MMDC.

e) For level 3 ART unit, the following equipments must be available.

i. ICSI machine and micromanipulator

ii. An ultrasound device, equipped with vaginal probe

iii. Laboratory microscopes, sperm counting chambers, semen warmer, test tube warmers, microscope camera, and laminar air flow.

iv. A clear and accurate system and regulations for collecting and analyzing samples, and for confirming the name and identity of the sample owner.

v. Methods and facilities for storing semen samples safely and accurately, ensuring that they are only accessed by the laboratory's authorized workers or the clinic supervisor.

6 ELIGIBILITY CRITERIA

6.1 Reviews on age limit

Since different countries have their own age limits for the ART procedures, the following are literature on upper and lower age for ART procedures.

6.1.1 Indian Society for Assisted Reproduction ethics committee 2018

1. "For women up to 45, ART could be offered after routine evaluation reveals that there are no underlying medical conditions that would significantly increase the obstetrical and neonatal risks. Expert opinion suggests that women up to 50 could potentially be medically considered with the same criteria for risk assessment based on the age of menopause and life expectancy. Additional counseling regarding the increased risks added by age for maternal and fetal health must be given"
2. "For men up to 50, ART may be offered after routine evaluation reveals satisfactory parameters for sperm. Counseling regarding potential for genetic and other abnormalities needs to be provided"

6.1.2 Nice guidance 2013

1. In women aged under 40 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), offer 3 full cycles of IVF, with or without ICSI. If the woman reaches the age of 40 during treatment, complete the current full cycle but do not offer further full cycles.
2. In women aged 40–42 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), offer 1 full cycle of IVF, with or without ICSI, provided the following 3 criteria are fulfilled:
   - they have never previously had IVF treatment
   - there is no evidence of low ovarian reserve (see box D10)
   - there has been a discussion of the additional implications of IVF and pregnancy at this age.

6.1.3 The fertility society of Australia (2016)

Miscarriages increase from 15% in women below 30 years of age to 55% for those between 40 to 44 years of age. the risk of infertility, spontaneous abortion, ectopic pregnancy and chromosomal abnormalities increase in women from about age 30 with more pronounced effects in women aged over 35. The risk of preterm births and stillbirth increases from paternal

age 35 with more pronounced effects from age 40. Male fertility starts to decline at about age 45 and the risk of fathering a child with developmental problems including autism spectrum disorders increases after age 40.

6.1.4 Frontiers in Endocrinology 2019

"Advanced maternal age (AMA; >35 year) is associated with a decline in both ovarian reserve and oocyte competence".

6.1.5 American College of Obstetricians and Gynecologists 2023

"Women begin life with a fixed number of eggs in their ovaries. The number of eggs decreases as women get older. Also, the remaining eggs in older women are more likely to have abnormal chromosomes. And as women age, they are at higher risk of disorders that can affect fertility, such as uterine fibroids and endometriosis".

6.2 National Eligibility Criteria:

In view of the literature on ART treatments, and the risk of ART on mother and the unborn baby, couples are eligible under the following conditions, provided that treating doctor shall decide on further proceedings on ART.

6.2.4 Couples having a valid marriage certificate from a magistrate court / family court of the Maldives. Non-Maldivian couples shall provide originals and notarized marriage certificate from a registered law firm of the Maldives.

6.2.5 Investigations confirming fertility issues in spouses, sexual dysfunction and acquired conditions predisposing to diminished ovarian reserve and male infertility issues, and there is no chance of pregnancy with expectant management where assisted reproduction is the only effective treatment.

6.2.6 Both spouses consented for ART treatment and undertake necessary follow-up.

6.2.7 Women under 40 years who have not conceived after 1 year of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), offer 3 full cycles of IVF, with or without ICSI. If the woman reaches the age of 40 during treatment, complete the current full cycle but do not offer further cycles.

6.2.8 In women aged 40-42 years who have not conceived after 1 year of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), offer 1 full cycle of IVF, with or without ICSI, provided that the following 3 criteria are fulfilled:

i. They have never previously had IVF treatment
ii. There is no evidence of low ovarian reserve
iii. There has been a discussion of the additional implications of IVF and pregnancy at this age.

6.2.9 If the spouses meet the above criteria, clinicians at the facility shall ensure couples are educated on the reasons for clinical decision. The decisions shall be documented in patient record book.

