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*Original Article*

# Evaluation of medical equipment of the infertility treatment centers in North western of Libya

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## Abstract

Background Cell culture, particularly in vitro fertilization (IVF) and intracytoplasmic sperm injection (ICSI) are both of which assisted reproductive technology (ART) approaches that are most frequently utilized to treat infertility around the world. **Objective** Highlight the differences and similarities in instruments and equipment in ART laboratories that govern their success, limitations, and potential differences between laboratories by identifying the facilities of laboratories to improve outcomes of ICSI and IVF techniques in clinical centers on the western coast of Libya. **Method:** descriptive study, comparison of five (5) assisted reproduction laboratories instrument and equipment parameters using the same quality-control application in clinical centers on the western coast of Libya.**Result**: Among the seven clinical centers specializing in the diagnosis and treatment of infertility that were contacted, four infertility treatment centers and the Medical Research Center (MRC) provided a response. The MRC and four clinical centres had good laboratory facilities for ICSI and IVF techniques compared to Jordan ART laboratory facilities.**Conclusion**: This study highlights the imperative of enhancing laboratory infrastructure to support optimal implementation of ICSI and IVF procedures**.**

**Keyword:** ICSI, IVF, Instruments, Equipment, laboratory, Infertility, Libya

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## Introduction

Cell culture is an important aspect in the field of medicine and science, particularly in assisted reproductive technology (ART) laboratories, which are integral to assisted reproductive medical practices. In these laboratories, proactive efforts are made to obtain laboratory and scientific updates and advance the science involved in clinical studies and research whenever possible. The aim of ART laboratories is to improve the quality of their services and increase the success rate of treatment courses. To achieve these expectations, a quality control system is implemented, which includes establishing procedures and maintaining quality standards [1]. ART procedures include in vitro fertilization (IVF) and intracytoplasmic sperm injection (ICSI). These laboratories process human eggs, sperm, and embryos with the purpose of achieving pregnancy [2, 3, 4, 5, 6, 7].

The ideal workflow is based on standard guidelines for in vitro cultured cells used in IVF procedures [8]. Various factors influence the results, such as the laboratory environment, including the avoidance and detection of microbiological contaminants, the composition of the culture media, oxygen levels, temperature, and pH. These factors can affect the phenotype and development of human embryos conceived through IVF [9].

International Organization for Standardization (ISO) standards play a crucial role in ensuring quality, safety, and reliability in various industries and scientific fields. In infertility laboratories, ISO standards are vital in maintaining excellence, security, and consistency in assisted reproductive techniques. Following these standards, such as ISO 17025, which ensures the competence and technical proficiency of laboratories conducting tests and calibrations, is essential for accurate analyses and assessments in IVF and ICSI procedures [10]. ISO 9001 promotes a comprehensive approach to quality management in organizations, including IVF and ICSI laboratories, leading to improved internal processes, customer satisfaction, and overall efficiency [11].

It's important to note that although ISO 15189 is a general standard applicable to medical laboratories, it can be implemented in IVF and ICSI laboratories to ensure quality management and competence requirements specific to these specialized areas. [12] ISO 20387 focuses on general requirements for biobanks to ensure the quality, safety, and traceability of biological material. In IVF laboratories, where the handling of reproductive cells is essential, compliance is crucial to maintaining the integrity of biological samples. [13]

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the other hand, ISO 10993 is essential for evaluating the biocompatibility of medical devices and is relevant to the development and use of devices in IVF and ICSI procedures, ensuring the safety and compatibility of materials used in reproductive technologies [14]. Additionally, ISO 13485 was specifically prepared for institutions involved in the design, production, and maintenance of medical devices, and is highly relevant to IVF and ICSI laboratories, emphasizing the importance of maintaining stringent quality management systems for reproductive technologies [15].

Compliance with ISO standards is important because of the role it plays in maintaining the performance of IVF and ICSI laboratory equipment, particularly in improving the performance of carbon dioxide incubators and enhancing the results of infertility treatment for patients [16]."

### Objectives

The main objective of the current study is to explore the available possibilities for cell transplantation and identify the fundamental supporting requirements in IVF and ICSI laboratories within clinical centers for infertility treatment.

