SECTION 2. THEORETICAL MEDICINE: BASIC DEVELOPMENT TRENDS

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NAVIGATING THE DIGITAL HEALTH INTERVENTION LANDSCAPE: THEORETICAL APPROACHES AND REGULATORY CONSIDERATIONS

НАВІГАЦІЯ ЛАНДШАФТОМ ІНТЕРВЕНЦІЙ ЦИФРОВОЇ ОХОРОНИ ЗДОРОВ'Я: ТЕОРЕТИЧНІ ПІДХОДИ ТА РЕГУЛЯТОРНІ АСПЕКТИ

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Introduction. The digital transformation of healthcare, driven by information and communication technologies (ICT), is a global priority as evidenced by strategic documents from international organizations such as U.S. Agency for International Development (USAID) [1]. Digital health interventions (DHIs) are revolutionizing healthcare systems by improving service accessibility, quality of care, resource optimization, and patient engagement [2]. However, implementing these technologies requires robust scientific justification, comprehensive evaluation, and effective integration strategies. Current research primarily focuses on technological aspects, with a notable gap in studies addressing medical, management and human factors in digital health transformation [3; 4; 5].

This study addresses this gap by analyzing frameworks for DHI implementation, evaluation, and examining regulatory aspects to ensure safe and effective is implementation into medical practice.

The aim of the study is to analyze and synthesize the theoretical landscape for implementing and evaluating digital health interventions, encompassing conceptual, methodological, and regulatory aspects.

The methodological foundations of the research are based on a comprehensive analysis of scientific literature, international recommendations, and regulatory documents in the field of digital health. Methods of system analysis, comparative analysis, and synthesis were used to identify key theoretical approaches to the implementation and evaluation of DHIs.

Results. The study analyzed key theoretical foundations for implementing and evaluating DHIs, revealing the World Health Organization's (WHO) leading role in shaping their conceptual basis. WHO developed a comprehensive DHI classification with four main user-based categories: clients, healthcare workers, health system managers, and data services. This classification provides unified terminology, facilitating evidence base consolidation, national registry creation, and recommendation development [6]. Additionally, WHO published guidelines for using DHIs to strengthen health systems, offering 10 recommendations that emphasize the overall digital ecosystem, including governance, infrastructure, training, and interoperability [7]. While primarily focused on mobile applications, these guidelines are also applicable to non-mobile digital devices.

The research identified several key theoretical frameworks for DHI development and evaluation. The DEDHI (Development and Evaluation of Digital Health Interventions) framework integrates perspectives from behavioral medicine, medical informatics, and information systems research [8]. It outlines four key stages of DHI creation: preparation, optimization, evaluation, and implementation, defining specific goals, tasks, and evaluation criteria for each stage. The TFDD (Theoretical Framework for Designing Digital Based Change Interventions) integrates ideas from goal-setting theory, the transtheoretical model, and behavior change methods [9]. It emphasizes adapting methods to an individual's stage of change and developing users' abilities, opportunities, and motivation.

For DHI effectiveness assessment, the Evidence DEFINED framework provides a structured process for rapid evaluation, including a checklist for DHI-specific issues such as trial reporting and data transparency [10]. The World Bank developed an economic evaluation system for DHIs, comprising five key steps that consider context-dependency, complexity, and AI-related aspects [11]. WHO created a monitoring and evaluation guide that distinguishes between monitoring and evaluation processes, linking them to DHI maturity stages [12].

Regulatory aspects of DHIs also play a key role in their implementation. In the European Union, the main regulatory documents are Regulation (EU) 2017/745 on Medical Devices (MDR) and Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR) [13]. These documents establish risk class classification and basic safety and effectiveness requirements. Additionally, the General Data Protection Regulation (GDPR)

and the Data Act regulate personal data processing and data sharing respectively [14]. Even if DHIs are not classified as medical devices, they are still subject to regulation in aspects of data protection, cybersecurity, and compliance with industry standards.

Conclusions. This study on DHIs underscores the need for an integrated approach to their implementation and evaluation. It reveals that effective DHI deployment requires not only technological solutions but also contextual understanding and organizational considerations. The research identifies the need for a comprehensive framework managing DHIs throughout their lifecycle, encompassing medical, managerial, technological, and economic aspects.

By synthesizing existing theories and highlighting areas for further research, this study contributes to the effective integration of digital solutions in medical practice, paving the way for improved patient outcomes and system efficiency.

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