7 RESPONSIBILITIES

7.1 The ART unit

7.1.4 The ART unit shall be responsible for the following and ensure:

i. All procedures, conditions and controls in this standard are followed at all times.
ii. Medical reports from a hospital/health facility licensed by Ministry of Health are obtained, showing diagnosis of the case and providing the ability to procreate and the permissibility of medical interventions to trat infertility. No medical interventions shall be performed to treat incurable infertility, such as azoospermia in males or premature ovarian failure in females.
iii. Medical records are kept in accordance with Regulation No. 2019/R-1070 (Regulation on Medical Records). And the unit shall comply with S.11 of the "Regulation on Medical Records" which states minimum information every document prepared by healthcare centre should include.
iv. Rules, internal policies and Standard Operating Procedures (SOPs) are followed by the staff at all times. Internal policies shall clearly state roles and responsibilities of individual staff.
v. Staff are sensitized to their consequences for breach of duty under the Act No. 13/2015 (Health Professionals Act).

vi. That grievance mechanism and issues lodged are remedied in accordance with applicable laws and regulations.

vii. Annual reports/surveillance stipulated in chapter 14 of this standard to QARD are reported.

viii. Couples are informed about the total cost of the procedure, risks, success and other possibilities of the procedure.

ix. Provisions in S. 38 (a) of the Act No. 29/2015 (Health Services Act) and S. 61 of the Regulation No. 2021/R-28 (Regulation on Operating Healthcare Centers), are available for general or public reference.

x. All necessary measures against the intentional and unintentional fault or negligence are investigated.

xi. Record of the names, academic qualifications and duties of their employees are maintained. They shall have the organizational structure that clarifies job structure and identifies the person in-charge.

xii. Procedures for methods of treatment and all the procedures are reviewed annually and have a management procedure for non-conformities relating to incidents, audits and inspection findings.

xiii. Ensure ART procedures are in accordance with Islamic Shariah.

7.1.5 The unit in-charge/treating physician

i. Supervise all stages of treatment, anticipating the occurrence of any complications and taking necessary measures to prevent them or initiate treatment when they occur, and delegating qualified replacement in his absence.

ii. Setting and annually reviewing, precise rules for the method of treatment and sample collection, preparation and receipt and precautions necessary to avoid hyperovulation induction, multiple pregnancies, complications and procedures for their treatment should they occur.

iii. Obtain proof of subsisting marriage before starting the procedure and keep a copy of all such documents in patient's file.

iv. Ensure presence of a chaperon when the husband and the wife is being examined.

v. Be fully responsible for all damages caused by a treatment error on their part, and shall be subject to provisions in Health Service act (29/2015) and Health Professional Act (13/2015) and other relevant laws and regulations.
vi. Document all information, data and procedures carried out and, record treatment courses, types and results with accuracy.
vii. Have the right to take embryo samples for examination or send them for specialist genetic examination within Maldives and out of country.
viii. Destroy unused embryos, sperms and specimens in the event of death or divorce of any spouse, within 5 days of informing divorce or death.
ix. Shall maintain patient treatment records.

7.1.6 The unit employees shall:

i. Ensure identity of the specimen during every stage of the procedure. Understand that they are responsible for their negligence, fault, or failure that results in the mixing or replacement of sperms, oocytes and embryos.
ii. Understand that negligence is subject to provisions in Act No. 13/2015 (Health Professionals Act).

7.2 The regulatory authority

As the regulatory authority QARD shall supervise and regulate functions of ART units. This includes;

i. Registration, licensing and service approval.
ii. Undertake all responsibilities assigned under this standard.
iii. Conducting oversight and inspection work through periodic annual inspection and surprise inspections on laboratories and treatment units to assess application of principles of good practice and quality standards and ensure compliance with standards and regulations.
iv. Ensure the facility destroys unused specimens in the event of death or divorce of any spouse.

v. Revoke or immediate suspension of license of the unit or individual in the event of proven negligence, misconduct or violation of laws and regulations and Islamic sharia.

7.3 The couple

i. Inform ART unit when death, dispute or divorce has occurred between couple within 24 hours.

ii. Understand terms and provisions stipulated in this standard and ART treatment in Islam.

iii. Obtain counselling and all information regarding ART treatment before consenting.

