Universal Library of Medical and Health Sciences **Research Article**

ISSN: 3064-6545 | Volume 3, Issue 3

Open Access | PP: 65-69

DOI: https://doi.org/10.70315/uloap.ulmhs.2025.0303008

Organization and Launch of a Turnkey Embryology Laboratory

Kyrylo Alpatov

CEO Company Stoik LLC, Kyiv, Ukraine.

Abstract

The study provides an analysis of the organization and subsequent launch of a turnkey embryology laboratory. The necessity of the study is determined by the fact that assisted reproductive technologies (ART) are a principal element of modern reproductive healthcare, where effectiveness directly depends on the organization and quality of work of the embryology laboratory. The aim of the work is to systematize key stages in the creation of turnkey laboratory infrastructure and to develop a scientifically substantiated concept of its highly effective operation. The methodological basis comprised analysis and synthesis of current scientific publications, clinical recommendations of leading international societies (ESHRE, ASRM) and regulatory documents. The result is an integrative model that combines architectural and planning solutions with projected throughput capacity in terms of number of cycles and identifies critical parameters in the choice of technical equipment and consumables. Special attention is given to strict zoning of the laboratory space (wet, clean and sterile zones), organization of high-purity medical gas supply systems and a set of measures for air quality control, including monitoring of volatile organic compound (VOC) concentrations. The conclusion of the study is that achieving stable high indicators of clinical efficacy and safety requires exclusively a comprehensive, holistic approach in which all laboratory components — from engineering and technical design to validation protocols — are regarded as a single interconnected entity. The practical value of the work lies in providing substantiated recommendations for heads of medical centers, clinical embryologists, medical equipment engineers and specialists in healthcare facility design.

Keywords: *Embryology Laboratory, Assisted Reproductive Technologies (ART), Laboratory Design, Quality Control, Cleanroom, Volatile Organic Compounds (VOCs), Cryopreservation, ICSI, Equipment Validation, Medical Gases, Turnkey IVF Laboratory, Embryo Culture Systems, IVF Laboratory Quality Control, Advanced Embryo Culture Techniques.*

INTRODUCTION

In the context of the rapid increase in the number of assisted reproductive technology (ART) cycles, which reached 960,347 procedures in 2022 (EIM) [13], the task of creating turnkey embryological laboratories becomes particularly urgent. Empirical data indicate that the quality of the air environment directly affects the efficiency of ICSI and embryo morphogenesis: non-compliance with HEPA and VOC filtration parameters may complicate the implantation process [1]. At the same time, there is no unified methodology that integrates engineering and technological design, the selection of equipment and consumables, the displacement-based organization of functional zones, and the medical gas supply scheme. This reveals the following key scientific gaps: a lack of a holistic approach to zoning taking into account Laminar Air Flow and the separation of wet, clean, and sterile spaces [2]; the absence of a clear typology of devices and consumables depending on the projected laboratory workload [7]; as well as a mismatch between international air quality standards (ASRM, ESHRE) and the practical implementation of $CO_2/O_2/N_2$ systems [5].

The aim of the study is to systematize the key stages in the creation of turnkey laboratory infrastructure and to develop a scientifically grounded concept for its highly efficient operation.

The scientific novelty lies in the proposal of an integrated scheme in which architectural and planning solutions, equipment scaling in accordance with patient flow, and air-quality validation protocols act as a unified mechanism for optimizing clinical outcomes.

The author's hypothesis is that early coordination of zoning, equipment selection, and microclimate control

Citation: Kyrylo Alpatov, "Organization and Launch of a Turnkey Embryology Laboratory", Universal Library of Medical and Health Sciences, 2025; 3(3): 65-69. DOI: https://doi.org/10.70315/uloap.ulmhs.2025.0303008.

systems within a cohesive strategy ensures higher and more stable effectiveness of ART cycles compared to a fragmented, stepwise approach.

