Development of Managerial Thinking as a Prerequisite for Implementing Improvements in an Embryology Laboratory

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Abstract

Within the present study, an expanded analysis of managerial thinking is performed as a pivotal factor determining the success of modernization in embryology laboratories within assisted reproductive technologies (ART). Against the backdrop of accelerating growth in demand for in vitro fertilization (IVF) procedures and the objective necessity to adopt automated solutions, the human component of management acquires a system-forming significance, since it is precisely this component that sets the logic for aligning the technological, temporal, and quality contours of the laboratory process. The analytical focus is placed on a shift in the managerial paradigm from reactive models aimed at eliminating deviations after they have occurred, toward proactive practices that assume preventive risk management and anticipatory design of process resilience. Substantial attention is devoted to the implementation of Lean principles as an instrument for standardization, loss reduction, and improved reproducibility of critically important procedures.

Separately, the problem of balancing algorithmic support and professional reflection is conceptualized: expanding the use of artificial intelligence (AI) in laboratory diagnostics and management (including AI-based embryo selection) and the development of robotic complexes increase efficiency only under conditions of a mature managerial culture capable of integrating technologies with protocols, staff training systems, and risk-oriented control. It is established that isolated implementation of technical innovations without transforming the cognitive and organizational leadership patterns limits the potential clinical effect and increases dependence of outcomes on non-formalized practices.

As a result, a methodological framework is formed for the managerial tier of ART clinics, oriented toward increasing pregnancy rates through a targeted transformation of managerial attitudes and process architecture that ensures synergy among standardization, competency development, and quality monitoring.

Keywords: managerial thinking, embryology laboratory, key performance indicators (KPI), assisted reproductive technologies (ART), Lean manufacturing, artificial intelligence, standardization, quality management, CAPA, leadership.

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Introduction

The global assisted reproductive technologies (ART) sector is entering a phase of systemic restructuring whose scale over the coming decades takes on the character of a structural shift [1]. This dynamic is driven not only by demographic trends and expanded access to medical care, but also by technological renewal of laboratory infrastructure, which changes the "production logic" of service delivery. At the same time, the expected expansion of activity is associated with pronounced resource strain: meeting the forecasted demand implies an additional need for approximately 43,000 embryologists and the necessity to establish new specialized centers [1]. Under conditions of personnel and infrastructure deficits, traditional extensive growth trajectories lose effectiveness, which highlights the transition toward qualitative reconfiguration of managerial contours.

The embryology laboratory functions as the central unit of an ART clinic, where finely organized biological processes are embedded within a strictly regulated technological environment. Historically, the performance of the laboratory block has been associated primarily with the level of embryologists' biological competence and the characteristics of culture media. However, contemporary observations demonstrate that, even when the materials used are comparable and protocols are formally similar, outcomes across centers may differ markedly [2, 19]. A substantial portion of this variability is explained by the presence of a "managerial gap"—a mismatch between organizational architecture and the pace and complexity of internal and external challenges, as a result of which the system is insufficiently sensitive to sources of deviation and fails to ensure stable reproducibility of outcomes.

Within this frame, managerial thinking is interpreted not as an auxiliary administrative function but as a basic cognitive prerequisite that determines the effectiveness of implementing improvements. Its content includes the capacity for systemic process analysis, reconstruction of causal relationships between organizational decisions and biological outcomes, and readiness for continuous reflection and adaptation of procedures. Technological innovations—including the use of AI systems for analyzing embryo morphokinetics and automated monitoring of culture parameters—impose requirements on laboratory leadership that go beyond technical awareness: a shift in managerial optics is required, from a linear control model toward management of complexity, where priority is given to aligning protocols, flows, quality, and risks within a unified logic [3].

The relevance of the study is determined by the demand for a conceptual management model that enables embryology laboratories to scale while consistently improving IVF cycle efficiency without loss of reproducibility. The analytical focus is directed toward identifying how the development of specific leader competencies—from critical thinking to Lean tools—relates to key indicators of the laboratory stage, including blastocyst formation rate and fertilization rate, and ultimately to the live birth rate.