8 COUNSELING

All ART units shall keep couples informed about the decisions. The following information shall be included in couple counseling;

8.1 Counseling regarding ART from Islamic perspective

8.2 Diagnosis and management options.

8.3 Success and associated risks of ART treatment.

8.4 Proposed procedure and required investigations.

8.5 Risk of cycle cancellation due to no response or over response to ovarian stimulation.

8.6 Risk of multiple pregnancies and the associated morbidity to the mother and unborn child.

8.7 Woman with preexisting comorbidity, shall start treatment only after appropriate preconception counseling.

8.8 Other areas also to consider when providing counseling

i. Treatment cost

ii. Length of treatment

iii. Requirement of written consent from both spouses before every stage of treatment

iv. The option to revoke consent by either spouse at any point in treatment

v. The cessation of treatment and disposal of samples in case of death of a spouse

vi. The cessation of treatment in case of divorce or dispute between spouses, and disposal of samples if there is no continuation in marital status or if the spouses no longer want to resume treatment

vii. The option to resume treatment if both parties are willing to continue treatment following a reconciliation

viii. The grievance mechanism through which spouses can lodge complaints in the event of mishaps.

9 MEDICAL AND RELIGIOUS CONSIDERATIONS

Medical interventions may be carried out to treat infertility resulting from a treatable disease based on medical reports. All ART units MUST follow the following points.

9.1 Proof of existing marriage must be obtained before embarking on ART procedures.

9.2 An egg from wife may be collected who cannot conceive and fertilized with husband's sperm outside the uterus and then returned to the uterus again.

9.3 It is prohibited to fertilize a wife's egg with the husband's sperm after divorce or death, and the Obstetrician and Gynecologist shall stop the fertilization process and refrain from implanting eggs or transferring the sperm to the wife's uterus if the husband dies, dispute or a divorce has occurred between spouses. In such case the Obstetrician and Gynecologist shall not fulfill the wish of any or both of them to go on with the fertilization or artificial insemination. The unit shall ensure cessation of further proceedings when this occurs.

9.4 The fertilized egg shall not be implanted in another wife or another woman. No insemination shall take place with sperm other than husband's and no fertilization of an egg other than that of the wife shall take place.

9.5 All necessary actions shall take place to ensure husband's sperm is not mixed with sperm of other men, or the wife's egg with other women.

9.6 No more than 3 (three) embryos or zygotes shall be returned to the wife's womb in one course of an episode of embryo transfer with IVF or ICSI.

9.7 The transfer of reproductive organ or part is considered a prohibited manipulation of sex cells or genes. Any procedure to manipulate genetic characteristics are prohibited.

10 ETHICAL CONSIDERATIONS

The ART units shall be fully responsible for its work. The following MUST be taken into considerations during the entire treatment course.

10.1 The unit must observe absolute confidentiality in patient information, except where disclosure is required by law or pursuant to an order of court or any requirement of legal process, or where the Ministry orders disclosure of patent information for its purposes. Such disclosure does not require consent of the couple.

10.2 In other cases where disclosure of the information is required, prior approval of the spouse is required.

10.3 The Obstetrician shall inform the spouses all medical procedures in the treatment, risks involved, and the probability percentages of success and failure of the procedure.

10.4 The Unit shall ensure that the spouses are informed about their rights under relevant laws and regulations.

10.5 No medical or educational research on samples (sperms, eggs, zygotes, embryos) collected under this standard shall be conducted by the unit in violation of the Regulation No. 2019/R-1006 (Health Research Regulation). As required under this Regulation, before commencing any such research on the samples, the unit shall obtain prior written approval of the National Health Research Council and written consent of the people whose samples were taken.

10.6 An informed written consent shall be obtained from both spouses at all stages of treatment. informed consent in annex 4. The following are stages whereby informed consent shall be obtained from both spouses.

i. To undergo ART treatment
ii. Collection of samples or collection of female's egg and male's sperm
iii. Storage, handling, and transfer of samples

iv. Implantation and insemination procedure

v. Reconciliation between divorce or separated couples.

10.7 All the ART unit to have ways to address and compensate for any misconduct/negligence on their part.

11 COUPLE AND SAMPLE IDENTIFICATION

11.1 The ART unit shall have documents on policies and procedures stating how and when to determine the identity of the couple, sperm, oocyte and embryo, and who has the authority to do so.

