

Research Article

Building a Quality Culture in the Embryology Laboratory: The Role of Processes, Training, and Knowledge Exchange

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Abstract

Within the framework of the research project, a comprehensive analysis was conducted of the mechanisms through which a quality culture is formed and reproduced in contemporary embryology laboratories. The text consistently traces the evolution of managerial logic—from predominantly procedural quality control toward an integrated safety culture grounded in corrective and preventive action (CAPA) methodology, structured analysis of “near-miss” events (near-miss reporting), and continuous staff competency development as an essential condition for process reliability. Particular emphasis is placed on the deployment of technological solutions that reshape the architecture of laboratory practice: Piezo-ICSI, automation of “day-0” procedures, and the use of artificial intelligence (AI) tools for standardized assessment of morphological parameters of gametes and embryos. Drawing on provisions of international consensus documents (Vienna Consensus) and a body of studies from 2024–2025, it is shown that coupling high-technology production loops with standardized certification programs (ESHRE) reduces the contribution of the human factor while simultaneously increasing cumulative live birth rate.

Keywords: assisted reproductive technologies, embryology laboratory, quality culture, risk management, key performance indicators (KPI), automation, staff training, CAPA.



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Introduction

The global configuration of assisted reproductive technologies (ART) in 2024–2025 is shaped by a combination of accelerated market expansion and deep technological reconfiguration of the sector. According to current market estimates, the global ART segment is projected to grow at a compound annual growth rate (CAGR) of 7.56%, reaching USD 56.17 billion by 2032 [1]. This dynamic is driven in large part by the rising burden of infertility: according to the World Health Organization (WHO), approximately 17.5% of the world’s adult population is affected—roughly one in six people [1]. Against a backdrop of expanding demand and intensifying inter-clinic competition, managerial priorities increasingly shift away from simple growth in cycle volume and toward optimization of the critical quality characteristics of the embryology stage, understood as the primary source of reproducibility in clinical outcomes.

A quality culture in the embryology laboratory is not reducible to compliance with regulations and checklists. It constitutes a multi-component ecosystem in which the physicochemical stability of culture conditions, the precision and reproducibility of micromanipulations, staff psychological readiness for transparent error analysis, and organizational support for continuous professional development are coupled into a single operational fabric. Historically, clinical embryology developed as a field substantially dependent on an individual specialist’s technique and craft competence—the “manual factor.” However, empirical data from 2024 indicate a stable shift toward standardization and reduced dependence of outcomes on personal performer characteristics, achieved through process automation and implementation of AI systems [1].

Modern laboratories simultaneously experience pressure associated with changing patient profiles: the trend toward delayed childbearing correlates with reduced ovarian reserve and deterioration in oocyte quality, thereby strengthening the rationale for using more gentle micromanipulation technologies. In this context, Piezo-ICSI-class methods are increasingly viewed as

tools for minimizing mechanical trauma and reducing the cell's induced stress response during sperm injection [2]. In parallel, the development of digital quality infrastructure—implementation of electronic quality management systems (eQMS) and systematic incident registration—forms datasets suitable for advanced analytics, detection of latent patterns, and prevention of recurring failures at the system level [5].

This study undertakes a systems-level analysis of how process design, educational loops, and interdisciplinary exchange of practices contribute to building a sustainable model of quality. Quality is conceptualized not as a static result but as a continuously closed cycle (a QA loop), in which fertilization indicators, blastocyst formation dynamics and quality, and implantation frequency function as feedback signals for updating training modules and refining technological protocols. International experience—primarily from European countries, North America, and the Asia-Pacific region—is considered in relation to the introduction of safety systems and updated competency standards relevant to the 2025 agenda.

The aim of the article is to analyze how process design, staff training, and experience exchange shape and sustain a quality culture in the embryology laboratory amid the technologization of ART (CAPA/near-miss, KPI, automation, and AI).