The aim of the work is to identify and substantiate how the development of managerial thinking in the head of an embryology laboratory ensures successful and sustainable implementation of improvements (Lean/standardization, KPI/CAPA, digitalization and AI), with a final orientation toward increased reproducibility of embryological indicators and ART outcomes.

The author's hypothesis is based on the assumption that the clinical effect of automation and AI (as well as "point" technical innovations) becomes reproducible only with a transition to proactive, risk-oriented management that links process time discipline, standardized protocols, continuous training, and KPI monitoring into a unified self-learning system.

The scientific novelty lies in the fact that the work proposes a management framework for embryology laboratories that operationalizes "managerial thinking" through measurable contours (timing as a critical quality variable; KPI as an early warning; Lean tools 5S/VSM; near-miss/CAPA as a mechanism of organizational learning) and demonstrates on large datasets that the key to improvements is not reduction of workload volume, but management of variability and integration of digital solutions with culture and process architecture.

Materials and Methods

The methodological toolkit included complementary analytical procedures. In the statistical block, multifactor linear regression and generalized estimating equations (GEE) were applied, which enabled identification of associations between managerial parameters (intensity of staff workload, duration and structure of time intervals) and biological results while accounting for key confounders, including maternal age, male-factor infertility, and culture conditions. In the machine learning component, the predictive validity of AI algorithms was assessed when modeling the clinical pregnancy rate (CPR), and their function was considered as an instrument for standardization and objectification of individual staff KPI. The conceptual contour of the study was supplemented by developing the "Routine, Relief, Resilience" (Three R) model and the "Innovation

Culture Cycle" model, intended for diagnosing laboratory readiness for implementing improvements and for sustainable adoption of change. To analyze production organization, a Lean audit was applied with a focus on the performance of the 5S methodology and value stream mapping (VSM) under embryology cleanroom/bench conditions.

Research procedures were implemented in compliance with principles of scientific ethics; all data were subject to de-identification. The analytical emphasis was shifted from describing direct effects to identifying second- and third-order relationships between the type of managerial thinking and the stability of laboratory indicators, which allowed variability of outcomes to be considered as a derivative not only of biotechnological factors but also of the cognitive–organizational architecture of management.

Results and Discussion

Within the conducted study, empirical evidence is obtained that records a direct linkage between managerial decisions and the quality of the embryological stage of ART. The set of results is logically grouped around three interrelated contours: operational performance, standardization regimes, and mechanisms for embedding digital technologies into laboratory practice.

In the plane of operational efficiency, the central managerial parameter is the architecture of workload distribution across personnel. The common premise that an increase in manipulation volume inevitably reduces procedure quality was not verified within the analyzed dataset. A retrospective review of 7,986 cycles demonstrated the absence of a statistically significant association between the daily number of performed procedures—both at the laboratory level and per operator—and the mean blastocyst formation rate (m-BR) [5]. This result points to the principled possibility of high-throughput operation of large laboratories without degradation of biological outcomes, provided that the managerial system ensures alignment of schedules, correct task routing, and predictability of production flows.

At the same time, it is identified that the most vulnerable link is not the quantitative volume but the time discipline of the process. Strictness of procedural timing acts as a critical factor for outcome stability: managerial optics focused on controlling time intervals as a quality parameter is statistically associated with cycle success. In this context, timing should be treated not as a formal regulation but as a controllable variable through which the organizational system translates biological constraints into reproducible technological actions (see Table 1).

Table 1. Influence of time intervals between ART stages on the blastulation rate (m-BR) and statistical significance [5].

