ORGANIZATIONAL AND MANAGEMENT ASPECTS OF ARTIFICIAL INTELLIGENCE IMPLEMENTATION IN REPRODUCTIVE CENTERS

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INTRODUCTION

The dynamic development of artificial intelligence (AI) technologies, particularly machine learning and deep neural networks, opens new horizons for personalized medicine. In the field of reproductive health, AI demonstrates high potential in tasks such as predicting the success of in vitro fertilization (IVF), automated analysis of embryo morphology, and interpreting complex genomic data for preimplantation genetic testing [1, 2]. These technological capabilities theoretically allow for increasing the efficiency of ART cycles, reducing the time for clinical decision-making, and, potentially, increasing the accessibility of high-tech care.

However, there is a significant gap between proving an algorithm's efficacy in research settings and its sustainable integration into routine clinical practice, known in contemporary literature as the "implementation gap" [3]. The bulk of publications focus on the development and validation of specific AI models, while the organizational, economic, and managerial aspects of their integration remain on the periphery of scientific discourse [4]. Implementing AI is not merely purchasing software; it is a comprehensive transformation of a medical organization's business processes, requiring a review of financing models, personnel management, quality assurance, and regulatory compliance [5].

Thus, the relevance of this study is driven by the acute need for scientifically based management approaches that would enable reproductive centers to realize the potential of AI in practice.

The objective of this work is to identify key organizational and management barriers to the implementation of AI technologies in the activities of reproductive centers and to develop a practical model for their step-by-step integration.

Material and Methods: Study design: qualitative, combined (mixed methods). The study was conducted from January to June 2024 and consisted of two consecutive stages.

Systematic Literature Analysis. A search for publications was conducted in the PubMed, Scopus, eLibrary, and CyberLeninka databases for the period 2019–2024 using keywords: "artificial intelligence," "reproductive medicine," "management," "implementation," "barriers" (and their English equivalents). Forty-eight publications met the inclusion criteria: original research, reviews, and analytical articles directly addressing non-clinical aspects of AI use in medicine. The goal of this stage was to form a theoretical framework and a primary list of potential barriers.

Expert Interviews. To verify and deepen the data obtained from the literature, a series of semi-structured interviews was conducted. The developed guide included questions grouped into thematic blocks: technology perception, barrier assessment, expected organizational changes, requirements for implementation support. The target sample of experts (n=12) was formed using the "snowball" method and included:

Group 1 (Strategic Management): Chief Physicians and Commercial Directors of reproductive centers (n=4).

Group 2 (Operational and Clinical Management): Heads of Embryological Laboratories, Heads of ART Departments (n=5).

Group 3 (Technological Specialists): IT Directors and Data Scientists working in the field of medicine (n=3).

The average interview duration was 45–60 minutes. All interviews were recorded (with respondents' consent), transcribed verbatim, and coded.

Data Processing and Analysis. The method of qualitative content analysis with inductive categorization was used to analyze the interview texts. Expert statements were coded and grouped into categories, which subsequently formed the basis for barrier classification. SWOT analysis of the AI integration process was applied for information synthesis and strategic planning. The integration model was developed based on the principles of the process approach and staged change management.

Results: Classification of Organizational and Management Barriers.

Based on the content analysis of the interviews, a hierarchical classification of barriers was developed, consisting of 4 main groups and subcategories:

Regulatory and Legal: "There is no clear algorithm for registering AI as a medical device specifically for embryology... We are entering a gray area" (Chief Physician, expert #1). "Who will be responsible if AI misses an aneuploid embryo? The developer, the doctor, the clinic?" (Head of Lab., expert #6).

Economic: "For a private center, this is significant" (Commercial Director, expert #2). "We cannot bill the patient for a separate 'AI analysis' line item. It is not currently tariffed" (Accountant, expert #12).

Organizational and Personnel: "Embryologists with 20 years of experience ask: 'Why do I need this if I can see everything myself?' Powerful explanatory work is needed" (Head of ART, expert #5). "A new role will emerge – a 'biomedical analyst,' who will serve as the link between embryologists and AI" (Data Scientist, expert #10).

