وزارة الصحة
Ministry of Health

Amendment of the Implementing Regulations of the Law of Fertilization, Utero-Fetal and Infertility Treatment Units

وزارة الصحة
Ministry of Health

In the Name of Allah, the Most Gracious, the Most Merciful

Royal Decree No. M/76

Dated: 21/11/1424H.

We, Fahd bin Abdulaziz Al Saud,

The King of the Kingdom of Saudi Arabia

Pursuant to Article (70) of the Basic Law of Governance, promulgated by Royal Decree No. (A/90) dated 27/8/1412H; Article (20) of the Law of the Council of Ministers promulgated by Royal Decree No. (A/13) dated 3/3/1414H; and

Articles (17) and (18) of the Shura Council Law promulgated by Royal Decree No. (A/91) dated 27/8/1412H; and

Having perused the Shura Council Resolution No. (1/1) dated 3/3/1424H; and The Council of Ministers' Resolution No. (260) dated 23/9/1424H,

Have decreed the following:

First: Approval of the Law of Fertilization, Utero-Fetal and Infertility Treatment Units, as attached.

Second: HH the Deputy Prime Minister, and the ministers, each in their respective capacity, shall implement this Decree.

Fahd bin Abdulaziz

[Signature]

وزارة الصحة
Ministry of Health

Kingdom of Saudi Arabia
Council of Ministers

Secretariat General

In the Name of Allah, the Most Gracious, the Most Merciful

Resolution No. 260

Dated 23/9/1424H

The Council of Ministries,

Having perused the correspondence received from the Office of the Presidency of the Council of Ministers No. 7/B/18476 dated 18/4/1424H, including the letter of HE the Minister of Health No. 6202/1/S/11 dated 5/9/1419H regarding the draft Law of Fertilization, Utero-Fetal and Infertility Treatment Units; The aforementioned draft Law; Minutes No. (281) dated 18/8/1421H, No. (187) dated 19/4/1422H, and No. (247) dated 24/7/1424H prepared at the Bureau of Experts; Shura Council Resolution No. (1/1) dated 3/3/1424H; and The recommendations of the General Committee of the Council of Ministers No. (388), dated 3/8/1424H, and No. (430), dated 2/9/1424H,

Hereby decides as follows:

To approve of the Law of Fertilization, Utero-Fetal and Infertility Treatment Units, as attached. A draft Royal Decree has been made to this effect as attached hereto.

[Signature]

Prime Minister

وزارة الصحة
Ministry of Health

Kingdom of Saudi Arabia
Ministry of Health

In the Name of Allah, the Most Gracious, the Most Merciful

No.: 280/1/12

Dated 6/1/1426H

Attachments:

Ministerial Resolution

No. / / Dated / /14 H.

The Minister of Health

Pursuant to the powers vested in him; and

Having perused the Royal Decree No. M/76 dated 21/11/1434H, approving the Law of Fertilization, Utero-Fetal and Infertility Treatment Units;

The Council of Ministers' Resolution No. (260) dated 23/9/1424H, approving the Law of Fertilization, Utero-Fetal and Infertility Treatment Units; and

Article (40) of the Law of Fertilization, Utero-Fetal and Infertility Treatment Units, which stipulates that the Minister of Health shall issue the Implementing Regulations of this Law and in accordance with the requirements of the public interest,

Hereby decides as follows:

Article (1): Approval of the Implementing Regulations of the Law of Fertilization, Utero-Fetal and Infertility Treatment Units, as attached to this Resolution.

Article (2): This Resolution shall be published in the Official Gazette and shall come into force one hundred and twenty days after the date of publication thereof.

[Signature]

Minister of Health

Hamad bin Abdullah Al-Manea

PART I:

General Provisions

Article (1):

The following words and expressions, wherever they appear in this Law, shall have the meanings assigned to them hereunder, unless the context requires otherwise:

1. Minister: The Minister of Health.
2. Ministry: The Ministry of Health.
3. Fertilization, Utero-Fetal and Infertility Treatment Unit: Every governmental or private medical unit specialized in fertilization, utero-fetal procedures and infertility treatment, whether it is independent or affiliated with a health institution.
4. Supervisory Committee: The committee supervising fertilization, utero-fetal procedures and infertility treatment.
5. Fertilization: The fusion of haploid gametes, egg and sperm, to form the diploid zygote. This happens when the sperm penetrates the outer membrane of the egg.
6. Infertility: The inability to conceive after 12 months of unprotected sexual intercourse under an existing marital relationship.
7. Sperm: A man's sperm.
8. Zygote: The egg when it is fertilized by the husband's sperm.
9. Embryo: The fertilized egg (the zygote) undergoes cell divisions in the pre-organogenesis stage, that is, during the first two weeks.
10. Ovulation induction: Administration of drugs to induce multiple ovulation.
11. Artificial insemination: The technique in which semen with living sperms is collected from the husband, concentrated in the lab and then introduced into the wife's uterus.
12. In Vitro Fertilization (IVF): The process by which eggs (oocytes) are retrieved from the 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.
13. Intracytoplasmic sperm injection (ICSI): The technique in which a single sperm is injected directly into the cytoplasm of a mature oocyte in the laboratory, preserving it under certain conditions, and then returning the embryos to the wife's uterus, after ensuring proper cell division.
14. Micromanipulations: Microscopic procedures performed on eggs, sperms or embryos to perform specific analyzes, take a cell to monitor its nature and study chromosomes in it, etc.

Regulation:

A.1/1 In addition to the definitions provided by the Law, the following words and expressions, wherever they appear in these Regulations, shall have the meanings assigned to them unless the context requires otherwise:

1. Reproduction Techniques: Every procedure that deals with sex cells or reproductive organs.
2. General Anesthesia: Anesthesia that requires assisted breathing (intubation).

Article (2):

Medical intervention may be carried out to treat sterility resulting from low fertility or a treatable disease based on a medical report. Fertilization procedures shall not be performed to treat incurable infertility.

Regulation:

A.2/1 R: Medical reports from centers or units licensed by the Ministry shall be obtained, showing a diagnosis of the case and proving the ability to procreate and the permissibility of medical intervention to treat infertility. No medical intervention shall be performed to treat incurable infertility, such as azoospermia in males or ovarian insufficiency in females.

A.2/2 R: An egg may be collected from a wife who cannot conceive, fertilized with her husband's sperm outside the uterus, and then returned to the uterus again.

Article (3):

In carrying out their activities, Fertilization, Utero-Fetal and Infertility Treatment Units shall abide by the fatwas issued by the Council of Senior Scholars in the Kingdom.

Regulation:

A.3/1 The Supervisory Committee shall circulate all the relevant fatwas issued by the Council of Senior Scholars in the Kingdom to the Fertilization, Utero-Fetal and Infertility Treatment Units.

A.3/2 Each Fertilization, Utero-Fetal and Infertility Treatment Unit shall hand over a copy of the fatwa issued by the Council of Senior Scholars in the Kingdom in both Arabic and English to all its employees while keeping a copy of the fatwa at the Unit in a special file for fatwas.

A.3/3 All workers in the Fertilization, Utero-Fetal and Infertility Treatment Units shall read, understand and abide by the fatwas issued by the Council of Senior Scholars in the Kingdom.

Article (4):

Before proceeding with the treatment, evidence of subsisting marriage shall be required. It is prohibited to fertilize a wife's egg with the husband's sperm after divorce or death, and the physician shall, when this occurs, stop the fertilization process.