MATERIALS AND METHODS

Modern concepts of the organization and launch of a turnkey embryology laboratory are based on the integration of international quality guidelines and operational standards proposed by specialized associations. Thus, Walker J. V. et al. [2] identify key requirements for infrastructure and quality control procedures, emphasizing the development of validation protocols for critical processes and regular audits. Vitagliano A. et al. [5] systematizes recommendations on management and operational governance, including personnel management, documentation and performance monitoring, ensuring consistency of approaches in the comparative analysis of results from different laboratories. Sjöblom C. [10] focus on adapting these standards to regional regulations and the resource constraints of clinics. Despite the common goal of ensuring reproducibility and safety of ART procedures, discrepancies are observed among these documents in the level of detail regarding equipment validation requirements and calibration frequency, indicating the absence of a unified international standard.

When designing facilities and selecting equipment, special attention is paid to ergonomics and instrument compatibility with contamination control requirements. In the ASPIRE Guidelines Latif Khan H. et al. [6] a modular layout of workstations is proposed to minimize cross-contamination when transitioning between sample processing stages. Harbottle S. [7] details the selection and technical specifications of necessary consumables, from aspiration tubes to sterile containers, as well as the optimal parameters for microscopes and incubators. The authors stress that correct equipment selection directly influences oocyte recovery and viability and recommend using devices with integrated HEPA filtration systems to prevent the ingress of particulate matter.

In the context of ensuring the embryonic microenvironment, air quality control and the implementation of sustainable practices play a significant role. Sciorio R., Rapalini E., Esteves S. C. [1] in a mini-review demonstrate that modern laboratories should include systems for monitoring volatile organic compounds (VOCs) and microorganisms, since even minor changes in air composition can negatively affect embryo development. Hernaez J. et al. [12] conducted episodic measurements of air parameter fluctuations and found that short-term oscillations exert minimal impact on final embryo selection outcomes. Farlie F. et al. [3], based on expert group opinion, recommend integrating sustainable development principles – reducing energy consumption, disposing of biological waste and choosing reusable consumables – without compromising sterility.

Risk management and error minimization remain critically important areas. Ifenatuoha C. W., Mohammed C., Malhotra K. [8] conducts a systematic analysis of potential human and technical factors leading to errors (sample labeling, protocol confusion, equipment failures) and proposes applying the FMEA methodology (failure mode and effects analysis) for early identification of vulnerabilities.

Alongside traditional approaches, innovative solutions for remote ART have emerged in recent years. Berger D. S. et al. [4] describe remote embryology protocols in which some preparation and evaluation stages are conducted under specialist guidance via telemedicine platforms. This approach expands access to ART services for patients in regions with limited infrastructure but introduces new risks related to data transmission quality and the need to standardize equipment throughout the interaction chain.

Finally, evaluating service volumes and the effectiveness of implemented processes is impossible without reliable registries.de Neubourg D. et al. [11] in the ART in Europe 2022 report present detailed data on cycle numbers, clinical pregnancy rates and distribution by country, enabling interregional comparisons and identification of optimal organizational models. The ESHRE press release based on EIM consortium data for 2022 reports that, with a decrease in the total number of ART cycles to ~960 thousand compared to 2021, clinical pregnancy indicators for IVF/ICSI/FET remained stable. The proportion of single-embryo transfer increased (from 60,5% to 62,6%), which was accompanied by an increase in the proportion of singleton births (to 91,5%) and a decrease in the number of twin births (to 8,4%) [13].

The literature analysis reveals several contradictions. First, among international guidelines (ARCS, ASRM, ASPIRE, ASEBIR) there is no unified standard for the level of detail in equipment validation and control frequency, which hinders the unification of practices. Second, the work [1] and the observations [12] diverge in their assessment of the impact of short-term air parameter fluctuations on ART outcomes, indicating the need for additional experimental research. Meanwhile, issues of integrating sustainable practices while maintaining the highest standards of sterility and procedural efficiency remain poorly addressed: the existing recommendations [3] are based predominantly on expert opinion and require support from data on the influence of eco-friendly materials on biological outcomes. Research on the legal and technical aspects of remote embryology [4] is insufficiently represented, and the topics of digital documentation management and personnel training in the context of risk management are not fully developed.