Time interval	Study range	Effect on blastulation rate (m-BR)	Statistical significance
Ovulation trigger — oocyte denudation	36–44 h	Decrease by 1.6% for each additional hour of delay	$p < 0.001$; 95% CI: -2.1 to -1.1
Retrieval — oocyte denudation	2–6 h	Longer duration reduces the probability of obtaining at least one blastocyst	Adjusted OR: 0.91

The obtained results demonstrate that practical "optimization" of laboratory activity is often determined not by capital-intensive purchases of new equipment, but by precise tuning of personnel-flow logistics that ensures adherence to the "golden window" of key manipulations. Within this configuration, reduction of variability becomes a priority: managerial thinking oriented toward process concentrates on minimizing deviations from temporal constants as critical determinants of reproducibility of biological outcomes.

In the standardization domain, confirmation is obtained for the position that the greatest efficiency gain is achieved not through isolated implementation of individual improvements but through their systemic coupling. A synergistic effect is recorded under simultaneous deployment of three mutually reinforcing elements: unified protocols, formalized quality control (QC) systems, and continuous staff training programs [11]. The combined use of these components forms a stable contour for managing variability, in which the protocol sets a normative action structure, QC ensures early detection and prevention of deviations, and continuous training supports stability of execution and transfer of “best practices” into daily work mode.

Further, Table 2 describes the components of embryology laboratory standardization: mechanism of influence and expected results.

Table 2. Components of embryology laboratory standardization: mechanism of influence and expected results [11].

Standardization component	Mechanism of influence	Laboratory outcome
Protocol formalization	Reduces the influence of subjective experience across embryologists	Increased reproducibility of results
Continuous QC (pH, temperature)	Ensures stability of the microenvironment for embryos	Compliance with international safety standards
Staff training	Increases professional competencies and responsibility	Increased fertilization rate and probability of pregnancy

It is established that implementation of a system of key performance indicators formed on the basis of the Vienna consensus performs functions that go beyond retrospective fixation of outcomes: such KPI acquire the meaning of an anticipatory control instrument enabling detection of early signs of adverse shifts in the process before their clinical materialization. A fundamentally important enhancer of this approach is the use of AI models in analytical interpretation of KPI, since algorithmic decomposition of indicator variation provides statistical “cleaning” of embryologist assessment from patient-driven influences (age, BMI, etc.), thereby increasing the objectivity of comparing individual effectiveness and reducing the risk of managerial errors associated with false attribution of causes [7].

In parallel, it is shown that the managerial optics of the laboratory leader cannot be reduced to internal optimization of the laboratory contour and requires institutionalized interaction with the clinical block. Results from analysis of 51,728 cycles indicate a reliable relationship between the choice of controlled ovarian stimulation (COS) protocol and the dynamics of embryological KPI [6]. Consequently, variability of laboratory outcomes is substantially shaped by “input” clinical decisions, and sustainable improvement in efficiency is possible only when clinical and laboratory strategies are aligned within a unified system of controllable parameters.

The range of differences in blastocyst formation rate (BLR) across protocols demonstrates that COS scheme choice can create fundamentally different “starting conditions” for the embryological stage [6]. Such an amplitude of variation emphasizes the necessity for laboratory leadership involvement in the clinical decision-making contour when developing personalized patient management strategies: adequate interpretation of constraints set by the quality of the initial biomaterial enables realistic calibration of expectations and correct configuration of technological routes within the laboratory. In this sense, managerial thinking manifests as the ability to align clinical parameters with laboratory resources and risks, forming a unified causal frame from stimulation protocol to reproducibility of embryological outcomes [7].

In the aspect of risk and incident management, a gradual evolution of sectoral managerial culture is noted toward greater transparency and institutionalization of patient safety. According to an international survey, a substantial proportion of centers have implemented systematic nonconformity reporting [8, 9]. This observation reflects a shift away from "silent" practices toward the formation of a procedural organizational memory: documenting deviations and potentially hazardous situations is treated as a source of learning and prevention rather than as an instrument for identifying culpable individuals. As a result, the resilience of laboratory processes increases under conditions of rising workload and an increasingly complex technological environment (see Table 3).