Technological: "Our historical data is fragmented: some in Excel, some in the MIS, some on paper. It would take years to structure it for model training" (IT Director, expert #9). "The integration module for our MIS costs almost as much as the AI itself" (Tech. Specialist, expert #11).

SWOT Analysis of the AI Integration Process.

A SWOT analysis was conducted for a strategic vision of the process. Its results formed the basis for developing a practical model aimed at maximizing opportunities and minimizing threats.

Strengths (S): Potential for improving key performance indicators (implantation rate, live birth rate); Standardization and objectification of embryo assessment; Reduction of cognitive load on the embryologist.

Weaknesses (W): High initial investments; Dependence on a third-party developer; Risk of technical failures.

Opportunities (O): Formation of a competitive advantage in the ART market; Creation of own unique datasets; Participation in shaping industry standards.

Threats (T): Rapid technological obsolescence; Tightening of regulatory control; Risks associated with the protection of personal and biometric data.

Practical Model for Phased AI Integration.

Based on the identified barriers and the SWOT analysis, a three-level model, implemented cyclically, is proposed.

Stage I: Formation of a working group (clinic, IT, finance) → Data readiness audit (Data Maturity) → Analysis of the legal landscape and risks → Financial modeling.

Stage II: Selection of 1-2 priority processes (e.g., blastocyst assessment) → Contract signing with a vendor (with buyout option) → Parallel validation (AI vs. standard method) → Training of key users → Assessment of intermediate KPIs*.

Stage III: Decision to scale to all processes → Technical integration with MIS/LIS → Adjustment of regulations and job descriptions → Continuous monitoring and assessment of clinical and economic effectiveness.

*Intermediate KPIs: time to analyze one embryo, intra-laboratory consistency coefficient (Cohen's kappa), staff satisfaction.

Each stage is accompanied by management actions: at Stage I – approval of the budget and roadmap; at Stage II – daily monitoring of the pilot and feedback from personnel; at Stage III – institutionalization of changes, inclusion of new KPIs in the incentive system.

Discussion: The study results confirm the thesis that the main obstacles on the path to digitalization in medicine are not technical but organizational and managerial in nature [6, 7]. The identified barrier structure aligns with models proposed for other areas of medicine, such as radiology and oncology [8], yet has its own specifics. In reproductive medicine, due to high ethical and emotional stakes, issues of responsibility and trust in the "algorithm's decision" are heightened [9]. As one expert noted, "the patient pays for human expertise, not a machine's," which presents the center's management with a complex marketing and communication task.

The proposed three-stage model aims to reduce risks associated with large investments. The "pilot project" strategy allows testing the technology in real-world conditions with a limited budget, assessing its actual impact on workflows and staff attitudes before deciding on full-scale implementation. This approach aligns with the principles of agile management and evidence-based management in healthcare [10].

A key practical conclusion is the necessity of creating an interdisciplinary working group at the very start of the project. Success depends not only on embryologists and IT specialists but also on the active involvement of lawyers, financiers, and quality service managers. Only such a comprehensive approach allows for adequate assessment of all

aspects: from compliance with Federal Law No. 152 (on personal data) to calculating the breakeven point.

Study limitations are related to the qualitative interview method and the limited sample of experts primarily from large private centers. The perspective of public institutions and regional centers may differ. Future research prospects lie in the quantitative assessment of the economic effectiveness (cost-effectiveness analysis) of AI implementation in ART and in the development of standard organizational and administrative documents (regulations, job descriptions) for centers beginning digital transformation.

Conclusion: The implementation of artificial intelligence technologies in reproductive centers is associated with a complex of interrelated barriers, the leading ones being regulatory uncertainty and high economic risks.

Overcoming these barriers requires the management of medical organizations to apply a systematic management approach, focusing not only on the clinical validation of the technology but also on the transformation of business processes, change management, and building a financial model.

The developed practical model of phased integration, based on the principles of cautious scaling and constant assessment of intermediate results, provides reproductive center managers with a structured tool for planning and implementing digital transformation projects, minimizing risks and increasing the likelihood of success.

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