The author's hypothesis is based on the assumption that stable growth in the reproducibility of laboratory KPIs and clinical outcomes (up to and including an increase in cumulative live birth rate) is achieved through the simultaneous integration of three loops—standardized processes (CAPA/FMEA and KPI monitoring), continuous competency-based training (including certification/simulation), and institutionalized experience exchange (near-miss reporting)—strengthened by automation and AI.

Scientific novelty lies in proposing a holistic “QA loop” model of quality culture for the embryology laboratory, in which the technological layer (Piezo-ICSI, day-0 automation, AI-based morphology/time-lapse assessment) is linked with high-reliability managerial mechanisms (CAPA, near-miss, contextual interpretation of KPI/stratification) and an educational infrastructure (ESHRE/simulation) as a unified system for reducing the human factor and outcome variability.

Materials and Methods

The methodological foundation of the study was formed on the basis of a systematic review and meta-analytical processing of publications indexed in Scopus, Web of Science, and PubMed. To reconstruct an integrated model of quality-culture formation, an interdisciplinary design was used, integrating tools from clinical embryology, managerial approaches to risk assessment and mitigation, and analytical frameworks from health economics.

The empirical base was built from several groups of primary sources. The market analytics block included reports from Markets and Data, Research and Markets, and Towards Healthcare, providing statistical parameters of the global ART market, IVF cycle performance indicators, and trends in adoption of AI solutions. The regulatory–conceptual contour was formed by materials of the Vienna Consensus, ESHRE (European Society of Human Reproduction and Embryology) standards, and recommendations of Alpha Scientists in Reproductive Medicine, which establish key performance indicators (KPI) for embryology laboratories and principles for their interpretation. The clinical corpus for the year was represented by data from multicenter studies of Piezo-ICSI technologies, automated “day-0” solutions (pearls), and comparative analyses of ovarian stimulation protocols with emphasis on their effects on laboratory metrics [1, 4].

Evaluation of workforce preparation relied on analysis of ESHRE certification programs for clinical embryologists and on empirical data regarding the use of simulation training models as instruments for skill standardization and reduction of manipulation variability [5, 14]. Environmental and engineering parameters of the laboratory setting (VOC, CO₂, temperature tolerances) were examined in relation to industrial hygiene norms and specialized review works devoted to sustainability of ART laboratory infrastructure [16].

Results and Discussion

Interpreting the formation of a quality culture in the embryology laboratory outside the framework of global economic conditions is methodologically unsound, because those conditions set the pace, standards, and architecture of competition in the ART sector. In 2024–2025, the market demonstrates a stable movement toward provider consolidation and accelerated technologization of the production loop, under which the quality of the embryology stage becomes not an auxiliary characteristic but a central parameter of managerial effectiveness. The development vector is determined not only by clinical need but also by transformations in social behavior: the rising share of delayed motherhood cases increases the frequency of patient presentations with unfavorable baseline biological prerequisites. Reduced ovarian reserve and variability in oocyte quality in such cohorts objectively complicate achievement of reproducible outcomes and thereby increase demands for procedural precision, microenvironmental stability, and discipline of technological protocols [1].

To systematize the results obtained and to discuss them within a single “QA loop” logic (processes → competencies → knowledge exchange → managerial mechanisms → environment), Table 1 below presents a structured comparison of the key loops through which a quality culture is formed in an embryology laboratory, alongside their managerial instruments, technological solutions, and the expected effects on laboratory KPIs and the reproducibility of clinical outcomes.