Table 3. Incident reporting and communication practices in embryology laboratories: prevalence and comments [8]

Type of reporting/communication	Comment
Systematic error reporting	Predominantly supported by digital infrastructure
Near-miss reporting	Has high preventive potential, enabling interception of real errors
Regular meetings to review incidents	Treated as a tool for collective learning and the formation of shared practices
Informing patients about critical errors	Reflects movement toward transparency and ethical accountability

Notably, even where internal procedures for incident documentation are in place, the completeness of external reporting remains limited: many laboratories transmit information to national oversight bodies selectively, primarily for the most severe events, while reports of less pronounced deviations often remain within the organization [8]. This asymmetry can be interpreted as a manifestation of persistent institutional concern about administrative consequences, which in practice complicates the transition from a logic of formal compliance to a mature safety culture grounded in systemic learning through the capture of "weak signals." Such an asymmetry is interpreted as an indicator of persistent institutional fear of administrative consequences, which in practice blocks a transition from formal compliance logic to a mature safety culture based on learning the system through fixation of weak signals.

Development of managerial thinking appears as a multilevel trajectory that transfers an embryology laboratory from a "workshop" mode into a high-technology production format while preserving the human dimension. The key meaning of this transformation lies in a shift of the cognitive frame: what becomes manageable is not only individual operations, but also the interconnections among routine, innovation, risk, and knowledge that determine outcome reproducibility.

As an integrative support, the "Three R" model is considered, describing the required balance between Routine (routine stability), Relief (functional relief), and Resilience (system survivability) [4]. The routine contour sets the foundation of reproducibility and includes adherence to SOP, maintenance of temperature regimes, and data integrity; in the absence of stable routine, any technological "improvements" take on the character of destabilizing intervention. The relief contour sets the goal-setting of digitalization: automation, including AI screening and automated planning, should reduce cognitive load, freeing resources for critical assessment of nonstandard situations. Within this logic, reduction of schedule chaos is linked to decreased labor costs and increased team morale as a consequence of flow predictability [4]. The resilience contour reflects the laboratory's ability to remain operable during failures and crises; a managerially mature system relies on "flexible" infrastructure, where staff interchangeability and process scalability are not merely declared but are ensured by training and standardization architecture.

A comparison of reactive ("Riverside") and proactive ("Evergreen") organizational models underscores a fundamental difference in the cognitive pattern of change management. A reactive configuration initiates transformations mainly under pressure from external stimuli—new regulatory requirements or emergency situations—thereby forming inertia and accumulation of latent risks. A proactive configuration treats innovation as a continuous cycle: idea — pilot — implementation — reflection — scaling; it is precisely cyclicity and reflexivity that act as markers of managerial adequacy under high uncertainty.

The embryology laboratory is methodologically well compatible with Lean principles, although medical organizations traditionally show resistance to "industrial" approaches. A substantial argument in favor of Lean implementation is recognition that process inefficiency can increase treatment cost, thereby moving the problem of losses from an abstract managerial plane into a clinical-economic one. Within the managerial field of attention are hidden losses characteristic of the laboratory contour: overproduction and excessive inventory expressed in consumption of an excessive volume of materials or storage of media nearing expiration; waiting and delays arising from misalignment between laboratory and clinic actions, leading to idle time; unnecessary motion caused by irrational layout of incubators and microscopes and increasing embryo time outside a controlled environment; defects, including labeling errors or gamete damage during manipulations [10]. Embedding the 5S methodology (sort, set in order, shine, standardize, sustain) forms an environment of visual control where deviations from the standard become obvious, and the Poka-yoke principle sets an orientation toward designing processes so that error is structurally hindered rather than heroically corrected post factum.