11.2 Annual review of the process used for identifying couple and the specimen shall be carried out and documented.

11.3 The unit shall be responsible for the mixing or replacement of sperms, oocytes or embryo and shall be subjected to the provisions in Act no. 13/2015 (Health professionals act) and Act no. 29/2015 (Health service act) and other relevant laws and regulations.

11.4 At least 2 specialists/ technologist in the infertility treatment unit shall verify that the identity and medical record number of both spouses are identical when carrying out the insemination procedure. Follow section 11.12 of this standard on sample identification.

11.5 All ART units shall adopt an accurate system for organizing/retrieval of sperms, oocytes and embryos, ensure precautions are in place to avoid mixing or replacing them unintentionally or not.

11.6 The Obstetrician/unit shall be fully responsible for damages caused by mixing of or replacement of sperms, oocytes or embryos

11.7 The unit shall be responsible for damages caused by negligence on their part in any form and shall be subjected to the provisions in Act no. 13/2015 (Health professionals act) and Act no. 29/2015 (Health service act) and other relevant laws and regulations.

11.8 The treating Obstetrician shall ensure there is no suspicion of mixed sperms and eggs by confirming the identity during all stages of the procedure.

11.9 A critical work area contains only one person or couples' sperm, oocytes, embryos or tissues at a time. The area MUST be labelled with patient's identifiers as in section 11.13 of this standard.

11.10 Critical identification checks

11.10.4 The unit shall identify when critical identification checks should take place in the process where critical identification are crucial.

11.10.5 The following are critical identification points where critical identification checks MUST be performed.

i. Receiving semen sample
ii. Collecting oocyte
iii. Transferring sperm, eggs, or embryos between vessels.
iv. Inseminating (returning husbands' sperm and embryo to wifes' uterus)
v. Disposing of living sperm, oocyte, or embryos
vi. Receiving sperms, oocytes, embryos at the unit
vii. Sending sperm, oocyte, embryos out of the unit

11.11 Double checking

11.11.4 Double checking shall take place in every critical identification point

11.11.5 Double checking shall involve two independent checks. The checks shall be made by:

i. Laboratory technicians who performed the laboratory procedures and by a barcode system
ii. The second person may be the gynecologist who is performing the procedure.
iii. In receiving the semen sample the second person could be the male spouse.

11.11.6 There shall be a record of identification checks. This includes:

i. The process checked
ii. Date and time
iii. Full names, Designation and signature of the people performing the check

11.11.7 The unit shall maintain a register of all staff authorized to perform identification checks.

11.12 Sample identification

11.12.4 Sample identification shall include the following

i. Unique identifier of its parent/reference number

ii. Full name of the husband/wife

iii. Type of sample

iv. Date and time of sample collection

11.12.5 In manipulation operations, the embryo, not the person shall be given a unique number

11.12.6 The same patient identifiers need to be on paper during checking

11.12.7 The unit shall describe the process it uses to determine identity of the stored samples.

11.13 Patient identification

Patient shall be identified using the standard identifies listed below

11.13.4 Name of the patient

11.13.5 National Identification card number

11.13.6 Date of birth

11.13.7 Hospital number/unique identification number for the couple

11.14 Authority

11.14.4 The ART unit shall give every person performing a check the authority to check or stop the process if that person has any degree of uncertainty about identification.

11.15 Handling identity uncertainty

11.15.4 The in-charge of the unit shall have the highest authority when it comes to resolving disputes related to identity.

11.15.5 The unit shall have a written procedure/protocols for making decision on next step when a person performing a check is uncertain about the identification.

11.15.6 Uncertain samples shall never be used for any ART procedures.

11.16 Risk reduction

11.16.4 Periodic internal audits shall be conducted covering all steps in patient and sampling identification process.

11.16.5 All identification error or near-miss shall be documented and reported to the regulatory authorities. Root cause analysis is suggested to perform.

11.16.6 The unit shall have risk reduction plans in place and mitigate factors known to increase chances of misidentification.

