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Improvement Of ART Laboratories: Increasing Quality, Efficiency And Clinical Outcomes

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Abstract

This article examines the specifics of improving ART laboratories. The objective of the study is to systematize and analyze advanced approaches to optimizing the operation of embryology laboratories by constructing an integrated model that combines technological innovations, quality management standards and methods for assessing staff professional competence to enhance the efficiency of ART procedures. As the methodological basis, a review of scientific publications and specialized reports for the period 2021–2025 was carried out, dedicated to the key parameters of embryology unit functioning. In the course of the analysis the following were examined in detail: integration of ISO 9001 requirements into the quality management system, application of artificial intelligence algorithms in embryo selection, implementation of noninvasive preimplantation genetic testing (niPGT-A) and harmonization of key performance indicators (KPI). On the basis of the obtained data an integrative management model Quality–Efficiency–Outcome (КЭР) is proposed, demonstrating the synergistic effect of comprehensive innovation implementation. It was revealed that the use of AI increases the accuracy of embryo viability prediction compared with traditional morphological assessment, while KPI standardization ensures a reduction in interlaboratory result variability. The results confirm that the transition from local to comprehensive solutions is the determining factor for sustainable improvement in ART cycle success rates. The practical significance of these materials is especially high for heads of reproductive medicine clinics, managers of embryology departments and related specialists.

Keywords: Assisted reproductive technologies, embryology laboratory, quality management, artificial intelligence, noninvasive preimplantation genetic testing, key performance indicators, clinical outcomes, automation, embryo selection, vitrification, warming, embryo culture in laboratory conditions.

Introduction

The importance of improving the quality and performance of reproductive technology laboratories is substantiated by the increasing demands on the outcomes of IVF programs and the growing proportion of patients with reproductive disorders. Traditional morphological methods of embryo assessment are largely subjective, which contributes to considerable variability of conclusions and limits the clinical effectiveness of procedures [11]. The implementation of lean manufacturing principles (Lean) in recent years has reduced the duration of pre- and post-analytical phases in clinical laboratories by 13% with minimal additional costs [1]. In parallel, modernization of quality management systems in accordance with ISO 15189:2023 requirements increases the accuracy and reproducibility of laboratory protocols [3]. The emergence of continuous monitoring technologies (time-lapse monitoring, TLM) and the application of artificial intelligence (AI) have made it possible to create predictive models with accuracy up to 93% for predicting blastocyst formation [7] and to equalize the level of expertise between junior and senior embryologists [12].

Objective of the study is to systematize and analyze advanced approaches to optimizing the operation of embryology laboratories by constructing an integrated model that unites technological innovations, quality management standards and methods for assessing staff professional competence to enhance the efficiency of ART procedures.

Scientific novelty lies in the proposal of an integrative concept of quality and efficiency management for the embryology laboratory, based on a through analysis of the interaction of technological, organizational and personnel factors influencing key clinical indicators.

It is postulated that the synergistic implementation of AI systems for embryo selection, noninvasive genetic testing and standardized key performance indicators (KPI) is capable not only of increasing the frequency of pregnancy occurrence, but also of reducing the variability of results between different laboratories.

Materials and Methods

In recent years in the field of ART laboratories, research aimed at optimizing processes and improving the quality of services has come to the fore. Thus, Letelier P. et al. [1] demonstrated the advantages of applying Lean management principles at the preclinical stage of laboratory work, which made it possible to significantly reduce the time required for biomaterial processing and decrease the number of errors. Similar approaches to optimizing ovarian response monitoring processes in ovarian stimulation protocols for IVF were proposed by Fernandes H. M. L. G. et al. [2], emphasizing the role of regulation and continuous improvement of work instructions.

Concurrently, attention to quality standardization in accordance with international norms intensified. de la Villa Porras I. [3] examined the innovations of ISO 15189:2023, paying special attention to requirements for risk management and staff competencies. The Cairo Consensus Group et al. [4] formulated a consensus on the accreditation of IVF laboratories as the basis of their future readiness, aimed at uniformity of quality and safety criteria on a global scale.

One direction of improvement was the implementation of continuous embryo monitoring systems using time-lapse microscopy. Bhide P. et al. [5] developed a protocol for an individual meta-analysis of randomized controlled trials aimed at assessing the impact of such systems on clinical outcomes, whereas Campbell A. et al. [6] conducted a review of one of the completed randomized controlled trials, indicating methodological limitations and ambiguity of the results obtained.

Methods of artificial intelligence for embryo selection have also undergone active development. Thus, Kalyani K., Deshpande P. S. [7] introduced a deep learning model for predicting blastocyst formation based on cleavage-stage images. Boucret L. et al. [8] proposed an alternative approach using matched high-quality embryos for neural network training. Canat G. et al. [9] focused on automatic recognition of morphokinetic events. Borna M. R., Sepehri M. M., Maleki B. [10] developed an algorithm that takes into account the existing laboratory workflow to select the most viable embryos. A broader perspective on the application of AI in IVF laboratories was summarized by Hew Y. et al. [11], emphasizing improvements in accuracy and efficiency of processes.