Digitalization and AI introduction create a new managerial dilemma related to the ratio of algorithmic accuracy and preservation of professional reflection. It is noted that AI demonstrates high predictive validity when modeling outcomes, exceeding human capabilities in a range of tasks [7]. At the same time, regular reliance on algorithmic prompts can lead to erosion of critical analysis skills in junior specialists due to an effect of "cognitive offloading" [11, 12]. In such a context, critical thinking is defined as the ability to analyze, evaluate, and synthesize information for a reasoned decision; in knowledge management it performs a verification function, enabling reconstruction of why an algorithm produced a specific output and whether that output carries risks in the given biological context [13, 18]. Mature managerial thinking implies positioning AI as a "second opinion," not as an unconditional regulator of action.

The link between critical thinking and knowledge management is traced at three levels: the individual level—through the embryologist's ability to reflect on personal results; the interpersonal level—through a culture of knowledge exchange where questions and doubts are not suppressed by hierarchy; the organizational level—through conversion of individual experience into collective assets, including knowledge bases and updated SOP [13]. In this way, a mechanism is set through which local expertise becomes stable reproducibility.

A shift in managerial paradigm in high-technology and science-intensive environments is described through the "Next Management" (TNM) concept, emphasizing adaptivity, collaboration, and epistemological "humility" before the complexity of biological systems [3]. Within this approach, six key leadership strengths relevant to a laboratory head are identified: social intelligence as the ability to manage relationships in an interdisciplinary team; flexibility of leadership style depending on staff maturity and situation complexity; empowerment through delegation of responsibility; development of trust through behavioral demonstration of declared values; risk management as a permanent function of protecting patient safety; and "big-picture" vision ensuring understanding of the laboratory's place in healthcare and pathways for translating scientific advances into local practice [14, 17].

Of special significance is the creation of a psychologically safe environment for reporting errors. Under the dominance of fear of punishment, the CAPA (Corrective and Preventive Actions) system is reduced to formal reporting, while real risks move into a latent zone. A contemporary managerial configuration, by contrast, stimulates registration of near-misses, treating them as a resource for prevention and learning that reduces the probability of severe events [15, 16].

Institutionalization of improvements requires structured implementation trajectories; a directive order by itself does not ensure consolidation of innovations in routine practice. An effective scheme includes "innovation champions" in different laboratory sections acting as early adopters and conduits for peer training; interdisciplinary committees synchronizing the laboratory with IT, supply chains, and administration to enable seamless integration of data and resources; pilot projects as a mechanism for testing changes on a limited number of cycles; and success metrics that provide an operationalized understanding of outcomes [4]. At the same time, implementation of AI and automation is described not only as an engineering task, but also as an ethical-managerial challenge including requirements for transparency, correct handling of patient data, and preservation of the human dimension in communication as an element of professional responsibility.

Conclusion

Development of managerial thinking is a basic prerequisite for sustainable functioning and technological modernization of the embryology laboratory in the context of medicine's digital transformation. The obtained results demonstrate that ART procedure effectiveness is substantially determined not by quantitative metrics of staff workload, but by the quality of organizational architecture, discipline of adherence to time regulations, and the presence of mechanisms for institutional self-improvement.

The set of conclusions allows the following statements. First, managerial planning at a number of critical points exceeds biological–technical variables in significance: strict execution of time "windows" (in particular, intervals between trigger and denudation) is a key predictor of blastocyst yield and therefore requires high precision of the logistical contour synchronizing staff, rooms, equipment, and protocols. Second, standardization forms not a constraint but an infrastructure for innovation: only when synergy is achieved among unified protocols, the quality control contour, and a continuous staff training system are conditions created in which digital solutions—including AI instruments—can produce a reproducible effect rather than episodic improvement. Third, a risk management culture sets long-term resilience: institutionalization of near-miss registration and transition to open reflection on errors move the laboratory from reactive elimination of consequences into a self-learning organization model capable of extracting preventive benefit from weak signals. Fourth, new-type leadership is defined by a combination of technological literacy and social intelligence: a managerially competent leader does not replace professional judgment with an algorithmic hint, but builds a balance between applying powerful AI tools and maintaining staff critical thinking as a key line of defense against context-dependent risks.

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