Regulation:

A.4/1 It is required to provide proof of subsisting marriage by legal documents before starting treatment. The Unit shall keep a copy of such documents in the case file.

A.4/2 The physician shall stop the fertilization process and immediately refrain from implanting the fertilized egg or transferring the sperm to the wife's uterus if the husband dies - unless there is a written fatwa issued by the Council of Senior Scholars in the Kingdom - or a divorce or dispute has occurred between the spouses. In such cases, the physician shall not fulfill the wish of any or both of them to go on with the fertilization or artificial insemination.

A.4/3 Subject to the exception set out in the previous Article of these Regulations, the physician shall destroy the sperm and eggs, both fertilized and unfertilized, if the husband dies or divorce has taken place.

Article (5):

A fertilized egg shall not be implanted in the womb of another wife or another woman. Likewise, no insemination shall take place with sperm other than the husband's, and no fertilization of an egg other than the wife's shall take place.

Regulation:

A.5/1 All necessary precautions, meticulousness and attention shall be taken to ensure that the husband's sperm is not mixed with the sperm of other men, or the wife's eggs are not mixed with those of other women.

A.5/2 No more than three embryos or zygotes shall be returned to the wife's womb in one course of treatment with IVF or ICSI.

Article (6):

An explicit written consent on the treatment method shall be obtained from the spouses, after familiarizing them with all treatment procedures, risks and possible outcomes.

Regulation:

A.6/1 The treating physician shall inform the spouses of all medical procedures for their treatment, the risks involved, and the percentage or probability of the success or failure of these procedures. The physician shall hand over to both spouses information booklets related to each stage of treatment.

A.6/2 The spouses shall be informed of the total cost of treatment before starting it.

A.6/3 An explicit written consent shall be obtained from both spouses regarding the method of treatment to which they have been introduced.

Article (7):

At least two specialists in the Fertilization, Utero-Fetal and Infertility Treatment Unit shall verify that the identity and medical record number of both spouses are identical when collecting samples, carrying out fertilization and transferring zygotes and embryos.

Regulation:

A.7/1 Fertilization, Utero-Fetal and Infertility Treatment Units shall ensure that there is no suspicion of mixed sperms and eggs by confirming that the identity and medical record number of both spouses are identical during all stages of treatment.

Article (8):

No manipulation of sex cells or genes may take place, except for the treatment of hereditary or genetic diseases that may affect embryos and can be treated with gene therapy, provided that such an action is approved by the Supervisory Committee before proceeding.

Regulation:

A.8/1 The transfer of reproductive organs or part thereof is considered a prohibited manipulation of sex cells or genes. This includes interventions on sex cells or genes through micromanipulations that result in modification or change in the genetic characteristics.

A.8/2 An exception to the prohibition set out in the previous article of these Regulations is when the intervention is aimed to treat hereditary or genetic diseases that may affect embryos and can be treated with gene therapy, provided that such an action is approved by the Supervisory Committee before proceeding.

A.8/3 No reproductive organs or any part thereof may be transferred from one person to another without the consent of both parties and the prior approval of the Supervisory Committee.

Article (9):

The Fertilization, Utero-Fetal and Infertility Treatment Units shall adopt an accurate system for organizing sperms, eggs, zygotes and embryos, ensuring the utmost care and precaution to avoid mixing or replacing them whether inadvertently or not. The Implementing Regulations of this Law shall determine the rules governing this.

Regulation:

A.9/1 R. Evidence of the implementation and review of the policies and procedures stating how and when to determine the identity of the patient, embryos and sperm, and who has the authority to do so, shall be submitted, documenting the same during all stages of medical procedures.

A.9/2 R. Evidence of the implementation and review of the process adopted for tracking embryos and sperm during all treatment procedures and in the case of transfer as well shall be provided.

A.9/3 R. Evidence of the regular annual review of the process used for identifying embryos and sperm shall be provided.

A.9/4 R. Reference shall be made to the Supervisory Committee's Technical Bulletin "Patient and Sample Identification" (Annex No. 2).

Article (10):

The physician shall be fully responsible for all damages caused by a treatment error on their part.

Regulation:

A.10/1 The treating physician shall be fully responsible for all damages caused by a treatment error on their part, and shall be subject to the provisions set out in the Law of Practicing Healthcare Professions in this regard.

Article (11):

The physician, assistant and/or technician shall be responsible for their negligence, fault, or failure that results in the mixing or replacement of sperms, eggs, zygotes or embryos.

Regulation:

A.11/1 The assistant and/or the technician shall be responsible for their negligence, fault, or failure that results in the mixing or replacement of sperms, eggs, zygotes or embryos, within their respective areas of competence, and shall be subject to the provisions set out in the Law of Practicing Healthcare Professions in this regard.

Article (12):

The Fertilization, Utero-Fetal and Infertility Treatment Unit shall observe absolute confidentiality regarding patient information. It shall not allow anyone to access such information except where necessary, subject to the approval of the Supervisory Committee or the judicial authorities.

Regulation:

A.12/1 The Fertilization, Utero-Fetal and Infertility Treatment Unit shall observe absolute confidentiality with regard to patient information. It shall not allow anyone to access it except:

A. With the prior written consent of the spouses.

B. Where necessary, subject to the prior approval of the Supervisory Committee or the judicial authorities.

Article (13):

Subject to the provisions of the relevant laws, Fertilization, Utero-Fetal and Infertility Treatment Units may not conduct research on sperm, eggs, zygotes and embryos, except after obtaining the approval of the persons from whom samples were taken as well as the approval of the Supervisory Committee.

Regulation:

A.13/1 The prior and scientifically justified approval of the Supervisory Committee shall be obtained before conducting research on sperm, eggs, zygotes and embryos. The purpose of such research shall be clear.

A.13/2 When conducting research, the controls of the National Committee of Bioethics (NCBE) and internationally recognized mechanisms of scientific research shall be observed. The provisions and treatment controls of these Regulations shall be also observed.

Article (14):

Fertilization, Utero-Fetal and Infertility Treatment Units shall submit an annual report to the Supervisory Committee, including comprehensive statistics and a statement of the cases that have been examined and treated.

Regulation:

A.14/1 All Fertilization, Utero-Fetal and Infertility Treatment Units shall submit an annual report to the Supervisory Committee, including comprehensive statistics of all their activities along with a complete statement of the cases that have been treated, documented with file numbers.

PART II

Supervisory Committee

Article (15):

A. A committee shall be formed to supervise fertilization, utero-fetal procedures and infertility treatment by a decision of the Minister as follows:

1.	MoH Undersecretary or his representative	as Chairman
2.	MoH Director General of Medical Licenses	as a member
3.	A faculty member from one of the faculties of medicine at Saudi universities with a degree not lower than an Associate Professor in Obstetrics Gynecology and Infertility Treatment to be designated by the Minister of Higher Education	as a member
4.	A consultant neonatologist to be designated by the Minister	as a member
5.	An andrology and infertility consultant to be designated by the Minister	as a member
6.	A Sharia advisor to be designated by the Minister of Justice	as a member
7.	A legal consultant to be designated by the Minister	as a member

B. The Committee shall be headquartered in the Ministry in Riyadh.

C. The remuneration of the Committee's Chairman and members shall be determined by the Council of Ministers.

Regulation:

A.15/1 The remuneration of the Committee's Chairman and members shall be determined by a decision of the Council of Ministers based on the proposal of the Minister.