Table 1. Loops of quality-culture formation in the embryology laboratory (QA loop): instruments, technological solutions, and expected effects on KPIs and outcome reproducibility [3, 11, 14, 20, 22, 24]

Quality-culture loop (QA loop)	What is demonstrated in the text	Tools/mechanisms (management)	Technological solutions (practice)	Which KPI/metrics the loop targets (per the paper’s logic)	Expected effect (per the discussion)
1) Process loop: standardization of operations and critical control points	The laboratory as an algorithmic chain with CCPs; the aim is to reduce variability and protocol drift	SOP standardization, protocol discipline, deviation control	—	Reproducibility of laboratory KPIs; process stability	Lower outcome variability; reduced “protocol drift”
2) “Gentle micromanipulation” technologies: Piezo-ICSI	Piezo-ICSI as a manageable, more standardizable modification of ICSI that reduces dependence on the “manual factor”	Managerial value: lower inter-operator variability; easier skill standardization	Piezo-ICSI (piezo pulses; controlled traversal of zona pellucida)	Oocyte survival, degeneration, fertilization, embryo quality	Less mechanical stress → higher manipulation reproducibility and improved laboratory outcomes
3) Day-0 automation: integration of routine steps into a single cycle	Evaluation is not reduced to one efficiency metric; the goal is to remove fatigue/protocol drift	Lower fatigue effect; routine standardization; repeatability control	Automated day-0 solutions (oocyte search/denudation/ICSI in one cycle)	Fertilization (as compared in the text); variability of procedure execution	Even with current fertilization gap vs expert manual work—gain in stability and controllability
4) AI loop: standardized morphology assessment and decision support	Shift to data-driven management; reduction of subjectivity and selection variability	Standardization of assessments; predictive analytics; cross-specialist comparability	AI sperm morphology; AI embryo selection (time-lapse); oocyte quality prediction pre-fertilization	Consistency of embryo selection; reduced subjective error; potentially improved cumulative outcomes	Less “human bias” in assessment → higher decision concordance and stronger quality controllability

5) Competency loop: certification and continuous training	Quality culture “rests” on competence; certification as the start of a continuous cycle	Competency-based training; regular skills evaluation; knowledge renewal	ESHRE certification; module updates (incl. AI ethics/data)	KPI reproducibility across operators; inter-operator variability	Baseline competence standardization → more stable KPIs under comparable conditions
6) Simulation training: a “safe loop” for novices	Separation of motor/cognitive skill formation from clinical flow	Achievement of competency thresholds (Vienna); reduced training-related risks	Skill Simulation Labs; models for ICSI/TE biopsy, etc.	Lower incident frequency; stable execution of critical manipulations	Fewer errors and “quality jumps” during onboarding → predictable professionalization trajectory
7) Knowledge exchange loop: near-miss reporting and blame-free review	Maturity appears when knowledge exchange is institutionalized and errors are “decriminalized”	Near-miss reporting; regular reviews; learning-oriented meetings	eQMS/incident registration (as data infrastructure in the text)	Incident recurrence; identification of latent process vulnerabilities	Earlier bottleneck detection → prevention before clinically significant violations
8) CAPA + RCA + FMEA: translating deviations into manageable change	CAPA as “detect → understand cause → implement prevention”; FMEA as a preventive optic	CAPA, RCA, FMEA, RPN, risk prioritization	Maintenance regulations; calibration; alarms; rebuilding control procedures	Repeat nonconformity frequency; risk profile (RPN); process robustness	From reactive symptom removal → prevention of recurrence at the system level
9) KPI loop (Vienna): measuring quality maturity + metric stratification	KPIs are context-dependent; without stratification, lab effect cannot be separated from patient profile/COS tactics	KPI dashboard; stratification (age, COS protocols); correct interpretation	—	Blastocyst rate/reaching blastocyst stage (as in the example); other Vienna KPIs	Objective quality control: comparability and fewer false managerial conclusions
10) Physical environment loop: stability of temperature/gases/air	Environment as a direct determinant of reproducibility; temperature as a distinct risk zone	Monitoring discipline; tolerance ranges; protocols for work outside incubator	Temperature/gas control systems; air cleanliness/VOC approaches	Risk of early stress exposure; developmental quality	Preventing latent stressors → more stable early-stage development
11) “2025+” loop: integration of data/ethics/sustainability/communication	The lab becomes part of distributed loops (data, ecology, communication)	Data governance; AI bioethics; sustainability policies; patient-centered transparency	Bioinformatics for PGT; AI monitoring platforms; carbon-footprint reduction	Patient trust/adherence (as a quality instrument); data controllability	Expanded notion of quality: from laboratory precision to systemic responsibility and transparency

The process loop of the embryology laboratory is a set of formalized algorithms governing staff interaction with equipment and biological material, in which each operation functions as part of a single chain of critical control points. In 2024–2025, the primary line of process improvement shifts toward technologies aimed at reducing cellular stress and, consequently, decreasing outcome variability driven by microtrauma and fluctuations in manipulation conditions.