12 DOCUMENTATION

12.1 The ART units shall maintain its records for lifelong and 6 years.

12.2 The following records shall be maintained in patient medical record books.

i. Patient demographics
ii. Obstetric and medical history
iii. Parental infertility diagnosis
iv. Clinical parameters of ART procedure
v. Information regarding resultant pregnancies and births.
vi. Identification of the patient/spouse
vii. Identification of the sample
viii. Types and amount of sample collected
ix. Number of collected eggs, and stored embryos
x. Number of collected eggs, resulted embryos and number of unsuccessful cycles per license embryologist per day
xi. Number of ICSI performed/ IMSI
xii. Assessment and investigations results
xiii. Progress notes

12.3 All ART units shall have written procedure on documentation and access control

12.4 The unit shall promptly comply with any request made by Ministry to obtain information with regard to treatment, patient information or any other record maintained by the unit.

12.5 Medical records should contain all essential details of the clients including but not limited to all demographic data, history (including past and present medical), cause of infertility if diagnosed earlier, new diagnosis if relevant, the treatment option(s), treatment carried out, outcome of treatment, follow-up and any other noteworthy point such as possible adverse reaction to drugs, etc must be recorded.

13 DATA REPORTING

13.1 All ART units shall maintain the following information and shall be reported to Ministry of Health annually and when requested. Annual surveillance (from start of January to end of December) includes the following:

i. Age of couples seeking ART treatment
ii. Total number of couples seeking fertility treatment
iii. Types of fertility disorders/conditions in couples and their total numbers
iv. Number of oocytes collected and preserved from each couple.
v. Number of preserved oocytes, sperm samples and embryos in the laboratory including name and identification of its parents/owner.
vi. Number of IVF cycles and resulted embryos and number of unsuccessful cycles
vii. Number of stored oocytes and number of stored embryos,
viii. Number of IVF cycles per licensed gynecologist
ix. number of ICSI cases performed per licensed embryologist per day,

13.2 The annual surveillance reports stipulated in 14.1 shall be reported to QARD before 10th of January every year. (Reports of the previous year)

13.3 All serious and untoward incidents associated with ART treatment MUST be reported to QARD immediately.

13.4 Record and report and submit data pertaining to reproductive health, as per schedule of Health Production Agency (HPA) reproduction health unit

14 ENFORCEMENT AND SANCTIONS

14.1 All ART units must comply with law, the terms and requirements of the standards, regulations and standard for healthcare facilities by the Ministry,

14.2 QARD may impose sanctions in relation to any breach of requirements under this standard and as per the Health Act, Ministry's regulations and standards for healthcare facilities.

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Annex 1 DESIGN AND FUNCTIONAL REQUIREMENTS

Infrastructure requirements

- Reception area
- Waiting room
- Administrative area and medical record room (in the unit/in hospital)
- Public toilets
- Consultation Room(s)
- Ultrasound Room(s)
- Sample collection room(s) with shower and toilet

Patient Procedural Area:

- Operating room for oocyte (egg) collection and re-implantation
- Recovery area
- Ante room for staff and patients

Laboratory Area:

- Laboratories (Embryology, IVF, ICSI, Andrology, Genetics)
- Cryopreservation facilities
- Gas Bottle Store

Support Area:

- Clean-up and disposal room
- Store rooms and sterile store

Functional Requirements

1. Reception area:
    a. This area provides the first point of contact for couples. This is area for couple registration and guidance to other services.
2. Waiting room:
    a. Area for couple and family. This area should have a calming and comfortable effect. The couple should be able to relax in privacy.
    b. Privacy for couples or gender segregated waiting area recommended due to the nature of the service and the procedures that the patient have to undergo.
3. Administrative Area / Record room:
    a. Computerized record keeping recommended as far as possible so that data is accessible retrospectively for analysis or when requested
    b. Meeting room
4. Public Toilets should be divided for gender separation
5. Consulting room:
    a. A room with privacy for interviewing and examining male and female independently is essential.
    b. Evaluation of infertility necessitates history taking of the most intimate sexual practices between the couples.
6. Ultrasound Room:
    a. The room must be equipped with an examination table and gynecological instruments for examining the female per vaginum, an appropriate ultrasonographic machine with a probe for transvaginal examination of the female and examination of the testes and excurrent male reproductive tract.
7. Sample collection rooms

