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Table of Contents

AI IN HEALTHCARE **2**

ETHICAL GOVERNANCE: IMPACT OF ROBOTICS AND ARTIFICIAL INTELLIGENCE ON PHYSICIAN-PATIENT RELATIONSHIPS *2*

HEALTH MANAGEMENT AND BUSINESS INTELLIGENCE **12**

ADVANCING JOB SATISFACTION AND DIGITAL TRANSFORMATION IN HEALTHCARE THROUGH INNOVATIVE METHODOLOGIES *12*

INTEGRATING HEALTHCARE AND TOURISM FOR SUSTAINABLE GROWTH IN CENTRAL MACEDONIA / GREECE *19*

TRANSFORMING HEALTHCARE WITH GREEN LEAN SIX SIGMA: CHALLENGES AND OPPORTUNITIES IN THE DIGITAL ERA *24*

ENHANCING MEDICAL TOURISM FOR SPECIAL NEEDS AND ELDERLY PATIENTS THROUGH DIGITAL INNOVATION AND GREEN LEAN SIX SIGMA *29*

DIGITAL INNOVATION IN HEALTHCARE GOVERNANCE: OPPORTUNITIES AND HUMAN RIGHTS CHALLENGES *35*

PRIVACY CHALLENGES IN DIGITAL HEALTH GOVERNANCE: ETHICAL IMPLICATIONS *44*

QUALITY ASSURANCE IN HEALTH UNITS **53**

THE IMPACT OF INTERNAL AUDITS ON UPGRADING INFORMATION SYSTEMS IN GREEK PUBLIC HOSPITALS: ADDRESSING CORRUPTION AND TECHNOLOGICAL DEFICIENCIES *53*

HUMAN RESOURCES AND HEALTHCARE: FLIPPED TEACHING PRACTICES FOCUSED ON SOCIALIZATION OF WORKERS IN HEALTHCARE UNITS *62*

E-HEALTH POLICIES **73**

THE NEED TO IMPLEMENT THE DIGITAL HEALTH SYSTEM IN THE PENINTIARY SYSTEM IN ALBANIA: A CROSS-SECTIONAL STUDY. *73*

EVALUATION OF THE PERFORMANCE LEVELS OF NURSES WORKING IN EMERGENCY AND INTENSIVE CARE UNITS REGARDING ADVANCED CARDIAC LIFE SUPPORT *87*

EVALUATION OF POST-GRADUATE ORIENTATION PROGRAM FOR SURGICAL NURSING SIMULATION BASED LEARNING EXAMPLE *97*

QUALITY ASSURANCE IN HEALTH UNITS **109**

DIGITAL THERAPEUTICS AS AN EFFECTIVE MEANS TO ADDRESS PSYCHOEDUCATION AND HEALTH SERVICES *109*

ISBN: 978-618-5630-22-5

AI IN HEALTHCARE

ETHICAL GOVERNANCE: IMPACT OF ROBOTICS AND ARTIFICIAL INTELLIGENCE ON PHYSICIAN-PATIENT RELATIONSHIPS

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ABSTRACT

Health Technology assessments and health outcomes research deals with two areas of focus patients and healthcare providers when put into practice. The relationship between physicians and patients is the utmost importance to broaden healthcare systems' efficacy by using Artificial Intelligence (AI) and robotics technologies in support to mitigate the burden of disease through symptoms assessment and treatment. However, the rapid advancement of AI technology has led to an increasing need for ethical standards, laws, and regulations. Innovative technologies, like AI in diagnosis and treatment, can raise ethical concerns and it is critical to examine these concerns in greater detail and update the ethical standards. Trust in these technologies compared to traditional physician-patient dynamics, is often in doubt and perceived as an apprehension or even threat. Medical ethics recognized various challenges in the physician-patient dynamic models. The most successful approach is considered a shared decision-making process. This study evaluated the impact and perception of AI and robotic technologies on Physician-Patient interaction and presented a 'Instructive Model of Physician-Patient Relationship.'