RESULTS AND DISCUSSION

Based on the conducted analysis an integrated model for the organization and commissioning of an embryology laboratory has been developed, including four interrelated components:

architectural-planning design and zoning; scaling and equipment selection; life support and environmental monitoring systems; and validation and commissioning protocols.

Architectural-planning design and zoning is focused on strict logical segregation of workflows with the aim of preventing cross-contamination of biomaterial and reducing the likelihood of operational errors. The laboratory complex is designed as an autonomous unit within the clinical structure, equipped with an access control system and divided into three functionally separate zones with a gradient of positive air pressure [7, 11].

Wet Lab (pressure +) is intended for initial processing and primary analysis of ejaculate. This section contains centrifuges and light microscopes necessary for the assessment of sperm morphology and motility; the air cleanliness requirements in this section are moderate.

Clean Area (pressure ++) serves as the main site for performing oocyte manipulations, fertilization (including ICSI), and morphological evaluation of embryos. This section employs Class II biological safety cabinets with laminar flow, as well as inverted microscopes equipped with micromanipulators.

Sterile/Culture Area (pressure +++) is the most critical part of the laboratory, where embryo culture is conducted in CO_2-incubators. Here, the air cleanliness level must comply with ISO 6 standard or higher, and the ventilation system must provide maximal excess pressure [6, 8].

In Figure 1 the zoning scheme of the embryology laboratory is presented, depicting the optimal routes for material and personnel movement, as well as the configuration of the pressure gradients.

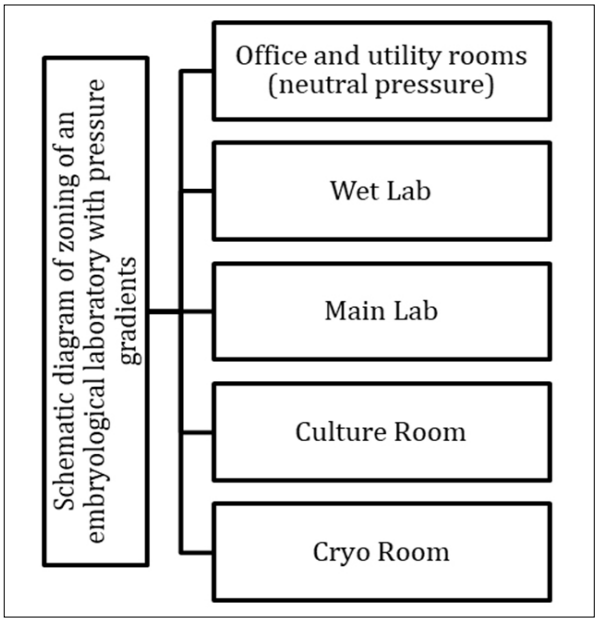

Fig. 1. Schematic diagram of zoning of an embryological laboratory with pressure gradients [6, 8, 11]

In the design of a laboratory complex, one of the primary tasks is the quantitative estimation of the required inventory of key instruments and equipment, which simultaneously makes it possible to eliminate periods of downtime and to prevent overloading of technical resources that could adversely affect procedure quality. Based on statistical analysis of the average duration of operations and the throughput of each type of equipment, a model for scaling the load of laboratory systems has been formulated (see Table 1).

Table 1. Distribution of ART cycles by types (EVMIR-2022) [13]

Type of cycle	Quantity, units
IVF	137,148
ICSI	317,415
FET	365,905
PGT	92,677
OD (donor oocyte)	41,138
IUI (partner)	126,185
IUI (donor)	42,532
Fertility preservation	30,758

The selection of the most rational type of incubator — between large-scale cabinets and compact benchtop systems — is regarded as a key strategic step. By virtue of reduced internal volume and minimization of thermogas microclimate losses upon door opening, benchtop incubators enable much faster restoration of specified temperature and gas parameters, which substantially lowers the level of stress imposed on developing embryos. In laboratory environments with a high volume of patients and frequent manipulations this factor acquires particular significance [7, 10].