Traditional intracytoplasmic sperm injection (ICSI) entails mechanical passage through oocyte envelopes, which, under unfavorable biomechanical parameters, may be associated with risk of cell lysis and/or persistent disruption of cytoskeletal architecture. Against this background, piezo-assisted microinjection (Piezo-ICSI) is conceptually positioned as a more delicate modification of the intervention, providing controlled traversal of the envelopes via pulsed energy and a more predictable penetration trajectory. Publications from 2024, including multicenter studies and sibling oocyte split trials, demonstrate a statistically significant advantage of Piezo-ICSI across a range of laboratory outcomes, interpreted as a consequence of reduced mechanical stress and improved manipulation reproducibility [4].

The mechanistic basis of Piezo-ICSI is associated with the use of high-frequency piezoelectric impulses enabling controlled passage of the micropipette through the zona pellucida with minimal deformation of membrane structures. By reducing the amplitude of mechanical impact, the intensity of cellular stress is attenuated, which is associated with higher gamete survival and greater reproducibility of the immediate manipulation result [11]. Within the logic of a quality culture, the technological transition to Piezo-ICSI has principled managerial significance: the procedure is more amenable to standardization and less dependent on subjective tactile and visual interpretation of the “piercing” moment, thereby smoothing inter-operator variability and narrowing the gap between differing levels of embryologist experience [11].

In 2024, the results of implementing sequential “day-0” automation systems (pearls), integrating oocyte search, denudation, and ICSI within a single operational cycle, became a subject of intensive professional discussion [11]. At the current maturity level of such solutions, fertilization rates under automated operation (64.3%) remain lower than those achieved by expert manual performance (81.0%). Yet evaluation of these systems within the quality contour is not exhausted by comparing a single efficacy metric: automation targets fundamental sources of variability—protocol drift arising from unintentional deviations from standard procedures, and operator fatigue effects that reduce precision and stability of routine micromanipulations [11].

By 2025, AI-based solutions had, in effect, become integrated into the infrastructure of quality control and predictive analytics, enabling a transition from retrospective assessment to data-driven management. Deep learning algorithms are applied in several key directions. First, automated morphological analysis of sperm [22]. Second, embryo selection: AI models analyze developmental kinetic parameters in time-lapse systems, reducing the probability of subjective error in selecting a transfer candidate and increasing decision consistency across specialists [3]. Third, assessment of oocyte quality: in 2025, projects are developing that aim to predict oocyte viability prior to fertilization (e.g., Fairtility), expanding the possibilities for individualized planning and increasing the precision of patient counseling regarding probability of achieving an outcome [24].

Figure 1 presents the architecture of the automated laboratory workflow (compiled by the author based on the sources cited in the text, including [11]).