## Methodology:

Study Design: A descriptive study was conducted to visit the infertility laboratory and review the electronic database for articles on the basic equipment used for cell transplantation technology in treating infertility [17,18].

Study Area: The study was conducted in infertility treatment centers specializing in the treatment of infertility and a medical research center on the west coast of Libya.

Data collected: All data collected in this study were gathered between April and November 2019. The data collection

### Methods included:

- Interviews with responsible managers and laboratory technicians.
- Registering all equipment and instruments related to IVF and ICSI present in the department.

## Result

The study results revealed that out of the 7 IVF and ICSI laboratories in infertility treatment centers, the following four were identified: the National Center (NC) for the diagnosis and treatment of infertility in Tripoli, the Salah al-Din Center (SC) for the treatment of delayed childbearing and infertility in Tripoli, the Tripoli Center for Infertility Treatment (TC), and the Medical Research Center (MRC). Additionally, there was a cell culture laboratory available at the Medical Research Center in Zawiya.

Table 1 provides a comprehensive list of the basic devices required in an IVF laboratory. These devices are essential for conducting various stages of the IVF process, including gamete handling, embryo culture, and cryopreservation. The variation in the quantity of different devices in the IVF and ICSI laboratories highlights their significance, particularly the carbon dioxide incubators, which are the most frequently found devices in the laboratories. Both SC and AC have five carbon dioxide incubators each. The

freezing system and freezer tanks are present in four quantities each in SC and AC. On the other hand, NC has four electrical pipettes and four variable pipettes.

**Table1:** Comprehensive Inventory of Essential Equipment and Devices in IVF and ICSI Laboratories: A Study Conducted at Infertility Treatment Centers and Medical Research Center

| | RASIT Proposed Law LEB | AFUIT -KSA | NC | AC | SC | TC | MRC |
|---|---|---|---|---|---|---|---|
| **CO2 incubator** | 2 | 2 | 4 | 5 | 5 | 4 | **3** |
| **CO2 (Fyrite) Analyzer** | 1 | 1 | 1 | 1 | 1 | 1 | **1** |
| **Freezing System** | 1 | 1 | 1 | 4 | 4 | 3 | **2** |
| **Freezing Tanks** | 1 | 1 | 1 | 4 | 4 | 3 | **2** |
| **Fridge** | 2 | 1 | 1 | 1 | 1 | 1 | **1** |
| **Centrifuge** | 1 | 1 | 1 | 1 | 1 | 1 | **1** |
| **Microscope** | 1 | 1 | 1 | 1 | 1 | 1 | **1** |
| **Micromanipulator** | 1 | 1 | 1 | 2 | 1 | 2 | **1** |
| **Inverted Microscope** | 1 | 1 | 1 | 2 | 2 | 3 | **2** |
| **Stereomicroscope** | 1 | 1 | 1 | 1 | 1 | 1 | **1** |
| **Laminar Hood** | 1 | 1 | 1 | 1 | 1 | 1 | **1** |
| **Electrical Pipettes** | 2 | - | 4 | 3 | 2 | 3 | **2** |
| **Variable Pipettes** | 2 | - | 4 | 3 | 2 | 3 | **2** |
| **Mackler Cell** | 1 | 1 | 1 | 1 | 1 | 1 | **1** |
| **Warm plate** | 1 | 1 | 1 | 1 | 1 | 1 | **1** |
| **Camera + Monitor** | 1 | 1 | 1 | 1 | 1 | 1 | **1** |
| **Computer** | 1 | 1 | 1 | 1 | 1 | 1 | **1** |
| **UPS back – up** | 1 | 1 | 1 | 1 | 1 | 1 | **1** |

Proposed Law LEB: Proposing a law regarding licensing fertility centers (in vitro fertilization units) in the Lebanese Republic. AFUIT: Amendment of the Implementing Regulations of the Law of Fertilization, Utero-Fetal and Infertility Treatment Units - Saudi Arabia.2004.