An important component in the life-support system is the control of air quality within incubation chambers. Volatile organic compounds (VOCs) generated under the influence of construction materials, furniture, cleaning chemicals and even staff cosmetics are capable of exerting toxic effects on embryos. To ensure that VOC levels do not exceed 50 $\mu g/m^3$, a multi-stage air-purification scheme within the HVAC system is required: preliminary filtration, high-efficiency HEPA filters of class H14 for capturing suspended particles and adsorption modules based on activated carbon or potassium permanganate for removal of gaseous impurities [3, 4].

Equally critical is the medical gas supply system (CO_2, N_2 and their mixtures), where the use of medical-grade gases 5.0 is mandatory. Gas pipelines are manufactured from inert materials — stainless steel or specialized polymers — in order to preclude the introduction of undesirable impurities into the working environment. A schematic representation of the gas connections is shown in figure 2.

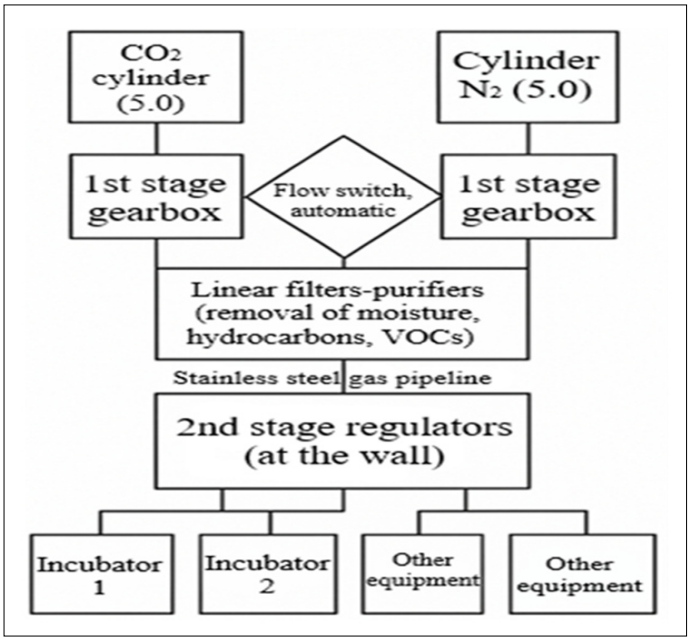

Fig. 2. Schematic diagram of the high-purity medical gas supply system [3, 4, 9]

Impossible to commission a laboratory complex without rigorous verification of compliance guaranteeing that all engineering and technical units and analytical instruments operate strictly within design specifications while ensuring the required level of safety and operational efficiency.

The compliance verification procedure is usually divided into three interrelated qualification stages. During the installation qualification (IQ) stage a comprehensive technical examination of the installation is conducted: verifying correct placement and secure mounting of equipment, compliance of communication routing with design schematics and correctness of all connections.

The operational qualification (OQ) stage includes evaluation of instrument performance under no-load conditions. Within this stage detailed mapping of temperature fields and CO_2 concentration distribution in incubators is performed, airflow parameters in laminar flow cabinets are measured, and quantitative analysis of particulate content in the air is conducted, allowing confirmation that microclimatic conditions and air purity meet the requirements of biological procedures.

In the final stage — performance qualification (PQ) — the ability of the laboratory environment to stably maintain the specified parameters under real production conditions is verified. A key test here is the biotest, for example the Mouse Embryo Assay, MEA, aimed at confirming the ability of the environment to support mouse embryo development to the blastocyst stage. A high blastocyst formation rate in the MEA is considered the golden standard of laboratory readiness for work with human biomaterial [12].

Comparison of the recommendations of ASRM [5], ARCS [2] and ASPIRE [6] has demonstrated that uniform standards for pressure and number of air exchanges are still lacking, requiring further harmonization of standards. The integrated approach provides early identification and correction of such nonconformities, guaranteeing fail-free laboratory operation in the long term.

CONCLUSION

The creation and commissioning of an embryology laboratory turnkey represents a task of exceptional complexity and multi-parametric nature, requiring comprehensive analysis of biological processes, engineering solutions and a quality management system. As a result of the conducted study the key stages of this process were detailed and hierarchically ordered, which allowed the formation of an integrated model based on current scientific achievements and international industry standards.