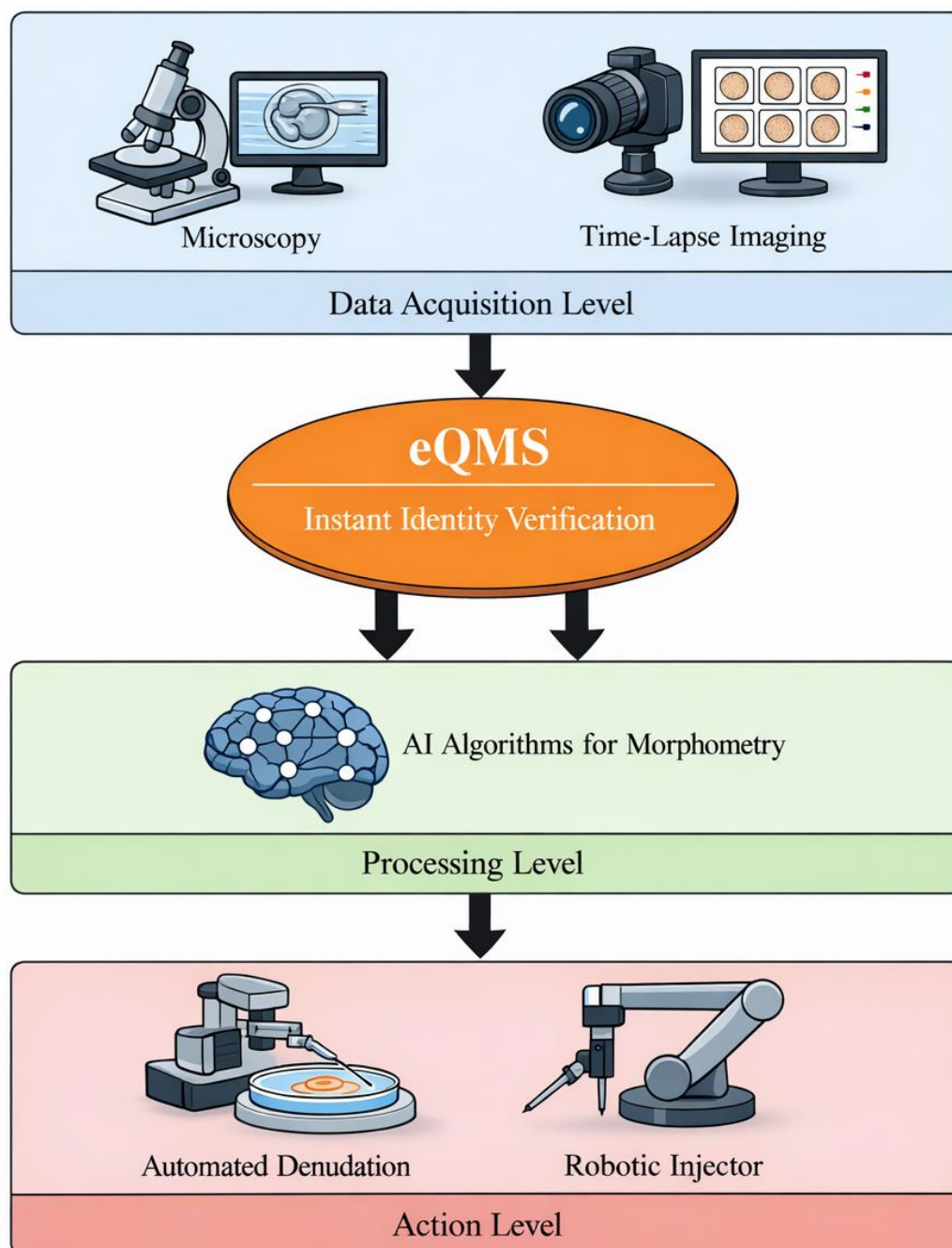


Fig. 1. Architecture of the automated laboratory workflow [6]

A quality culture in clinical embryology is structurally anchored in the level of staff professional competence, because the human factor ultimately determines both the precision of micromanipulations and the stability of protocol adherence under high operational load. In 2024–2025, international practice consolidated a paradigm of competency-based training, in which formal certification is interpreted not as a final verification of professionalism, but rather as a starting point for continuous development supported by regular skills assessment and systematic knowledge renewal [25].

The ESHRE certification program—operating for more than a decade and, in practice, functioning as a benchmark for training clinical embryologists—was expanded in 2024 through modules addressing bioethical aspects of AI use and core principles of data governance [14]. The examination architecture is built around competency control across eight key disciplines, ranging from molecular-genetic foundations of reproduction to organizational and managerial components of laboratory work. A ten-year retrospective of outcomes indicates that certified specialists demonstrate more stable reproducibility of key performance indicators (KPI), exceeding comparable groups of non-certified personnel under similar organizational conditions [14, 19]. In this logic, certification performs the function of standardizing baseline competence and reducing inter-operator variability—an effect that aligns directly with the objectives of building and sustaining a quality culture.