    Collection rooms shall be a well-appointed room with privacy and appropriate environment located close to the laboratory. The facility shall be inhouse rather than having the patient collect sample and bring to the laboratory for analysis, as in the latter case semen quality and identity is likely to be compromised.
8. Patient procedural area:

a. Treatment room should have the necessary items to conduct close examination of the reproductive tract and sexual organs.
b. Adequate measures must be taken to ensure that history taking and examination are carried out in strict privacy, maintaining the dignity of the patients.
c. In case a male doctor examines a female patient, there must always be a female attendant present.
d. The sterile area shall have the operation theatre, a room for intrauterine transfer of sperm or embryos and an adjoining embryology laboratory. Strict entry control to anteroom for changing shall be practiced. Sterile area shall be airconditioned where fresh air filtered through an approved filtration system is circulated at an ambient temperature (22-25^{0}C).
e. Operation theatres shall have the following:
    i. A 2D ultrasound device for transvaginal and abdominal scan with availability of needle biopsy guideline on TV monitor for the purpose of oocyte retrieval.
    ii. Adjustable operation theatre table
    iii. Oocyte retrieval system with vacuum system and tube warmer attached to it to maintain the tubes at 37^{0}C throughout the procedure.
    iv. Availability of patient monitoring system and equipments for emergency resuscitation procedures.
    v. Room for staff change and toilet facilities.
    vi. Room for intrauterine transfer of embryo shall be a sterile area in direct communication with the sterile laboratory having an examination table on which the patient can be placed for carrying out the procedure

9. Laboratory area shall have the following:
    a) Minimum floor area requirement for this embryology laboratory is 100 square feet (9.29 sq. m) with minimum ceiling height between 9 to 11 feet (2.74-3.35 m) to accommodate the minimal equipments required for an embryology laboratory which are the incubator, micromanipulator, laminar flow, stereo microscope and ICSI manipulator.
    b) All workbenches should be purposed-built and of nontoxic surface. The ICSI micromanipulator should be preferably placed on anti-vibration work top.

c) Design and materials used in construction should be compatible with a high level of cleansing and disinfection.
d) Use of toxic chemicals, radioisotopes, aerosol and pest control substances shall not be permitted in the laboratory.
e) Use of strong-smelling personal hygiene products e.g., perfume, deodorant, hair spray, after shave lotion etc. shall not be permitted in the confines of the laboratory.
f) The paint for the laboratory should be lead free and odorless.
g) Foodstuff shall not be permitted in the laboratory area.
h) Incoming air should be ducted via ceiling mounted air conditioning system. The air should be filtered by HEPA filters to remove particulate matter.
i) If the laboratory and ART operation theatre are not adjacent to each other, portable incubators should be used for maintenance of gamete/embryo temperature at 37 °C and pH between 7.2 – 7.4 during transportation as required.
j) A separate area should be provided for record keeping, data entry, computer data storage and related administrative functions.
k) All laboratory environment parameters shall be documented and verified on daily basis and records maintained.
l) Toxic chemicals or radioisotopes are not permitted in the laboratory, and this includes toxic cleaning agents. Aerosols and pest control drugs are also not allowed. All laboratories must have Volatile Organic Compound (VOC) detectors. Paintings used in the laboratories should also be VOC free.
m) HEPA filters where required, positive and negative air pressure rooms where required.
n) Easy pathway for waste removal from the laboratories shall be available

Annex 2 LABORATORY STANDARDS

Embryology/IVF/ICSI laboratory

1. The laboratory must have adequate space to follow good laboratory practices and easy movement.
2. Shall be located away from out-patient clinic and with direct relationship to the operating room for oocyte collection and re-implantation.
3. A pass-through hatch from the laboratory to each operating room is recommended.
4. The following equipments must be available:
    a. Carbon dioxide (CO_2) incubator with emergency power back up and preferable alarm system. The alarm system should monitor both power cut and low and high temperature variations and percentage of CO_2. Provisions shall be made to access a back up incubator should the main incubator malfunction.
    b. Stereo microscope for oocyte identification with a minimum range of 60 times magnification
    c. Inverted microscope with micromanipulators for ICSI procedure should have 40 to 400 times magnification.
    d. Warming devices and mechanisms shall be in place to ensure proper maintenance of temperature at 37^0C. the pH between 7.2-7.4 for media, gametes and embryos during the various phase of all procedures must be ensured and documented.
    e. Where inhouse media preparation is practiced there shall be access to a pH meter and osmometer for media adjustments.
    f. Gas cylinders should be placed in a designated area. Gas supply to the incubators must be of suitable quality with mechanisms to ensure continuity of supply.
    g. Written protocols shall be in place such that treatment outcomes will be minimally compromised in the event of equipment malfunction.
    h.
    i. Laminar flow hood with arm table surface to carryout procedures with circulation filtered air to prevent contamination