The main conclusions of the work are as follows. First, a mandatory condition for counteraction of microbial and chemical contamination is strict zoning of the laboratory space with implementation of a cascade of positive pressure in the ventilation ducts. Second, equipment configuration must strictly t correlate with the anticipated patient load, and when selecting hardware means it is necessary to be guided by their ability to stably maintain critical operational parameters (temperature regime, composition of gas mixtures). Third, air quality is one of the central factors directly affecting embryo viability: reduction in the concentration of volatile organic compounds is achieved by means of multilevel filtration systems and careful selection of all structural and consumable materials. And finally, the final stage of launch is stepwise validation of the laboratory environment with conduct of biological tests such as MEA, which serve as the ultimate criterion of readiness and safety of laboratory operation.

The proposed integrative concept — a synthesis of architectural-spatial solutions, engineering-technical requirements and biological criteria — confirms the hypothesis formulated in the study and serves as a practical tool in the design and organization of highly effective ART laboratories. Application of this methodology contributes not only to increased clinical effectiveness but also guarantees long-term stability and reproducibility of obtained indicators, which is the key priority of any assisted reproductive technology program.

REFERENECS

1. Sciorio, R., Rapalini, E., & Esteves, S. C. (2021). Air quality in the clinical embryology laboratory: A mini-review. Therapeutic Advances in Reproductive Health, 15, 1–11. https://doi.org/10.1177/2633494121990684
2. Walker, J. V., et al. (2024). Good practice in clinical embryology laboratories: Association of Reproductive

and Clinical Scientists Guidelines 2024. Reproductive BioMedicine Online, 49(6), 1–13. https://doi.org/10.1016/j.rbmo.2024.104102

3. Farlie F. et al. Sustainability in the IVF laboratory: recommendations of an expert panel //Reproductive biomedicine online. – 2024. – Т. 48. – №. 1. – С. 1-18. https://doi.org/10.1016/j.rbmo.2023.103600
4. Berger, D. S., et al. (2023). Remote IVF: A clinical and laboratory guide to performing remote oocyte retrievals. Journal of Assisted Reproduction and Genetics, 40, 2081–2089. https://doi.org/10.1007/s10815-023-02887-9
5. Vitagliano, A., et al. (2022). Comprehensive guidance for human embryology, andrology, and endocrinology laboratories: Management and operations: A committee opinion. Fertility and Sterility, 117(6), 1183–1202.
6. Latif Khan, H., et al. (2023). ASPIRE guidelines for assisted reproductive technology (ART) laboratory practice in low and medium resource settings. Fertility & Reproduction, 5(3), 115–133. https://doi.org/10.1142/S2661318223500184
7. Harbottle, S. (2022). Laboratory design, equipment and consumables for oocyte retrieval. In Manual of oocyte retrieval and preparation in human assisted reproduction, 65 - 75.
8. Ifenatuoha, C. W., Mohammed, C., & Malhotra, K. (2023). Errors in IVF laboratories: Risks assessments and mitigations. Middle East Fertility Society Journal, 28(5).
9. LaPointe, S., et al. (2024). Air pollution exposure in vitrified oocyte donors and male recipient partners in relation to fertilization and embryo quality. Environment International, 193, 1-10. https://doi.org/10.1016/j.envint.2024.109147
10. Sjöblom, C. (2023). The assisted reproduction technology laboratory: Current standards. In Textbook of assisted reproductive techniques, 17-35.
11. de Neubourg, D., et al. (2025). O-159 Assisted reproductive technology (ART) in Europe 2022: Preliminary results generated from European registers by the ESHRE EIM consortium. Human Reproduction, 40(1), 95–96. https://doi.org/10.1093/humrep/deaf097.159
12. Hernaez, J., et al. (2021). Air quality oscillations inside the IVF laboratory do not affect clinical outcomes. Human Reproduction, 36(1), 218-219. https://doi.org/10.1093/humrep/deab130.182
13. IVF and IUI pregnancy rates remain stable across Europe, despite an increasing uptake of single embryo transfer. Retrieved from: https://www.eurekalert.org/news-releases/1089296?utm_source (date of access: 18.07.2025).