Finally, an important aspect of AI implementation was its clinical acceptance and trust among specialists: Kim H. M. et al. [12] conducted a prospective survey, identifying factors influencing embryologists' willingness to use AI tools for embryo ranking.

Despite significant progress, contradictions persist in the literature. On the one hand, Lean systems and ISO standardization demonstrate an indisputable effect on work organization, but their direct clinical consequences have been little studied; on the other hand, the effectiveness of time-lapse systems is controversial due to heterogeneity of methodologies and statistical approaches. AI models, in turn, show promising results in studies of limited cohorts; however, a unified validation standard and algorithm transparency are lacking. Questions regarding the economic efficiency of implementing these technologies, regulatory and ethical aspects of AI application, as well as integration of process optimization methods with digital tools and evaluation of long-term clinical outcomes remain insufficiently addressed.

Results and Discussion

Modern ART laboratory represents a complex sociotechnical system in which performance is determined by the degree of alignment among organizational structures, technological equipment, and staff qualifications. Analysis of leading practices indicates that isolated improvements — whether acquisition of an innovative incubator or implementation of a single methodology — rarely yield a noticeable qualitative breakthrough.

Studies of time-lapse systems simultaneously provide non-invasive monitoring of embryos and the ability to collect morphokinetic data without interrupting incubation [5]. A systematic review by Campbell A. et al. demonstrated the absence of a significant increase in live birth rates when using TLM compared to standard incubators, which indicates the need to refine protocols and evaluation criteria [6].

Thus, substantial improvement in performance is possible only with the comprehensive implementation of the integrative paradigm Quality–Efficiency–Result (QER), based on three inextricably linked pillars: formalized quality management, the use of advanced technological solutions and objective monitoring supported by statistical data.

At the core of the QER model is the quality management system (QMS), structured in accordance with the principles of ISO 9001:2015 and regulating every stage of the laboratory process — from initial patient intake to cryopreservation and embryo transfer. Such formalization reduces variability caused by the human factor and ensures reproducibility of conditions. The key components of the QMS are proactive risk management and continuous analysis of multilevel key performance indicators (KPI), covering the entire laboratory workflow and comparable with international standards, in particular the Vienna consensus criteria [11].

Second central component of the Quality–Efficiency–Result model involves the purposeful implementation of innovative technologies, primarily artificial intelligence tools and non-invasive diagnostic methods. Traditional embryo evaluation protocols are based on single static morphological images, which entails a high degree of subjectivity and does not allow dynamic monitoring of their development. The integration of time-lapse incubators together with AI algorithms elevates the selection process to a new level — from expert, largely intuitive judgment to objective analysis of big data and prediction of success. Modern AI systems process thousands of parameters — from morphokinetic profiles to subtle textural features and fragmentation anomalies undetectable by visual inspection — and rank embryos according to the probability of effective implantation. As research results show [5], the application of such methodology not only increases selection accuracy but also standardizes practice among specialists, minimizing interobserver variability.

Implementation of AI directly affects clinical outcomes. Improving the accuracy of selecting the single most viable embryo for transfer (the eSET concept — elective single embryo transfer) leads to a reduction in the frequency of multiple pregnancies, which are associated with high risks for both mother and fetus. AI models have demonstrated superiority over classical embryo evaluation methods. [7, 10].

In the experiment by Kim H.M. et al. it was noted that with AI-guided evaluation interobserver agreement increased from 0.355 to 0.527 for junior and from 0.440 to 0.524 for senior embryologists [12]. This indicates the significant role of AI in standardizing expert assessments.

Recommendations of the Cairo Consensus Group impose requirements for optimizing the distribution of work zones, clear delineation of personnel responsibilities and regular quality audits [2, 4]. A comprehensive approach combining Lean management, ISO 15189 and AI technologies enables the creation of a laboratory of the future with high flexibility and reliability.

Additionally, modeling of clinical outcomes based on AI recommendations showed an increase in the probability of successful implantation compared to traditional evaluation. Taking economic evaluation into account, AI integration allows reduction of medium consumption and labor costs [10, 11].

The current stage of development of AI systems is closely intertwined with the in-depth evolution of genetic diagnostic methods. The introduction of non-invasive preimplantation genetic testing for aneuploidies (niPGT-A) represents a qualitative breakthrough, allowing rejection of invasive trophectoderm biopsy — a procedure that, despite confirmed safety when performed by experienced clinicians, retains potential risks for the embryo. At the same time the niPGT-A methodology requires additional optimization to ensure increased accuracy and reproducibility of results [7, 8], however its integration into routine practice can expand access to genetic examination and strengthen the efficiency of assisted reproductive technology programs through reliable selection of euploid embryos.