A.15/2 The designation of members, as provided for in paragraphs (3 and 6) means the prior agreement with the Minister on the nominated person.

Article (16):

The term of membership in this Committee is three years, renewable. If any member of the Committee is unable to continue to serve on the Committee for any reason, a replacement shall be appointed in the same manner.

Regulation:

A.16/1 Committee membership may be renewed by a decision of the Minister.

A.16/2 If a member is absent from the Committee's meetings for two successive times or three separate times in one year, or if unable to regularly attend the Committee's meetings due to their work conditions or for any other reason, the member shall be relieved from their duties and a replacement shall be appointed in the same manner.

A.16/3 The Minister shall nominate an alternate member to replace the main member in their absence.

Article (17):

The Supervisory Committee shall convene in the presence of at least two-thirds of its members. Its meetings shall be held at the invitation of its Chairman on a regular basis, or whenever the need arises. The Committee's decisions shall be issued by a majority of the votes of the members present, and the Minister shall approve those decisions. A grievance against the Committee's decision may be submitted to the Board of Grievances within sixty days from the date of its notification.

Regulation:

A.17/1 The Committee shall convene in the presence of at least two-thirds of its members, and shall hold its meetings at the invitation of its Chairman on a regular basis, at least one meeting every three months, or whenever the need arises. The Committee's decisions shall be issued by a majority of the votes of the members present, and in the event of a tie, the Committee Chairman shall have the casting vote. The Minister shall approve the decisions rendered by the Committee. A grievance against the Committee's decision may be submitted to the Board of Grievances within sixty days from the date of its notification.

A.17/2 An invitation to attend the periodic and non-periodic meetings of the Committee shall be sent to members and they shall be provided with the meeting agenda.

A.17/3 The General Directorate of Medical Licenses shall undertake the following:

a) The Committee's secretariat shall be responsible for preparing for the Committee's meetings and drawing up agendas.

b) Carrying out the technical and administrative secretarial work of the Committee and recording the minutes of its meetings, recommendations and decisions.

c) Coordinating and following up the Committee's work and the implementation of its decisions, and taking care of the procedures for disbursing members' remuneration in cooperation with the relevant authorities.

Article (18):

The Supervisory Committee shall have the competence to:

A. Recommend the licensing of the Fertilization, Utero-Fetal and Infertility Treatment Units and determine their activity level, after ensuring that the licensing conditions have been met;

B. Study fertilization, utero-fetal and infertility treatment methods and techniques, define their conditions, and approve them;

C. Consider requests for medical experiments or research in the field of fertilization, utero-fetal procedures and infertility treatment;

D. Form technical committees, whose remuneration shall be determined by the Council of Ministers, to ensure that the licensing conditions are met, examine reports and complaints, carry out oversight work on these Units, and handle any issue the Supervisory Committee deems appropriate; and

E. Perform any other task assigned to it under this Law or its Implementing Regulations. The Committee may seek the assistance of experts, scientific societies or centers, or specialized bodies for advice. The Implementing Regulations of this Law determine the work procedures and rules of this Committee.

Regulation:

A.18/1 The tasks of the technical committee set out in Paragraph (D), which is called "The Fertilization, Utero-Fetal and Infertility Treatment Unit Accreditation Committee," shall undertake the following:

a) Ensure that the licensing conditions are met according to the Unit Classification and express an opinion on the qualification of workers in the Fertilization, Utero-Fetal and Infertility Treatment Units;

b) Conduct oversight and inspection work through periodic annual visits and surprise inspections on clinics, laboratories and centers, in order to follow up the application of the principles of good practice and quality standards and ensure their compliance with the provisions of these Regulations;

c) Examine the reports, complaints and issues referred to it by the Supervisory Committee; and

d) Express an opinion on the price lists of medical services provided by the Fertilization, Utero-Fetal and Infertility Treatment Units.

A.18/2 The Supervisory Committee shall determine the costs and expenses of the Accreditation Committee, as well as the remuneration of the experts and specialists hired by the Accreditation Committee.

A.18/3 The costs of such services shall be collected from the units, centers and clinics requesting a license.

A.18/4 The Committee shall submit its proposals and recommendations on the expenses, costs, and remuneration of hired experts and specialized agencies, and how to provide and collect them, to the Minister who shall in turn submit the same to the Council of Ministers for approval.

A.18/5 The Minister, or whomever he authorizes, shall issue a decision granting a license to the Fertilization, Utero-Fetal and Infertility Treatment Unit, and determining its level of activity based on the Committee's recommendation.

A.18/6 The Committee's decisions shall be implemented from the date they are approved by the Minister.

PART III:

Requirements for Licensing Fertilization, Utero-Fetal and Infertility Treatment Units

Article (19):

No Fertilization, Utero-Fetal and Infertility Treatment Unit may be established or operated except after obtaining a license from the Ministry, based on the recommendation of the Supervisory Committee.

Regulation:

A.19/1 No Fertilization, Utero-Fetal and Infertility Treatment Unit may be established or operated except after obtaining a license from the Ministry, based on the recommendation of the Supervisory Committee to whose Secretariat General the license application is submitted. Where no special provision is made in this Law, the Fertilization, Utero-Fetal and Infertility Treatment Units shall be required to fulfill the licensing conditions set out in the Law of Private Health Institutions and Law of Practicing Healthcare Professions and their implementing regulations.

A19/2 The Secretariat of the Supervisory Committee at the General Directorate of Medical Licenses and Pharmaceutical Affairs shall ensure that all the licensing conditions and requirements stipulated in this Law and its Implementing Regulations are fulfilled before referring the license application to the Accreditation Committee, which shall in turn study the application to submit it to the Committee.

A.19/3 The license applicant shall pay the prescribed fees as stipulated in the Law of Private Health Institutions, prior to the issuance of the license.

Article (20):

Subject to the provisions of the Law of Practicing Human Medicine and Dentistry and the Law of Private Health Institutions and any rules issued thereunder, the Fertilization, Utero-Fetal and Infertility Treatment Units shall be licensed according to the following levels and under the conditions specified in the Implementing Regulations of this Law:

Level 1: Treatment of infertility with injectable ovulation induction drugs.

Level II: Treatment of infertility with IVF.

Level III: Treatment of infertility with IVF, ICSI and micromanipulations.

The Implementing Regulations of this Law determine the qualifications of supervising physicians and other technical physicians working at each of these levels.

Regulation:

A.20/1 Subject to the provisions of the Law of Practicing Healthcare Professions and Law of Private Health Institutions, and any rules issued thereunder, the Fertilization, Utero-Fetal and Infertility Treatment Units shall be licensed according to the following levels, taking into account that the license granted for a higher level includes lower levels:

A. For Level-I licensing, i.e. treatment of infertility with ovulation induction drugs through intravenous, intramuscular or subcutaneous injection, the following conditions are required to be satisfied:

1. The supervisor in charge must be a physician who has the Saudi Fellowship in Obstetrics and Gynecology or its equivalent, and is classified by the Saudi Commission for Health Specialties as a consultant of obstetrics and gynecology. Experience in infertility treatment and the use of vaginal

ultrasound devices is required. However, if experience in the use of vaginal ultrasound devices is not available, a vaginal ultrasonography specialist is required to closely monitor ovulation induction.