On the other hand, there are other materials utilized to ensure the efficient operation of the laboratory. These materials are used once and extensively throughout the IVF laboratory, encompassing tasks ranging from culturing eggs/embryos to storing various solutions. Among these materials are plastic tools, which

can be classified into different categories based on their functions. For example, there are specific plastic tools designed for egg culture dishes and plastic dishes used in embryo culture. Additionally, there are materials employed to maintain laboratory sterilization, such as disposable clothing and gloves. The quantities of these disposable materials are determined based on operational requirements and the management approach of the laboratory director in handling the medical supplies entering the laboratory.

## Discussion

Essential equipment and instruments in the IVF laboratory include culture incubators, necessary equipment, disposable supplies, and an IVF laboratory instrument [19,20,21]. Culture incubators play a crucial role in providing a stable and optimal environment for gametes/embryos, regulating factors such as temperature, gas levels, and humidity [22]. Moreover, the IVF laboratory must maintain a sterile, stable, and non-toxic environment, with clearly delineated non-sterile and sterile areas. The sterile area should be air-conditioned with filtered fresh air and equipped adequately [9].

Infertility treatment centers are committed to adhering to ISO standards to control devices and maintain a regulated laboratory environment in accordance with regulations. This commitment aims to create favorable conditions for the successful execution of embryo transfer work in the laboratory, while also ensuring the preservation of laboratory sterility. This is achieved through sterilization of tools and surfaces, as well as the implementation of infection control protocols to prevent laboratory contamination from infections.

CO2 Incubator

Regarding CO2 incubators, this study reveals that laboratories possess a significantly large number of incubators, which aligns with the regulations governing laboratories in Saudi Arabia. This is attributed to their vital role in artificial insemination and ICSI laboratories. The prevailing CO2 incubator utilized in most cell culture laboratories is the basic incubator, allowing for the adjustment of CO2 concentration and oxygen levels essential for the growth and maintenance of embryo cultures [19,20].

To ensure the optimal conditions for embryo culture, the CO2 (Fyrite) analyzer is employed to monitor the actual gas content within the incubator. This entails comparing the measured values with the digital values for each gas individually, thereby enabling necessary adjustments as required [19,20,22,23,24,25]. However, maintaining an ideal environment for embryo culture is of utmost importance, and CO2 incubators play a pivotal role in this regard. When selecting incubators, factors such as temperature regulation methods, type

of gas sensors, gas/atmosphere filtration, and other auxiliary materials should be taken into consideration [26].

**Cryopreservation**

Cryopreservation techniques have brought about a revolution in Assisted Reproductive Technology (ART) by enhancing cycle efficiency, enabling the preservation of embryos for future use, and saving time in cases of anticipated decline in fertility [27,28]. Cryopreservation equipment, including freezing systems and freezer tanks, holds significant importance in IVF and ICSI laboratories [29]. The study's findings further underscored the significance of cryopreservation techniques for infertility treatment centers, as evidenced by the presence of two to four freezing systems and freezing tanks in their IVF and ICSI laboratories. Thus, cryopreservation equipment, in conjunction with optimized culture media and solutions, plays a critical role in the successful cryopreservation of cells in ICSI and IVF laboratories.

Cryopreservation has become an integral component of ART, facilitating the long-term storage of surplus embryos and gametes, enhancing pregnancy rates through frozen embryo transfer, and enabling single embryo transfer [30,31]. The introduction of vitrification has contributed to improved cryosurvival and pregnancy rates [32,33]. Vitrification techniques have successfully extended to include oocytes and embryos, with mounting evidence supporting its efficacy [34].

Fridge

Considering the vital role of refrigerators in artificial insemination and ICSI laboratories, the study's findings confirmed that each centres ensures the provision of a refrigerator that fulfills the laboratory's requirements. Refrigerators are utilized to preserve crucial materials and culture media, playing a crucial role in maintaining the viability of the culture medium and the success of laboratory procedures [9]. With different sizes and types available, selecting the appropriate refrigerator for the laboratory depends on the nature of the stored materials, the types of tests/procedures conducted, and the expected storage duration. It is essential to choose refrigerators capable of maintaining temperatures within the specified storage range [18,19].

**Microscope:**

The study findings revealed that all laboratories included at least one inverted microscope, which aligns with the requirements of IVF and ICSI laboratories, where microscopes are considered essential equipment. Microscopes play a pivotal role in visualizing gametes and embryos throughout various IVF laboratory procedures, including oocyte retrieval, fertilization checks, embryo morphology assessment, and embryo transfer [35].