j. Laser system with inverted microscope for assisted hatching and for embryo biopsy
k. 24-hour monitoring system
l. Laboratory refrigerator
m. Fyrite CO2 and O2 analyzer
n. All embryo laboratories should have backup power supply, stable temperature and humidity
o. Positive pressure room
p. Hepa filler air quality and filtered gas supply
q. Electrical pipettes
r. Variable pipettes
s. Equipment for freezing embryos in a programmed manner
t. Electronic witnessing system- either barcode or Radio-Frequency Identification (RFID) system.

Andrology laboratory:

1. Andrology laboratory performs evaluation, testing, preparation and storage of sperm specimen.
2. Shall be close to the semen collection room and IVF/ICSI rooms.
3. The following are equipments required:
    a. Light microscope for semen analysis
    b. Centrifuge
    c. Lamina flow hood
    d. Sperm counting chamber/automatic sperm analyzing unit
    e. Variable pipettes
    f. Mackler cells
    g. Laboratory refrigerator
    h. CO2 incubators
    i. Electrical pipetts

j. Variable pipettes
k. Fyrite analyzer (CO2 and O2 gas analyzer)

Cryopreservation room:

1. Must have decent space on the number of tanks. Facilities for cryopreservation will include a separate room for frozen reproductive cells (gametes, zygotes and embryo) in liquid nitrogen tanks. Nitrogen tanks should be stored in an enclosed space in case of nitrogen leakage.
2. Cryopreservation storage areas should be in close proximity to the laboratory areas, with controlled access.
3. A monitoring system is required for low levels of nitrogen in the storage tanks and for high levels of nitrogen in the air.
4. Strict protocols on the method of storage and specimen labelling are required.
5. Cryopreservation room must be secured with double locks
6. 24 hours monitoring system
7. The following equipments are required:
    a. Liquid N2 tanks
    b. Storage tanks
    c. Alarming system
    d. LN2 cryo safety kit Negative pressure rooms
    e. Hepa filter air quality

Genetics laboratory

Laboratory equipment will require emergency power, temperature monitoring alarms. The construction of the laboratory should ensure aseptic and optimal handling of reproductive tissues during all stages of the process. Air conditioning for the laboratory will include HEPA filters, controlled humidity (20%) and access-controlled temperature (22-24 degrees).

1. Laboratory benches and storage units
2. Laminar flow IVF workstation cabinets
3. Benchtop microscope

4. Laboratory refrigerator
5. Handwashing facilities

Equipment specifications

The following equipments must be available in laboratories

a) Incubators with remote alarm system and emergency back-up electric power system. Appropriate temperature and gas content of incubators shall be checked daily and records maintained. Carbon dioxide shall be monitored via infrared or other gas analysis method and not by digital display alone.
b) Microscopes that are suitable for egg retrieval sterilization, semen analysis, egg and sperm treatment and microscopic treatment
c) Single use materials shall be used during procedures that involves exposure to body fluids
d) General supplies and tools for laboratories, glassware, sterilizers and refrigerators
e) pH meter and osmotic pressure gauge in order to monitor the culture media
f) Labelling of all equipments and chemicals used in laboratory.
g) Sterilizing area: if the ART unit is a stand-alone building, dedicated sterilizing facilities will be required

Annex 3 Standard Operating Procedures

The unit shall have the following standard operating procedures

1. Collection, handling and labelling, culture, preparation and storage of human gametes (sperms and oocytes)
2. Laboratory examinations on the specimens
3. Equipment specification and calibration
4. Sample identification, handling, transfer and authorization
5. Infection prevention and control
6. Invasive and non-invasive procedures to be caried out in the laboratories
7. Documentation
    1. Roles and responsibilities of all levels of staff
    2. Procedure for record keeping
    3. Risk reduction and management policy
    4. Patient and sample identification policy
    5. Grievance protocol