B. For Level-II licensing, i.e. treatment of infertility with IVF, the following conditions are required to be satisfied:

1. The supervisor in charge must be a physician who has the Saudi Fellowship in Obstetrics and Gynecology or its equivalent, and is classified by the Saudi Commission for Health Specialties as a consultant of obstetrics and gynecology. The Supervisor must possess at least two years of experience in the area of infertility treatment, and no less than one year of experience in using vaginal ultrasound devices.
2. Assistant physicians must have a degree in obstetrics and gynecology, not lower than a specialist degree, equivalent to those of the Saudi Commission for Health Specialties.
3. Technologists and technicians must have a bachelor's degree or its equivalent in science or laboratories, or a technical diploma in laboratories, provided that it is equivalent to those of the Saudi Commission for Health Specialties, and that they have conducted at least fifty tests in the Unit's activity during the training period.

C. For Level-III licensing, i.e. treatment of infertility with IVF, ICSI and micromanipulations, the following conditions are required to be satisfied:

1. The supervisor in charge must be a physician who has the Saudi Fellowship in Infertility and Surgery or its equivalent, and is classified by the Saudi Commission as a consultant of obstetrics and gynecology/ infertility and IVF.
2. The supervisor shall work in the Unit on a full-time basis.
3. Other physicians working in the Unit must be physicians who have the Saudi Fellowship in Infertility and Surgery or its equivalent, and are classified by the Saudi Commission as consultants of obstetrics and gynecology/infertility and IVF.

D. For licensing fertilization, utero-fetal and infertility treatment laboratories, the following conditions are required to be satisfied:

1. The area of the laboratory and its various sections shall be as explained and detailed in Article (21) and its interpretation, so as to ensure a convenient and secure work environment.
2. All medical devices necessary for operating the laboratory shall be provided as described in Article (21) and its interpretation.
3. The laboratory air filtration mechanism shall be in accordance with the laboratory standards and as described in Article (21) and its interpretation.
4. The alarms and television monitoring systems in the laboratory shall be in accordance with the laboratory standards and as described in Article (21) and its interpretation.
5. The number of laboratory technicians shall be proportional to the volume of work in the Unit. There shall be at least two qualified persons who can perform all technical services, provided that one of them is classified by the Saudi Commission for Health Specialties as a laboratory technician.
6. Embryo laboratory technicians must have a bachelor's degree from a recognized university, so that their main specialty is science or laboratories, or hold a technical diploma in laboratories. They must possess documented training experience in IVF laboratories for a period of one year for those with a bachelor's degree and two years for those with a technical diploma.

Article (21):

All necessary equipment and facilities for each level, according to the specifications determined by the Implementing Regulations of this Law, must be made available in every Fertilization, Utero-Fetal and Infertility Treatment Unit.

Regulation:

A.21/1 R: For Level-I licensing, the following equipment must be available:

1. The basic equipment of women's clinics as per the specifications of the Ministry of Health.
2. An ultrasound device, equipped with a vaginal probe, to measure the size and number of eggs.

A.21/2 R: For Level-II licensing, the following equipment shall be available:

1. Complete equipment for the clinic as per the specifications of the Ministry of Health.
2. An ultrasound device, equipped with a vaginal probe.
3. A laboratory that contains a centrifuge, a microscope, and a sperm counting device.
4. A clear and accurate system and regulations for collecting and analyzing samples, and for confirming the name and identity of sample owners.
5. Systems for keeping records and information and entering data in an accurate, clear and auditable way.
6. 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.

A.21/3 R: For Level-III licensing, the following equipment must be available:

1. Complete equipment for the clinic as per the specifications of the Ministry of Health.
2. An ultrasound device, equipped with a vaginal probe.
3. A laboratory that meets the requirements of the Unit.
4. A clear and accurate system and regulations for collecting and analyzing samples, and for confirming the name and identity of sample owners.
5. Systems for keeping records and information and entering data in an accurate, clear and auditable way.
6. 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.

A.21/4 R: All Fertilization, Utero-Fetal and Infertility Treatment Units shall have the following devices:

1. An ultrasound device with a vaginal probe, needle guide and egg collection needle.
2. Pulse monitoring device, blood pressure monitor, ECG, oxygen supply, airway management device, and artificial respiration bag.
3. General sterilization and dressing supplies as per the specifications of the Ministry of Health.
4. General supplies necessary for obtaining intravenous access (venipuncture).
5. An operating bed and adequate lighting fit for the purpose, with leg supports in lithotomy position.
6. Trolley bed to move patients to the recovery room.

A.21/5 R: The following facilities must be available in all Fertilization, Utero-Fetal and Infertility Treatment Units:

1. Public reception area.
2. A waiting room for women and another for men.
3. Separate toilet rooms for women and men.
4. Examination room.

5. Egg extraction and operating room, equipped with an air filtration system.
6. Recovery room.
7. Ultrasound room.
8. Patient record keeping area.

A.21/6 R: For licensing fertilization, utero-fetal and infertility treatment laboratories, the equipment described in Annex (1) must be available.

A.21/7 R: The Unit has the right to take embryo samples for examination or to send them to specialist genetic testing examination laboratories inside or outside the Kingdom. It should be noted that genetic testing sampling is an optional and non-obligatory service to be provided in all Units.

A.21/8 R: The embryo laboratory shall have an adequate space to guarantee working in convenient and safe conditions.

The laboratory design shall be also appropriate to the size of the procedures that are carried out in it, as follows:

a) The lab shall be in a safe, non-crowded area. It shall also be completely isolated from the andrology laboratory (that is, allocating a corner from another laboratory is not considered appropriate unless it is separated by a wall). Toxic chemicals or radioisotopes are not permitted in the laboratory, and this includes toxic cleaning agents. Aerosols and pest control drugs are not allowed.

b) A separate (walled) office shall be provided for record-keeping, data entry, and other related administrative tasks. A computer shall be also provided for data collection.

c) The materials used in building the lab shall be appropriate for the nature of its work. The same applies to ventilation and cleaning methods. Moreover, floors shall be also made of materials that are easy to wash and disinfect.

A.21/9 R: The following tools and equipment shall be made available, as a minimum, in all laboratories of Fertilization, Utero-Fetal and Infertility Treatment Units:

1. Incubator(s) with a remote alarm system and emergency back-up electric power. The appropriate temperature and gas content of incubators shall be checked daily before they are first opened for patients' use. Carbon dioxide shall be monitored via infrared or other independent gas analysis methods, and not by digital display alone.
2. Microscopes that are suitable for egg retrieval, sterilization, semen analysis, egg and sperm treatment, and microscopic treatment.
3. Adequate heating devices to maintain the temperature and pH of the culture media, eggs and embryos during the different stages of the procedure.
4. Only single-use materials (e.g. tissue culture plasticware) shall be used whenever possible during the steps that involve exposure to body tissues and fluids.
5. General supplies and tools for laboratories, such as glassware, sterilizers, and a refrigerator, proportionate to the size of the laboratory.
6. All laboratories shall have the capacity to use a pH meter and an osmotic pressure gauge in order to monitor the culture media regularly.
7. Laboratory personnel shall ensure that the materials that may come in contact with eggs or embryos are not toxic, using appropriate bioassay methods. This includes, but is not limited to, extraction supplies, transfer vials, plasticware and glassware, culture media and protein source.
8. Labels shall be placed on all chemical elements and reagents in the laboratories, indicating the dates of receipt, opening and expiry, where appropriate.