Reduction of training-related risks in preparing novice staff in 2024–2025 is supported by active expansion of simulation practices and specialized skill laboratories (Skill Simulation Labs, SSL). These infrastructures create a safe environment for repeated reproduction of critically important micromanipulations—including ICSI and trophectoderm biopsy—using surplus

biological material or high-fidelity artificial models, until competency thresholds specified in the Vienna Consensus provisions are reached [20, 21]. A central effect of simulation-based training is the separation of motor and cognitive skill formation from the clinical stream: incidents become less probable, performance becomes more predictable, and quality standards become institutionally fixed through reproducible trajectories of professional socialization [17, 18].

The most mature stage of quality-culture development becomes visible when an organizational environment is institutionalized in which knowledge exchange—both within the laboratory and across professional networks—functions not as optional communication but as a systemic instrument for error prevention and reduction of outcome variability. In 2024–2025, the ART sector shows intensified orientation toward high-reliability models, implying managed process transparency, standardized discussion of deviations, and translation of accumulated lessons into protocol correction.

During this period, implementation of safety approaches borrowed from aviation becomes more active, above all systems of near-miss reporting. Registration of incidents that could have led to an adverse outcome but were detected and neutralized in time provides access to a particularly informative class of signals about hidden process vulnerabilities. Such datasets make it possible to identify bottlenecks before they transform into clinically significant violations, and to prioritize preventive interventions based on recurrence patterns and the causal structure of episodes [23, 26].

A substantial element of this shift is the decriminalization of errors as a managerial stance: in organizations with a developed quality culture, the dominant logic is “blame-free” discussion, where the focus moves away from personal attribution of fault and toward correction of conditions, protocols, and safety barriers. Empirically, this is reflected in the fact that most episodes are reviewed at regular meetings without punitive rhetoric, instead in a mode of searching for systemic causes and subsequent modification of procedures [5]. As a result, a stable linkage forms between transparency, organizational learnability, and reduced incident recurrence—an effect that becomes critical in high-technology embryology.

To translate identified nonconformities into manageable change, structured CAPA (Corrective and Preventive Actions) and FMEA (Failure Mode and Effect Analysis) methodologies are applied. CAPA operates as a full-cycle response algorithm: detection of a deviation triggers not only immediate symptom correction, but also a formalized root cause analysis (Root Cause Analysis, RCA), followed by development and implementation of preventive actions aimed at eliminating recurrence risk [5, 10]. Typologically illustrative is the example of incubator temperature drift: what matters is not merely return to an acceptable range, but identification of the source—ranging from sensor defects and calibration peculiarities to organizational factors of maintenance and monitoring—followed by embedding changes in control regulations, technical service schedules, and alarm threshold criteria. FMEA, in turn, ensures proactive identification of potential failure modes with risk ranking, allowing quality to be managed at the level of prevention rather than post hoc reaction (see Fig. 2).

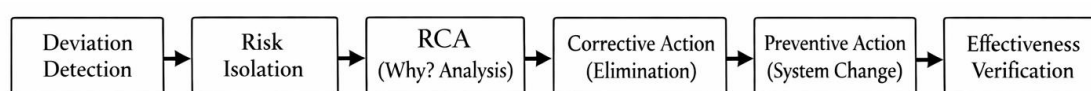


Fig. 2. The CAPA cycle within the laboratory quality management system [5, 9, 13]