The concluding and perhaps most significant element of the QER concept lies in building a data-driven culture and continuous professional development of specialists. Modern technological platforms generate colossal volumes of information — from time-lapse recordings and genomic sequences to key performance indicators. Without integration of specialized systems for their collection, processing and deep analysis this information loses its practical value. The implementation of laboratory information management systems (LIMS) and electronic systems for procedure registration (electronic witnessing) not only automates data recording and eliminates identification errors [9, 12] but also creates a reliable foundation for identifying trends and bottlenecks in workflows. As a result the role of the embryologist is transformed: instead of an operator of routine manipulations they act as an analyst and manager of complex technological platforms. Successful work in the new environment requires expanded competencies — the ability to interpret data, understanding of AI principles and modern genetic methodologies (table 1).

Table 1. Competency matrix for personnel of a modern embryology laboratory [9-12]

Competency area	Competent level	Expert / Trainer level
Micromanipulation (ICSI, biopsy)	Consistent execution of procedures with high fertilization/survival rates	Development and validation of new protocols, training junior staff, troubleshooting
Culture and selection	Confident assessment of morphology and morphokinetics according to standard criteria	Interpretation of data from AI systems, participation in validation of new algorithms, analysis of atypical developmental cases
Genetic testing (PGT)	Correct execution of biopsy procedures or collection of medium for niPGT-A, documentation handling	Understanding principles of genetic analysis, joint interpretation of results with a geneticist, implementation of new PGT protocols
Quality and data management	Working within the QMS, accurate record keeping in LIMS/EWS	KPI analysis, participation in internal audits, trend identification and proposal of corrective actions

The synergistic potential of implementing the Quality–Efficiency–Result model lies not in a simple aggregation of its elements but in each element's capacity to enhance the performance of the others. The quality management system establishes a robust framework for seamless integration and stable operation of advanced technological solutions. Artificial intelligence tools and other digital systems generate a reliable, verified data stream necessary for continuous monitoring and optimization of processes within the QMS. Meanwhile, a highly qualified team, equipped with modern analytical platforms and supported by technological infrastructure, makes evidence-based decisions that directly improve clinical effectiveness. As a result of such close interaction, the impact of the QER model becomes not merely additive but acquires a multiplicative character.

The following Table 2 will highlight the advantages, limitations and future trends in improving ART laboratories.

Table 2. Advantages, limitations and future trends in improving ART laboratories [4, 7, 10].

Category	Description	Details	Examples
Advantages	Key benefits of improving Assisted Reproductive Technology (ART) laboratories	• Enhanced embryo culture conditions leading to higher implantation rates • Improved workflow reduces handling time and stress on gametes and embryos • Better air quality and environmental control minimize contamination risks • Use of advanced equipment increases precision in procedures • Staff training programs raise technical competency and consistency • Data-driven quality management supports continuous improvement	HEPA filtration systems; time-lapse incubators; advanced micromanipulation tools
Limitations	Challenges and potential drawbacks in ART lab improvement projects	• High cost of upgrading facilities and purchasing new equipment • Need for ongoing staff training to adapt to new technologies • Possible disruptions during renovation or equipment replacement • Regulatory and accreditation requirements may slow implementation • Over-reliance on technology could reduce manual skill proficiency • Resource limitations in smaller clinics	Temporary reduction in lab capacity during facility upgrades
Future Trends	Predicted developments and innovations in ART lab quality and efficiency	• Greater integration of AI for embryo selection and predictive analytics • Expansion of fully automated embryo handling systems • Increased use of non-invasive embryo assessment methods • Personalized culture conditions based on patient-specific biomarkers • Global benchmarking databases for outcome comparisons • Implementation of smart lab environments with real-time monitoring	AI-driven embryo viability scoring; wearable sensors for lab environmental tracking

The evolution of assisted reproductive technology laboratories under contemporary conditions demands a shift from fragmented, isolated improvements to a holistic, integrated approach. The proposed QER model, which unites rigorous quality standards, technological innovation and continuous professional development, serves as a strategic roadmap for achieving the primary goal — a sustained increase in healthy birth rates in infertility treatment.

Conclusion

As a result of the conducted study, a systematization and analysis of modern methods for optimizing the operation of assisted reproductive technology laboratories were performed, on the basis of which an integrative management model Quality – Efficiency – Result (QER) was created. A comprehensive review of relevant publications revealed that most studies, despite the importance of implementing quality management systems, applying artificial intelligence, and progress in preimplantation genetic diagnostics, focus on isolated fragments of processes, failing to consider the laboratory as a unified, interdependent system. The proposed QER model overcomes this gap by combining three complementary elements: a refined quality management system based on strictly defined key performance indicators; the sequential introduction of advanced technologies (AI and downstream preimplantation genetic pinpoint diagnostics); and the continuous enhancement of personnel analytical skills when working with large volumes of data. The synergy of all model components yields a significantly greater effect than their sequential application. In particular, the unification of procedures within the QMS creates a reliable platform for the stable operation of high-tech equipment, and the objective information obtained through AI and LIMS serves as the basis for continuous improvement in quality management cycles. The implementation of a comprehensive approach leads to a predictable increase in key clinical indicators and a noticeable reduction in result variability both within a single laboratory and between different centers. Thus, the shift to a holistic management strategy contributes to transforming the ART laboratory into a highly efficient and stable structural unit of modern medicine.

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