Article (22):

The license granted to the Fertilization, Utero-Fetal and Infertility Treatment Units for a specific higher level includes lowers levels.

Article (23):

The Fertilization, Utero-Fetal and Infertility Treatment Units shall announce the licensed level together with the name of the respective Unit on its internal and external announcement boards and publications.

Regulation:

A.23/1 Each Fertilization, Utero-Fetal and Infertility Treatment Unit shall announce its licensed level inside and outside the Unit on prominent announcement boards that are visible to all visitors. The said announcement shall include sufficient clarification of the licensed level.

Article (24):

A fertilization, utero-fetal and infertility laboratory may only be licensed within a licensed Fertilization Unit.

Regulation:

A.24/1 An application for licensing a fertilization, utero-fetal and infertility laboratory shall be submitted in the name of the licensed Unit. It is required that the laboratory be affiliated with and linked to the Unit and located within its divisions, and no separate license may be issued for the laboratory.

Article (25):

Reproduction techniques that require laparoscopy or general anesthesia are only permissible for in-hospital fertility units or one-day surgery units.

Article (26):

The medical supervisor in charge of the Fertilization, Utero-Fetal and Infertility Treatment Unit shall be fully responsible for the work of the Unit. The Implementing Regulations of this Law specify the duties of the supervisor at each level, as well as the duties of assistant physicians, technologists and technicians.

Regulation:

A.26/1 R: The supervisor in charge of the Fertilization, Utero-Fetal and Infertility Treatment Unit, at all levels, shall be responsible for the following:

a) Ensuring that all procedures, conditions and controls mentioned in this Law and its Implementing Regulations are applied.

b) Supervising the Unit, following up all stages of treatment, anticipating the occurrence of any complications and taking the necessary measures to prevent them or initiate treatment when they occur, and delegating a qualified replacement physician in his absence.

c) Setting, and annually reviewing, precise rules for the methods of treatment and sample collection, preparation and receipt, whether sperm or egg samples, and the precautions necessary to avoid hyperovulation induction, multiple pregnancies, complications and procedures for their treatment should they occur.

d) Documenting all information, data and procedures carried out by the Unit, recording treatment courses, types and results with accuracy, clarity and honesty, keeping them for a period of at least ten years and submitting them to the competent authorities when requested for review.

e) Determining job names and responsibilities of all workers of the Unit, including physicians, technicians and others, subject to the provisions of this Law and its Implementing Regulations, and keeping complete records of their names, qualifications and licenses.

f) Appointing a person to be responsible for receiving and carefully examining patients' complaints, recording the results of examining them and taking the necessary action to address them.

g) Taking the necessary measures against any intentional or unintentional fault or negligence.

h) Enabling the Accreditation Committee's representatives in charge of inspection and control of these Units to carry out their duties.

A.26/2 R: The Unit's supervisor at the first level shall be responsible for the following:

1. Directly supervising treatment, determining doses, following up treatment stages, and anticipating the occurrence of hyperovulation induction, multiple pregnancies and complications, taking the necessary measures to prevent them and initiating treatment should they occur.
2. Explaining to patients the treatment method and possible complications.
3. Ensuring the availability of specialists who perform vaginal ultrasound examinations with the necessary efficiency, or conducting such examinations themselves.

A.26/3 R:

a) The Unit's supervisor at the second level shall be responsible for the following:

1. Carrying out general supervision over every procedure that is carried out in the laboratory, including semen analysis or preparation and result validation, ensuring that no mixing has occurred.
2. Taking responsibility for any error that may occur due to the Unit's failure to implement safety standards. Apart from that, technicians shall be responsible for any fault, negligence or failure that causes the mixing or replacement of sperms, eggs, zygotes or embryos.
3. Developing an integrated system for collecting and receiving samples, confirming the name and identity of sample owners, and delivering and using a sample only to return it to the womb of the wife undergoing treatment.
4. Keeping records accurately and honestly, and submitting the same to official authorities when requested for review.
5. Confirming the presence of a valid marital contract.
6. Setting rules and instructions explaining the ovulation induction method and the necessary precautions to avoid or limit the occurrence of complications, such as hyperovulation induction or multiple pregnancies, and procedures for their treatment should they occur.
7. Drawing up a set of internal work rules that include the method and steps for preparing the semen sample intended for use in artificial insemination.
8. Ensuring that the semen sample to be prepared has been collected at the Unit's premises.
9. Determining the precision tools used, the source of media, and the appropriate treatment conditions.
10. Ensuring that the devices and equipment necessary for this purpose are available and sterilized.
11. Explaining the method, cost, possible complications and success rate of the treatment, and obtaining the spouses' signatures to this effect.

b) Physicians and assistants carry out licensed infertility treatment work under the supervision of the supervisor in charge of the Unit. The supervisor in charge shall be also consulted when any difficulties or problems arise as prevalent in the medical profession, and shall determine the responsibilities and tasks of each of these physicians and assistants.

c) Technicians and specialists, at the second-level Units, process the semen sample, analyze it and prepare it for artificial insemination under the supervision of the laboratory supervisor. They report the results and follow the Unit's detailed rules to confirm the identity and medical record number of

spouses accurately to prevent any mixing between samples. They do whatever is necessary when having any suspicions and inform the Unit's supervisor should such incidents happen. The supervisor determines the responsibilities and tasks of each of them.

A.26/4 R (A): The Unit's supervisor at the third level shall be responsible for the following:

1. Supervising the operation of the Unit and directly following up all staff working in the Unit.
2. Clearly laying down, and annually reviewing, the regulations for treatment procedures.
3. Taking responsibility for any error that may occur due to the Unit's failure to implement safety standards. Apart from that, technicians shall be responsible for any fault, negligence or failure that causes the mixing or replacement of sperms, eggs, zygotes or embryos.
4. Preparing a written explanation of the method, cost, possible complications and success or failure rate of the treatment, and obtaining the signature of the spouses before the start of treatment.
5. Following up the occurrence of complications and providing the necessary treatment for them.
6. Documenting all procedures performed by the Unit, as follows:
    a) Recording all patient information accurately and confidentially.
    b) Preparing the Unit's paperwork and accurately clarifying treatment courses, types and results, and keeping them for a period of not less than ten years and submitting them to the competent authority when requested.
    c) Recording pregnancy results that are confirmed by ultrasound as a positive "clinical pregnancy" and not relying on the chemical pregnancy results in urine or blood or considering them in the result calculations.
7. Developing a mechanism for receiving and examining patients' complaints, and preparing a record for each complaint to prove the actions taken and the results reached.
8. Keeping complete records of the names, qualifications and licenses of the Unit's employees.
9. Being present, or assigning their representative to be present, when inspections are conducted by the competent authorities.
10. Ensuring that those in charge of microscopic treatment have demonstrated previous proficiency in performing those procedures, and have experience of not less than one year of training in an advanced infertility treatment center.
11. Determining the cases that require treatment with ICSI according to the appropriate conditions and criteria.
12. Determining the precision tools used, the source of media, and the appropriate treatment conditions.

(B) If there is a need to do a testicular biopsy, this shall be done by a urologist consultant or a consultant in the specialty of gynecology, obstetrics, infertility and IVF, authorized to perform such procedures.

(C) The internal regulations of the Unit shall specify the cases that require external treatment or ICSI, treatment method and sample collection technique.

(D) No more than three embryos may be transferred to the wife's womb in all cases without exception. If there are surplus embryos, they can be preserved by cryopreservation.