The effectiveness of such actions is evaluated through the Risk Priority Number (RPN) within the FMEA framework. Errors with elevated RPN values require immediate intervention. According to 2025 data, the highest laboratory risks remain concentrated at the patient identification stage, a reality that has driven broad implementation of electronic witnessing systems. To measure the “maturity” of a quality culture, standardized KPIs are used, updated within the Vienna Consensus framework [7, 8]. A notable methodological shift in 2025 was the consolidation of the idea that KPIs in embryology are context-dependent: key indicators do not possess a “universal” interpretive force and vary depending on clinical strategy, primarily the controlled ovarian stimulation (COS) protocol. Illustratively, the probability of reaching the blastocyst stage is statistically higher when long agonist protocols are used compared with microstimulation regimens [12]. Within the logic of a quality culture, objectivity of control is achieved through metric stratification—at minimum by patient age cohorts and therapy types—allowing separation of the laboratory performance effect from the influence of baseline biological resources and chosen therapeutic tactics [12, 15, 30].

A quality culture includes not only managerial procedures and technological protocols, but also disciplined maintenance of the physical environment as a component that directly determines reproducibility of embryological outcomes. Stability of temperature, gas composition, and air cleanliness constitutes a critical condition for preserving cellular integrity and preventing latent stressor exposures that, at early stages of embryo development, can exert a disproportionately large biological effect.

Temperature stability is treated as a distinct risk zone: manipulations outside the incubator require strictly controlled conditions, whereas even short-term temperature drops can trigger depolymerization of the oocyte meiotic spindle, potentially affecting subsequent developmental quality [27, 28]. The forward trajectory of ART in the 2025+ logic is increasingly

unambiguously tied to interdisciplinary integration: the embryology laboratory ceases to function as an autonomous “closed” module and becomes progressively embedded in distributed loops of data, ethics, ecology, and communication. Bioinformatics assumes an expanded role as an infrastructure for processing sequencing data in PGT-A/M and managing high-dimensional information arrays, where quality is determined not only by laboratory-stage precision but also by correctness of computational interpretation [29]. In parallel, sustainability shifts from an optional topic to a component of corporate responsibility: reducing the carbon footprint by optimizing incubator energy consumption and routing plastic recycling is beginning to be treated as part of the contemporary managerial standard for ART laboratories [16]. Finally, the patient-centered vector continues to strengthen: increasing transparency of results and informing patients about process stages, including via AI-based monitoring platforms, is associated with growth in trust and adherence, effectively placing communication among instruments of quality rather than service alone [26].

Conclusion

The formation of a quality culture in the embryology laboratory represents a dynamic, self-adjusting system in which technological innovation, regulatory standardization, and humanistically oriented management of human resources form a unified loop ensuring reproducibility of clinical outcomes. Synthesis of the 2024–2025 materials supports several foundational propositions.

First, technological reorientation toward methods that minimize cellular stress—including Piezo-ICSI and automation of “day-0” procedures—functions as one of the key levers for increasing predictability of laboratory outcomes. Within this logic, reducing oocyte degeneration rates and increasing blastocyst yield appear as realistic target benchmarks for centers that have structured process governance according to principles of high reliability and controlled variability.

Second, workforce preparation in clinical embryology is increasingly shifting from an episodic model of certification toward institutionalized continuous competency control aligned with the Vienna Consensus KPI framework. Use of simulation infrastructures that standardize formation of manual skills, combined with AI decision-support instruments, reduces risks of operational instability associated with the human factor and increases inter-operator consistency at critical points of the process.

Third, a mature quality culture is functionally impossible without managed transparency and formalized reporting channels. Replacing a punitive lens with a learning-oriented one—implemented through systematic analysis of near-miss episodes and application of CAPA methodology—moves deviation management from fragmented reactions to a mode of continuous organizational learning and prevention of critical failures.

Ultimately, ART competitiveness is determined less by possession of the most advanced equipment than by a medical organization's capacity to integrate technological infrastructure, human capital, and protocol discipline into a single self-learning quality management system. It is precisely this connectedness that enables maximization of the probability of delivering a healthy child against the backdrop of increasingly complex patient profiles and shifting global challenges that shape the organization and standards of reproductive care.

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