Semen analysis serves as the initial screening test in routine microscopy and forms the basis for the evaluation of male infertility. It provides valuable insights into parameters such as sperm count (x106/ml), sperm motility, viability, and the presence of elevated leukocytes (pyospermia) in the ejaculate.

An IVF laboratory typically requires three types of microscopes: a stereo dissecting microscope, an inverted microscope with micromanipulators, and an upright light microscope. The stereo dissecting microscope, equipped with transmitted illumination, allows for visualization of oocytes and embryos. Lower magnifications (7x-15x) can be used for scanning follicular fluid and facilitating embryo movement between culture dishes. Higher magnifications (30x-70x) enable oocyte classification and pronuclear identification. The inverted microscope should be equipped with lenses of 4x, 10x, 20x, and 40x, a heated work stage, and a micromanipulator for intracytoplasmic sperm injection (ICSI) and assisted hatching (AH). The upright light microscope should have lenses of 10x and 20x for sperm counting and a 100x oil immersion lens for morphological analysis [19, 20].

**Micromanipulation System:**

The findings of the study indicate that all surveyed IVF laboratories possess basic micromanipulation equipment, including an inverted microscope, micromanipulators, electrical pipettes, and variable pipettes. This adherence to international standards highlights the necessity of micromanipulation capabilities for performing ICSI procedures.

Micromanipulation techniques have been integrated into assisted reproductive technology (ART) to address infertility concerns and enhance our understanding of fundamental processes related to fertilization and embryonic development. Since the introduction of intracytoplasmic sperm injection (ICSI) in 1992, micromanipulators have become an indispensable requirement in IVF laboratories. The primary goal of micromanipulators is to facilitate precise manipulation, minimize damage to gametes and embryos, and help maintain the physiological conditions of the samples. Micromanipulation encompasses a range of techniques and tools designed for meticulous manipulation and microsurgery at the cellular level. These techniques have made significant contributions to both fundamental research and the advancement of clinical methodologies in the field of assisted reproductive technology [36,37,38].

**Centrifuge:**

A centrifuge machine equipped with a suitable rotor head is essential for semen preparation, allowing the accumulation of different tubes. The machine displays time and speed parameters necessary for the process [9,19]. Centrifuge technology plays a critical role in clinical laboratory

settings by facilitating the separation of liquid and solid components.

The study results indicate that all centers (MRC, TC, SC, AC, NC) require at least one centrifuge, which aligns with the proposed Lebanese law mandating the presence of a centrifuge in laboratories. This compliance with regulations emphasizes the importance placed on centrifuge usage [9].

Centrifuge techniques are routinely employed in embryology laboratories and enable the separation of particles based on their mass and size. For instance, these techniques aid in the separation of dead and motile sperm during gradient sperm preparation [39].

Computer

In the present day, most departments rely on smart computers for digital record keeping, allowing for the storage of records as soft copies. Additionally, printers are necessary for the printing of reports and other relevant documents. Computers serve various purposes, including email communication, data entry, and data storage [9].

It is recommended to have a minimum number of computers within the ART suite, and they should be switched off when not in use. To minimize potential off-gassing, new computers should be operated for 10 days outside the ART suite. Laptops and other low-power computers emit fewer volatile organic compounds (VOCs), while tablets and smartphones either produce no VOCs or emit very few, if any [40,41]. Each laboratory should conduct its own risk assessment concerning the use of computing equipment within the cleanroom laboratory [42].

The study outcomes indicate that all surveyed IVF clinics were equipped with desktop computers, which aligns with global standards for ART services.

**Laminar Flow Hood**

The results of the study revealed that all ART facilities examined possessed at least one laminar flow cabinet, which is in accordance with international standards mandating the presence of controlled and aseptic work areas that are safeguarded against external particulate **contamination**.