(E) In the event that surplus embryos are preserved, the written consent of both spouses shall be obtained, and the preservation period shall be determined.

A.26/5 R: Physicians and others specialists carry out licensed infertility treatment work under the supervision of the supervisor in charge of the Unit. The supervisor in charge shall be also consulted when any difficulties or problems arise as prevalent in the medical profession, and shall determine the responsibilities and tasks of each of these physicians and specialists.

Article (27):

Fertilization, Utero-Fetal and Infertility Treatment Units shall document all information, data and procedures carried out by them, record treatment courses, types and results with accuracy, clarity and honesty, keep them for a period of at least ten years and submit them to the competent authorities when requested for review.

Regulation:

A.27/1 All Fertilization, Utero-Fetal and Infertility Treatment Units shall lay down rules, instructions and internal regulations that clarify, in written and publicly disclosed documents, the work procedures and steps and specify the responsibilities of the concerned person.

A.27/2 All Fertilization, Utero-Fetal and Infertility Treatment Units shall keep records of the names, academic qualifications and duties of their employees, specialists and workers. They shall also set up an organizational structure that clarifies the job structure and identifies the person in charge. Such records and information shall be submitted to the official authorities when requested for review.

PART IV

Violation Review Committee

Article (28):

A. A Committee shall be formed to look into violations of the provisions of this Law and the Implementing Regulations thereof, impose appropriate penalties in accordance with this Law, except for prison sentences, and determine the amount of compensation for damages to the private right holders. The Committee shall be comprised of the following:

1. A judge of no lower rank than a judge (A) to be designated by the Minister of Justice — as Chairman
2. A faculty member from one of the faculties of medicine at Saudi universities, with a degree not lower than an Associate Professor in Obstetrics and Gynecology, to be designated by the Minister of Higher Education — as a member
3. An obstetrics and gynecology consultant, to be designated by the Minister, — as a member
4. An andrology and infertility consultant, to be designated by the Minister, — as a member
5. A consultant neonatologist, to be designated by the Minister — as a member
6. A legal consultant, to be designated by the Minister — as a member

B. The Committee shall be headquartered in the Ministry in Riyadh. Similar committees may be established in the regions of the Kingdom by a decision of the Minister.

C. The remuneration of the Committee's Chairman and members shall be determined by the Council of Ministers.

D. The Implementing Regulations of this Law determine the rules and work procedures of the Committee.

E. If the Committee deems that the violation requires a prison sentence, it shall refer the case to the Board of Grievances for consideration.

Regulation:

A.28/1 The remuneration of the Committee's Chairman and members shall be determined by the Council of Ministers based on the proposal of the Minister.

A.28/2 The designation of members, as provided for in paragraphs (1 and 2) of this Article, means the prior agreement with the Minister on the nominated person.

The Committee shall have a secretary to be appointed by the Minister. The secretary shall prepare for the Committee's meetings, ensure the completion of their work, and implement the relevant procedures and recommendations.

Article (29):

The term of membership in this Committee is three years, renewable. If any member of the Committee is unable to continue to serve on the Committee for any reason, a replacement shall be appointed in the same manner.

Regulation:

A.29/1 R: Committee membership may be renewed by a decision of the Minister.

A.29/2 R: If a member is absent from the Committee's meetings for two successive times or three separate times in one year, or if unable to regularly attend the Committee's meetings due to their work conditions or for any other reason, the member shall be relieved from their duties and a replacement shall be appointed in the same manner.

A.29/3 R: The Minister shall nominate an alternate member to replace the main member in their absence.

Article (30):

The Committee shall convene in the presence of all its members, at the invitation of its Chairman whenever the need arises. The Committee's decisions shall be issued by a majority of the votes of the members, provided that the Chairman is among them. In the event of a tie, the Committee Chairman shall have the casting vote. If no decision can be issued in this way, the case shall be referred to the Board of Grievances for consideration.

Regulation:

A.30/1 R: The Committee shall hold its sessions at the Committee's headquarters in the Ministry's Office or at the health district's headquarters in which it is decided to establish other committees.

A.30/2 R: In the event that the Committee cannot be convened with the presence of all its members, or if its decisions cannot be issued by a majority of the members provided that the Committee Chairman is among them, the Committee shall refer the case to the Board of Grievances for consideration.

A.30/3R: The secretariat of the Committee shall undertake the following tasks:

1. Coordinate with the Public Prosecutor regarding the procedures for referring cases that the Committee decides to refer to the Board of Grievances.
2. Coordinate with the Public Prosecutor to enable the latter to review the documents, investigation minutes and proceedings related to the cases presented before the Committee, and notify the Public Prosecutor of the dates of the Committee's sessions and the cases presented to it.
3. Keep the documents, papers, and investigation minutes, along with the relevant administrative decisions.
4. Invite Committee members at least ten days before the date of the meeting.
5. Coordinate with the relevant authorities regarding the nomination or replacement of Committee members.
6. Carry out all the Committee's technical and administrative secretarial work.
7. Implement the Committee's decisions.
8. Coordinate, upon the Minister's directive, with the Public Prosecution Office to nominate the Public Prosecution's representative before the Violation Review Committee investigating the violations of the Law of Fertilization, Utero-Fetal and Infertility Treatment Units. The Minister shall issue a decision appointing the said representative as Public Prosecutor before the Committee.
9. Notify involved parties of the Committee's decision within a maximum period of thirty days from the date of the decision, with documenting the date of their notification of the decision.
10. Coordinate with the Medical Licensing Department to collect the fees of publishing the penalty decision in the event that the violator refuses to pay those fees.

A.30/4 R: Where no special provision is made in these Regulations, the procedures stipulated in Article (36) of the Implementing Regulations of the Law of Practicing Healthcare Professions pertaining to cases brought before the Forensic Medical Committee shall be followed.

Article (31):

The Public Prosecution is represented before the Committee by a member of the Bureau of Investigation and Prosecution.

Regulation:

A.31/1 R: The Committee's Secretariat shall coordinate, upon the Minister's directive, with the Public Prosecution Office to nominate the Public Prosecution's representative before the Violation Review Committee investigating the violations of the Law of Fertilization, Utero-Fetal and Infertility Treatment Units. The Minister

shall issue a decision appointing the said representative as Public Prosecutor before the Committee.

A.31/2 R: The Committee's Secretariat shall coordinate with the Public Prosecutor to enable the latter to review the documents, investigation minutes and proceedings related to the cases presented before the Committee, and notify the Public Prosecutor of the dates of the Committee's sessions and the cases presented to it.

A.31/3 R: The Bureau of Investigation and Prosecution shall nominate an alternative to replace the Public Prosecutor in his absence.

PART V

Penalties

Article (32):

Without prejudice to any more severe penalty stipulated in other laws, one or more of the following penalties shall be imposed:

a) A fine of not less than two hundred thousand riyals and not more than five hundred thousand riyals.
b) Imprisonment for a period not exceeding five years.
c) Revocation of professional license.

On anyone who commits any of the following violations:

a) Practicing infertility treatment procedures without a license or within a level other than the licensed one.
b) Injecting sperm or embryos into a woman from a person other than her husband.
c) Injecting sperm or embryos after the termination of the marital relationship.
d) Transferring a woman's zygotes or embryos to the womb of another woman.
e) Deceiving patients or not applying sound medical principles to the method of treatment with intent to blackmail or exploit them.
f) Manipulating cells or genetics without prior approval from the Supervisory Committee.
g) Transferring reproductive organs.

