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MANAGEMENT STRATEGIES FOR IMPLEMENTING ARTIFICIAL INTELLIGENCE IN THE CLINICAL PRACTICE OF REPRODUCTIVE CENTERS: OVERCOMING THE "IMPLEMENTATION VALLEY"

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INTRODUCTION

Artificial intelligence (AI) technologies, including machine learning and deep neural networks, are becoming a key driver of personalized medicine. In reproductive medicine, AI demonstrates high efficacy in predicting the success of in vitro fertilization (IVF), automated assessment of embryo morphology, and analysis of preimplantation genetic testing data [1, 2].

These tools pave the way for increasing the effectiveness of assisted reproductive technologies (ART), reducing decision-making time, and expanding access to high-tech care. However, a significant gap persists between successful research and routine clinical application—the "implementation valley" [3].

Most publications focus on the development and validation of algorithms, while managerial, economic, and organizational aspects of their integration remain understudied [4]. Implementing AI represents a profound transformation of business processes, requiring a revision of financial models, personnel management, quality control systems, and ensuring regulatory compliance [5].

Thus, the relevance of this work is driven by the shortage of scientifically grounded management solutions necessary for the practical realization of AI's potential in reproductive centers.

The aim of the study is to systematize the key management barriers to AI implementation in reproductive centers and to develop a strategic model for their phased integration into clinical practice.

Materials and Methods: The study design is qualitative, employing mixed methods. The work was conducted from January to June 2024 in two stages.

1. Systematic literature analysis. A search was performed in PubMed, Scopus, eLibrary, and CyberLeninka databases (2019–2024) using keywords: "artificial intelligence," "reproductive medicine," "implementation," "management," "barriers" (and their English equivalents). Forty-eight publications (original research, reviews) addressing non-clinical aspects of AI application met the inclusion criteria. The goal was to establish a theoretical foundation and a preliminary list of barriers.

2. Expert interviews. To verify and deepen the data, a series of semi-structured interviews was conducted. The interview guide included questions on thematic blocks:

technology perception, barriers, expected organizational changes, implementation requirements. The target sample of experts (n=12) was formed using the "snowball" method:

- 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 in medicine (n=3). The average interview duration was 45–60 minutes. All interviews were recorded, transcribed, and coded. Data processing was performed using qualitative content analysis with inductive categorization. For strategic planning, SWOT analysis was used. The development of the integration model is based on the principles of a process-oriented approach and phased change management.

Results

1. Classification of Management Barriers to AI Implementation. Based on content analysis, a hierarchical structure of barriers was identified:

- Regulatory and Legal: "There is no clear algorithm for registering AI as a medical device in embryology. We operate in a 'gray zone'" (Chief Physician, expert #1). "It is unclear who is responsible if an AI misses an aneuploid embryo: the developer, the doctor, or the clinic?" (Head of Lab, expert #6).

- Economic: "High cost of implementation and support. For a private center, this is a serious investment" (Commercial Director, expert #2). "We cannot bill the patient separately for 'AI analysis.' This is not yet tariffed" (Accountant, expert #12).

- Organizational and Personnel-Related: "Embryologists with extensive experience ask: 'Why do I need this if I can see everything myself?' Systematic work on engagement is needed" (Head of ART, expert #5). "A new role will emerge – 'biomedical analyst,' a link between embryologists and AI" (Data Scientist, expert #10).

- Technological: "Historical data is fragmented: some in Excel, some in the MIS, some on paper. Structuring it for model training is a lengthy process" (IT Director, expert #9). "The cost of the MIS integration module is comparable to the cost of the AI solution itself" (Tech. Specialist, expert #11).

2. SWOT Analysis of the AI Integration Process.

- Strengths (S): Improvement in key performance indicators (implantation, live birth); standardization of embryo assessment; reduction of cognitive load on specialists.

- Weaknesses (W): High initial investment; vendor dependency; risk of technical failures.

- Opportunities (O): Formation of a competitive advantage; creation of unique datasets; participation in the development of industry standards.

- Threats (T): Rapid technological obsolescence; tightening of regulatory requirements; risks related to the protection of personal and biometric data.

3. Strategic Model for Phased AI Integration.

A three-stage cyclical model is proposed:

◦Stage I. Strategic Preparation and Audit: Creation of an interdisciplinary working group (clinic, IT, finance, legal) → Data Maturity Audit → Analysis of the legal field and risks → Development of a financial model and roadmap.

◦Stage II. Pilot Implementation and Validation: Selection of 1-2 priority processes (e.g., blastocyst assessment) → Contracting with a vendor → Parallel validation (AI vs. standard protocol) → Training of key users → Assessment of intermediate KPIs*.

◦Stage III. Scaling and Institutionalization: Decision to expand to all processes → Technical integration with MIS/LIS → Updating of regulations and job descriptions → Continuous monitoring of clinical and economic effectiveness.

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

Discussion

The results confirm that the key obstacles to digitalization are managerial, not technical, in nature [6, 7]. The identified barrier structure aligns with the experience of other medical fields (radiology, oncology) [8] but has its specifics. In reproductive medicine, due to the high ethical and emotional stakes, issues of responsibility and trust in algorithmic decisions are particularly acute [9]. As noted by the experts, "the patient pays for human expertise," which creates additional communication challenges for management.

The proposed three-stage model minimizes the risks of large investments through a pilot project strategy. This approach allows for evaluating the technology in real-world conditions, its impact on processes, and personnel perception before full-scale implementation, aligning with the principles of agile and evidence-based management in healthcare [10].

The key conclusion is the necessity of forming an interdisciplinary working group at the project's outset. Success depends on the coordinated work of embryologists, IT specialists, lawyers, financiers, and the quality service head for a comprehensive assessment of all aspects: from compliance with data protection laws to calculating economic efficiency.

Study limitations are related to the qualitative design and the sample of experts predominantly from large private centers. The perspective of state and regional institutions may differ. Future research prospects include quantitative assessment of the economic effectiveness (cost-effectiveness analysis) of AI implementation in ART and the development of standard organizational regulations for digital transformation.

Conclusion

The implementation of AI in reproductive centers is associated with a complex of interrelated management barriers, the key ones being regulatory uncertainty and high economic risks.

To overcome them, management requires a systematic approach focusing not only on the clinical validation of algorithms but also on process transformation, change management, and building a sustainable financial model.

The developed strategic model for phased integration, based on the principles of cautious scaling and continuous outcome assessment, provides reproductive center

managers with a structured tool for planning digital transformation. It allows for minimizing risks and increasing the likelihood of successful project implementation.

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