Laminar flow hoods are imperative for creating sterile work environments within the laboratory whenever such conditions are required. These workstations or biological safety cabinets play a crucial role in various IVF procedures and associated tasks, including gamete and embryo manipulation, as well as the preparation of culture dishes. The primary objective of the IVF workstation is to prevent microbial contamination of the IVF culture sample, offer protection to the operator, and contribute to maintaining the physiological conditions of the gametes and embryos during manipulation procedures. The type of hood utilized for different workstations in the laboratory depends on the level of

protection against microbial contamination that is necessary. Class II cabinets provide protection for the operator, the environment, and the product. These hoods should be used when the operator handles body fluids such as blood or semen, for procedures like semen analysis and semen preparation. On the other hand, vertical or horizontal laminar hoods provide protection for the product and equipment but not for the operator or the environment. Such hoods are employed for procedures involving open containers (petri dishes, flasks, vials, test tubes) of culture medium and reagents that contain or will be used to contain gametes and/or embryos, for instance, IVF insemination and denudation of oocytes [43].

**Camera**:

To ensure optimal efficiency and accuracy in the field of IVF, it is highly recommended to have video monitoring equipment installed at each IVF workstation. This enables a witness to observe procedures as required and to confirm patient identity when necessary. Such video monitoring establishes a visual chain of command for critical procedures including oocyte insemination, transfer of oocytes/embryos to new dishes, and cases involving embryo biopsy. If this equipment is also present in the patient procedure room, the patient can actively participate in the identification process during retrievals and transfers. Additionally, it is suggested to provide each patient with a picture of their embryos at the time of embryo replacement. Furthermore, a camera and/or digital video recorder (DVR) can be utilized to record other laboratory procedures [20].

The study results revealed that all surveyed IVF laboratories were equipped with a camera and monitor system, which is consistent with international standards for ART facilities.

UPS back – up:

An additional battery known as an uninterrupted power source (UPS) is conventionally employed as a temporary power supply in the event of a power failure. It is essential for all ART and IVF laboratories to have an automatic emergency generator backup system in place to address power failures [19, 44].

The study results indicated that all surveyed IVF laboratories have implemented a UPS backup system, which aligns with international standards for ART laboratories. These standards recommend the presence of backup power sources to ensure the protection of sensitive instrumentation and to prevent disruptions to embryo culture. The UPS serves as an emergency battery backup during blackouts, allowing equipment to remain functional for a limited duration until the backup generator takes over.

Study limitations

In the context of IVF and ICSI laboratories, there is a limited number of specialized facilities that focus on intrauterine tube insemination. Moreover, there is a scarcity of studies, particularly those that adhere to rigorous inclusion criteria. Additionally, it is worth noting that the techniques employed in IVF laboratories can exhibit significant variations across different centers.

## Conclusion

In conclusion, the establishment of clinical human artificial insemination laboratories requires the utilization of an advanced array of equipment, tools, and basic materials. These resources are crucial for ensuring the success of assisted reproductive techniques and play a pivotal role in achieving high success rates in fertility treatments, thereby enabling patients to fulfill their reproductive aspirations.

Moreover, when setting up a laboratory to meet the requirements for successful operation, careful selection of primary equipment is of utmost importance. This involves choosing the appropriate type of equipment, implementing an effective work system, and establishing a robust quality control program. Additionally, ensuring the availability of an adequate quantity of equipment and maintaining its quality at all times will maximize the center's utilization of these resources.

## Recommendation

It is highly recommended to provide comprehensive support for studies conducted in the field of IVF and ICSI laboratories. This support aims to enhance and develop techniques utilized in these laboratories, thereby increasing their effectiveness and practicality of application. Furthermore, it is essential to identify the success factors associated with IVF and ICSI laboratories, as well as assess the efficiency of embryos. Conducting long-term studies is crucial to monitor and evaluate the outcomes of laboratory work and gain a comprehensive understanding of the long-term effects.

To foster scientific exchange and practical application, it is crucial to share research findings with both the scientific and medical communities. This sharing of results will facilitate the dissemination of knowledge and promote collaborative efforts in the field.

Additionally, it is recommended to direct these studies and their outcomes to the relevant authorities within the country, particularly the Ministry of Health. This step aims to initiate the development of regulations and legislation that can effectively govern and regulate IVF and ICSI laboratories, ensuring adherence to established standards and guidelines.

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