Article (33):

Without prejudice to any more severe penalty stipulated in other laws, and with the exception of the violations stipulated in Article (32) of this Law, any person who is proven to have violated any of the provisions of this Law or its Implementing Regulations shall be punished with one or more of the following penalties:

a) Warning.
b) A fine of not less than twenty thousand riyals and not more than two hundred thousand riyals.
c) Imprisonment for a period not exceeding two years.
d) Revocation of the professional license.

Article (34):

In the case of flagrante delicto or the availability of evidence likely to secure conviction of the violation, the Minister may temporarily suspend the professional license until the Violation Review Committee's decision on the violations stipulated in Article (28) of this Law is issued. Nevertheless, if such temporary suspension is likely to cause harm to the patients, the Minister shall take whatever is necessary to ensure that patients continue to receive their treatment needs. The parties issued with the suspension decision may appeal against it to the Board of Grievances within thirty days of being notified of it.

Regulation:

A.34/1 R: The Minister of Health shall issue a decision to temporarily suspend the professional license in the case of flagrante delicto or when there is evidence likely to secure conviction of the violation.

A.34/2 R: A party issued with a decision to temporarily suspend their professional license may appeal against this decision before the Board of Grievances within thirty days from the date of notification of the decision.

A.34/3 R: The Minister of Health shall take appropriate measures to ensure that patients continue to receive their treatment needs in the event that the temporary suspension would cause harm to them.

Article (35):

A grievance against the penalty decision may be submitted to the Board of Grievances within sixty days from the date of its notification to the person against whom it was issued.

Regulation:

A.35/1R: The Committee's Secretariat shall notify involved parties of the Committee's decision within a maximum period of thirty days from the date of the decision, with documenting the date of their notification of the decision.

Article (36):

The Minister may order the implementation of the decision issued to revoke or temporarily suspend the professional license from the date of its issuance. The immediate implementation of the decision shall not prevent submitting a grievance against it before the Board of Grievances, noting that the submission of such grievance does not result in stopping the immediate implementation of the decision.

Regulation:

A.36/1 R: The Minister may order the immediate implementation of the Committee's decision to revoke or temporarily suspend the professional license from the date of its issuance.

A.36/2 R: A grievance may be lodged with the Board of Grievances against the immediate implementation of the decision to revoke or temporarily suspend the professional license.

A.36/3 R: Submission of a grievance against the immediate implementation of the decision to revoke or temporarily suspend the professional license shall not result in stopping the immediate implementation of the decision.

Article (37):

In the event that the professional license is revoked, no new license application may be considered before the expiration of a period of three years from the date of the revocation decision.

Regulation:

A.37/1 R: A new license application may be submitted after at least three years have passed from the date of the professional license revocation decision.

A.37/2 R: Submission of a new license application means that the old license is deemed non-existent and has no effect.

Article (38):

The final penalty decision may include publishing the decision at the violator's expense in not more than three local newspapers, at least one of which is issued at the violator's residence. If there is no newspaper in the area, then the decision shall be published in the newspaper issued in the nearest area.

Regulation:

A.38/1 R: The final penalty decision may be published in three local newspapers at most, one of which is issued in the place of residence of the violator, or in the newspaper issued in the nearest area in the event that no newspapers are issued in the area in which the violator resides.

A.38/2 R: The violator shall bear the costs of publishing the penalty decision.

A.38/3 R: The Committee's Secretariat shall coordinate with the Medical Licensing Department to collect the fees of publishing the penalty decision in the event that the violator refuses to pay those fees.

PART VI

Final Provisions

Article (39):

Where no special provision is made in this Law, the Fertilization, Utero-Fetal and Infertility Treatment Units shall be subject to the Law of Practicing Healthcare Professions, the Law of Private Health Institutions, and any other relevant laws.

Article (40):

The Minister shall issue the Implementing Regulations of this Law within one hundred and twenty days from the date of the publication thereof. These Implementing Regulations shall be published in the Official Gazette.

Article (41):

This Law shall be published in the Official Gazette, and shall come into force one hundred and twenty days after the date of publication thereof. The Fertilization, Utero-Fetal and Infertility Treatment Units existing at the time of the issuance of this Law shall be required to meet the necessary conditions and requirements and rectify their position within a period of one hundred and twenty days from the date of its coming into force. After this period has passed, the case of the respective Unit shall be presented to the Supervisory Committee to consider the continuation of its license.

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Requirements for Licensing Fertilization, Utero-Fetal and Infertility Treatment Units (Annex 1)

Embryology laboratory:

- The embryology laboratory must have adequate space to follow good laboratory practice a minimum 25 m2
- The Essential equipment for the embryology laboratory commonly used:
  - Carbon dioxide incubator, a minimum of two is recommended
  - Laminar flow hood with warm table surface to carry out procedures with circulation filtered air to prevent contamination
  - Stereo microscope for oocytes identification
  - Inverted microscope with micromanipulators for ICSI procedures
  - A Laser system with inverted microscopes for assisted hatching and for Embryo biopsy (optional)
  - 24 hours Monitoring system
  - Refrigerator
  - CO2 Analyzer
  - PH Meter
  - All embryo laboratories should have back up power supply
  - Positive pressure room
  - Hepa filter Air quality

Andrology Lab:

- Should be close to the semen collection room
- The essential equipment for the andrology lab commonly used:
  - Light microscope for semen analysis
  - Centrifuge
  - Lamina flow hood
  - Sperm counting chamber

Cryopreservation Room:

- Must have a decent space depending on the numbers of the tanks
- Negative pressure room
- Hepa filter air quality
- Cryopreservation room must be secured with double locks
- 24 hours monitoring system
- The essential equipment for the cryopreservation room:
  - Liquid N2 Tank
  - Storage tanks
  - Alarming system
  - LN2 Cryo safety kit

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Technical Bulletin (Annex 2)

Patient and Sample Identification

Through the Technical Bulletin, the Supervisory Committee aims to assist the Fertilization, Utero-Fetal and Infertility Treatment Units with enhancing the quality of their service to patients. The Technical Bulletin is an informative communication, offering advice and guidance, to all Units and the Accreditation Committees concerned with licensing these Units.

Introduction

The Supervisory Committee aims to help Units instill concepts of patient and sample identification and principles that Units can use in setting up their own operations.

The Supervisory Committee formed a working group of specialists to review and summarize the following:

1. Patient and sample identification guidelines from other countries or organizations.
2. General problems and solutions associated with identification checks, especially in the health sector.
3. Steps taken to reduce identification errors in non-Unit areas of specialties (e.g. WHO Surgical Safety Checklist).

Summary Statement:

Units shall adhere to strict and effective standards for accurate identification of patients, sperm, eggs, embryos and reproductive tissues.

These guidelines are primarily adopted when sperm, eggs, embryos and tissues are used or stored to help parents conceive a child.

I Critical Work Area (CWA) in the Unit

1. A critical work area contains only one person's or couple's sperm, oocytes, embryos or tissue at a time. The critical work area shall be labelled with the patient's identifiers, which could be the labelling of the vessels themselves.
2. The Unit shall define critical work areas and how they are used.
3. Carefully defining critical work areas is a key to preventing sample cross-over. Examples include:
    - An area where the semen sample is received and where all the tools necessary for a single sperm preparation is located.
    - An area containing a microscope and tools used to inseminate eggs.
    - Egg extraction room and an adjacent embryology workstation in the case of oocyte collection or embryo transfer.
4. Critical work areas shall be clear before use. Critical work areas are only safe if they are totally cleared of samples, tubes, pipettes, paperwork, etc. between procedures.