Annex 4 Informed consent

Informed Consent template for IVF / IUI/ ICSI/ IMSI treatment

ACKNOWLEDGEMENT OF INFORMED CONSENT AND AUTHORIZATION

1. Information

Mr **(name of the husband)** and Mrs **(name of the wife)** acknowledge that we, the undersigned, are voluntarily participating, as a married couple as husband and wife with the doctor **(name of the specialist)** in the **(name of the unit)** Fertility Center and that we will acknowledge our parentage of any child born to us through this technique. We acknowledge that for the procedure, eggs of the wife and sperm of the husband will be used.

We understand that even though the insemination/ transfer of eggs may be repeated as often as recommended by the doctor, there is no guarantee or assurance that the pregnancy or it will result in a live birth.

We acknowledge that the fertilized and unfertilized female eggs and male sperm will be stored in the facility for treatment purpose until the couple is divorced or deceased.

We have also been told that the outcome of pregnancy may not be the same as those of general pregnant population, for example in respect of abortion, multiple pregnancies, anomalies or complications of pregnancy or delivery.

The procedure (s) carried out does (do) not ensures a positive result. The success rate (the delivery of a live born infant) of IUI/IVF/ICSI/IMSI varies and depend on many factors. Some of the factors are: the age of the woman, the type of fertility medication used (if any) and the number of previous cycles of treatment and others.

We acknowledge that we have read and fully understand the information sheet and this written material; that we have considered treatment alternatives, and that all of our questions concerning

the treatment have been fully answered and explained to our satisfaction. Hence we acknowledge this is a well-informed decision.

We are aware that there are other centers in the area that offer IVF treatment and we have freely chosen to have our treatment at (name of the facility).

By participating in the program, we accept the responsibilities, conditions and risks involved as set out in this document and as explained to us by the (name of the facility) staff. In addition, we consent to the IVF/ IUI/ ICSI/ IMSI and procedures described in this document and explained by (name of the doctor)

We acknowledge and agree that our acceptance into treatment and our continued participation is within the sole discretion of the (name of the facility).

We understand that, should this IVF cycle could be unsuccessful, it may be determined that further treatment with IVF/IUI/ICSI/IMSI may not be appropriate. We also understand that we are financially responsible for any medical expenses associated with IVF treatment that are not covered by our insurance policy.

We understand that bodily tissues or fluids remaining will be discarded according to National standard and program procedures.

We also additionally acknowledge that if we are separated or divorced or if anyone of us is deceased, we have an obligation to inform to this (name of the facility) fertility Centre immediately.

2. Endorsement by the ART unit

I/we have personally explained to (**name of husband)** and (**name of wife)**

the details and implications of their signing this consent/approval from, and made to sure to the extent humanly possible that they understand these details and implications.

We understand that medical information concerning our treatment may be analyzed and could be used in a publication without any identifying information, and we authorize such analysis and publication. Furthermore, the agencies charged with publishing these statistics may randomly audit the **(name of the facility)** and may have access to and review the identifiable information in my medical record in order to verify the data that the Program is required to report.

We the undersigned, consent to undergo IVF/IUI/ICSI/IMSI treatment. We have read the Consent for IVF/IUI/ICSI/IMSI treatment and understand the purpose, risks and benefits of the IVF/IUI/ICSI/IMSI process, and we have been given the opportunity to ask questions, which have been answered to our satisfaction by the staff of the **(name of the facility).**

We also additionally acknowledge that if the couple was separated or divorced or if anyone of them is deceased, we have an obligation to inform QARD of ministry of health within 3 working days.

3. Authorization by the unit

a) Name and identity (National ID/passport/PMR/TMR, practicing license number) of the person conducting the procedure/authorizing on behalf of the unit
b) Name, registration and operating license number of the unit
c) Hospital/unit stamp
d) Date and time
e) Signature

4. Authorization by couple

Authorization shall have the following

a) Name and National Identity card number of the husband and wife
b) Date, time and signature of husband and wife
c) Two (2) witnesses
    i. Name and national identity card number of the witnesses
    ii. Date, time and signature

NOTE: This consent form is to be always attached with the information sheet provided by each facility.

**********END OF DOCUMENT**********