II Critical Identification Point (CIP):

1. Units shall identify and document the critical identification points when dealing with samples upon their arrival to the Unit, changing vessels, changing identity, or leaving the Unit.
2. Critical identification points include those when:
    - Collecting oocytes
    - Receiving a semen sample from a patient who has produced it
    - Collecting reproductive tissues
    - Inseminating eggs
    - Transferring sperm, eggs, embryos or tissue between vessels (e.g. in all steps followed in sperm preparation,

embryo culture, and sperm, oocyte, embryo and reproductive tissue freezing)

- Inseminating a woman (returning the husband's sperm to the wife's uterus)
- Disposing of living sperm, oocytes, embryos, or reproductive tissue
- Receiving sperm, oocytes, embryos or reproductive tissue at the Unit
- Sending sperm, oocytes, embryos or reproductive tissue out of the Unit

1. The Unit shall specify when identification checks should take place within the process. The time and number of checks shall ensure that any possible error would be detected.
2. Generally, checks shall occur upon the arrival of samples, vessels and records in the critical work area, but before any change to the vessels within which the samples arrive (i.e. if what goes into a critical work area is correct, then what comes out must be correct).
3. Checking shall occur before an irreversible error may occur. That is, checking shall be done before adding sperm to oocytes in IVF.
4. Checking may be done after all the steps in sperm preparation have been completed by checking all the vessels in the critical work area. This does not prevent errors, but detects an error before the sperm is used for insemination. When checking is done after completing a process, the Unit shall ensure that there is no way an error could be unidentified.

III Double-Checking:

1. Double-checking shall take place at every critical identification point.
2. Double-checking shall involve two independent checks. The checks shall be made by:
   a) The laboratory technician who performed the laboratory procedures and another person or an automated system designed to identify samples (e.g. barcode).
   b) The second person may be a patient (e.g. when receiving a semen sample, inseminating eggs, or transferring embryos to the wife's uterus).
3. Identification checks have up to five dimensions:
   a) People bringing or receiving samples
   b) Samples themselves (e.g. sperm, oocytes, embryos, and reproductive tissues)
   c) Laboratory vessels (e.g. Petri dishes, tubes, and pipettes)
   d) Laboratory procedure (e.g. insemination, embryo transfer, and tool disposal)
   e) Written instructions (e.g. patient's consent, treatment plan, application)
4. Scientific opinions differ as to whether double-checking should be shared (e.g. read out aloud) or not (e.g. read silently). The advantage of reading aloud is that it involves two senses, sight and hearing, while the advantage of reading silently is that the second checker is not influenced by the first checker.

Medicine generally uses reading aloud (e.g. before surgery and giving medications) so the working group suggests that this approach should be used as well.

5. Double-checking is the minimum preventive measure that shall be followed; it can be reassuring to involve the patient as a third person, for instance at embryo transfer. Identification checks shall be recorded at the time they are done.
6. The person responsible for the procedure shall conduct an identity check before performing the procedure, and record the check upon completion of the procedure. Thus, the record covers both the check and the completion of the procedure.
7. The person doing the second check shall perform the second check before the procedure, and record the check at that time.
8. There shall be a record of identification checks. The record shall include:

- The process checked
- Date and time
- Signatures of the persons performing the check

9. The Unit shall maintain a register of the signatures of staff authorized to perform identification checks.
10. Identification checking records must be a part of the person's medical record.

IV Cases Where Single Checking Is Permitted:

1. Single checking is permitted when there is only one sample (sperm, oocytes, embryos or reproductive tissue) being processed in the same laboratory over the same period of time (e.g. when there is only one sperm sample is prepared to be used for insemination before receiving the next sample in the laboratory).
2. A Unit shall conduct a risk analysis and document the circumstances when single checking is permitted.
3. It is recommended that single checking is only performed when the circumstances for single checking are met, and when a second person is not available to perform an independent second check.

V Patient's Sample Identifiers:

1. Patient's sample identification shall normally include the following identifiers:
   a) Full name
   b) Date of birth
   c) Civil registry number
2. In manipulation operations, the embryo, and not the person, shall be given a unique identifier.
3. The same key identifiers need to be on paper during checking.
4. Where there is insufficient space for the three identifiers (e.g. on a Petri dish), two identifiers may be used, one of which shall be the Unit's unique identifier:

Example: Embryo culture dish:

- Name
- Unit's unique identifier for the person or couple

5. Three identifiers shall be used for long-term stored vessels.
6. Two identifiers may be used for vessels used for less than 7 days duration (e.g. sperm preparation or fresh embryo culture).
7. The Unit shall describe the process it uses for determining the identity of stored samples before this bulletin was introduced, to determine whether the sample identification process is weaker than that described in the bulletin.

VI Labelling Lab Vessels:

1. Units shall minimize pre-labelling vessels.
2. Pre-labelling is widely used in fertilization Units where lab vessels need to be equilibrated or set up for a particular patient in advance. However, pre-labelling is often done where it is not needed, such as when giving containers for bringing semen to the lab.

VII People Identification:

1. 1. When identifying a person during the treatment stages, the Unit's staff shall ask the person about their full name, date of birth, and civil registry number.

VIII Training:

1. People performing checks shall be trained so that they are familiar with the Unit's procedures. Their training shall be documented and recorded if they are not registered health professionals.

2. The person performing the second identity check must understand what laboratory procedure is taking place, since the check covers both the identity of the person or sample, and the instruction or procedure performed.

IX Authority:

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

XHandling Identification Uncertainty:

1. The Unit shall have a written process for making decisions on what to do next when a person performing a check has any degree of uncertainty about identification.
2. It is strongly recommended that a third person, preferably more senior, be involved in resolving any identification uncertainty.

XI Risk Reduction:

1. Internal audit shall cover all steps in the patient and sampling identification processes.
2. Every identification error or near-miss shall be recorded by the Unit's quality system. A Root Cause Analysis (RCA) is suggested to be performed.
3. The Unit shall have risk control plans to identify and mitigate factors known to increase the chance of misidentification. Risk control plans shall cover:

Guidelines on staff workload, including:

a) Maximum working hours than can be spent without a break, and the nature of the break (daily break), maximum working hours in a day, and maximum days worked in a row.

b) Interruptions.

c) Recognition of staff tiredness or other factors that may impair concentration.

d) Last minute changes to scheduling of procedures.

e) Preparing risk control plans helps identify potential risks, and to find proactive solutions.

f) Units shall perform a risk assessment before changing an existing identification process.

g) Units shall determine the level of training needed when changing a patient or sample identification process used in the Unit, and document that training in writing in the Unit's records.

h) The Unit shall have a written contingency plan that describes what should be done when identification systems used in the Unit break down or are unavailable.

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Summary

1. Clearly determine the critical work areas.
2. Check that the CWA is clear of any lab tools before starting the subsequent lab procedure.
3. Double check everything coming into the CWA at all times.
4. Double check every change in the identity of persons or samples.
5. Check:
   - Patient
   - Sample
   - Laboratory tools
   - Laboratory procedure to be performed
   - Instructions
6. When performing an identification check, the following shall be observed:
   - Having complete focus during the checking process
   - Searching for discrepancies
   - Signing