This study examined asymmetries in decision-making, influence on patient-centric interpersonal interactions, public perceptions of technologies and addressed transparency concerns for both healthcare professionals and patients. The results of the study showed that the majority of healthcare professionals (82.1%) and non-healthcare professionals (77.6%) are open to using AI to assist in decision making. A total of (13.9%) of participants are open to the restricted usage of robotics and AI technology

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to assist healthcare practitioners. Only 1.9% of respondents said they were unwilling to utilize AI-based services due to ethical concerns.
Key Words: Artificial Intelligence, Robotics technology, Physician-Patient relationship, Ethics governance

INTRODUCTION

The integration of Artificial Intelligence and robotics technologies in healthcare has emerged as a transformative force, offering the potential to enhance diagnostic accuracy, streamline treatment processes, and address existing healthcare system inefficiencies. Despite these promising opportunities, the rapid adoption of these technologies raises substantial ethical concerns regarding the physician-patient relationship, transparency, data privacy, and the equity of care delivery. AI systems, particularly those employed in diagnostics and treatment, often operate as "black boxes" (European Commission, 2018) with a limited transparency of their internal decision-making processes and complicating informed consent (Rigby, 2019). Patients may struggle to trust AI-driven recommendations, given their lack of understanding of how these systems work. This raises critical questions about the role of physicians as mediators in explaining AI-generated recommendations and ensuring that patients' autonomy is respected. Furthermore, the ethical challenges associated with AI in healthcare are exacerbated by the risk of reinforcing social biases inherent in training data (Rigby, 2019). AI systems, if not carefully designed and validated, may perpetuate existing healthcare disparities by offering suboptimal care for underrepresented populations. Studies have shown that AI technologies may struggle with accuracy in diagnosing conditions in these groups, thus deepening inequities in healthcare access and outcomes (Dowrick, 1997). Moreover, AI's reliance on vast amounts of patient data to function effectively necessitates robust data privacy and confidentiality safeguards. The use of sensitive medical information for training AI algorithms presents significant risks to patient privacy (Emanuel & Emanuel, 1992).

Despite these ethical concerns, the benefits of AI in healthcare are undeniable. AI can enhance the efficiency and accuracy of medical diagnoses, personalize treatment plans, and reduce operational costs, thereby improving patient outcomes and healthcare system sustainability (European Commission, 2018). However, in light of these advantages, there is a pressing need to revise existing ethical standards, regulatory frameworks, and laws to address the unique challenges posed by these technologies. Ethical guidelines must evolve to ensure that AI and robotics serve as adjuncts to human care, supporting, rather than supplanting, the critical interpersonal dynamics inherent in the physician-patient relationship (Emanuel & Emanuel, 1992). The integration of AI and robotics into healthcare presents an array of ethical challenges that must be systematically addressed to ensure that these technologies benefit all stakeholders. The physician-patient relationship must be preserved as a cornerstone of medical care, with AI functioning as a tool that enhances, rather than replaces, the human aspects of care such as empathy, trust, and shared decision-making. In order to realize the full potential of AI and robotics in healthcare, it is essential to establish transparent, equitable, and

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patient-centered frameworks that safeguard both patient rights and the integrity of medical practice (Rigby, 2019).

AI refers to systems that perform tasks typically requiring human intelligence, such as learning and decision-making. In healthcare, AI enhances diagnosis, treatment, and policy planning through data analysis. Despite its potential, challenges like infrastructure and ethical concerns limit widespread adoption, especially outside high-income countries (Vinuesa et al., 2020). Artificial Intelligence is increasingly used across healthcare for diagnosis, prediction, clinical care, health research, and drug development. In diagnosis, AI aids radiology, pathology, and genomics, assisting in disease detection and treatment recommendations. AI's potential in clinical care includes managing chronic conditions and providing real-time interventions through wearable technologies (Topol, 2019).

In research, AI optimizes clinical care and accelerates drug development by analyzing large datasets (Fleming, 2018). Despite its promise, challenges remain in data quality, privacy concerns, and the equitable distribution of AI technology (WHO, 2021; Liu et al., 2019). Robotics technology in medicine and healthcare encompasses a variety of applications aimed at improving patient outcomes and enhancing care efficiency. Hospital robots, such as Moxi, assist nurses by handling routine tasks, freeing up time for direct patient care (Kyrarini et al., 2021). Surgical robots like the Hinotori and Da Vinci systems enhance precision in procedures, offering minimally invasive options with better recovery times (Damani et al., 2021). Robots are also crucial in prosthetics and rehabilitation, providing functional support for patients with disabilities (Okamura et al., 2010). Despite their potential, challenges like high costs and patient acceptance remain barriers to widespread adoption.

Ethics in medicine involves principles guiding healthcare practices, ensuring respect for patient autonomy, beneficence, and justice. Medical ethics frameworks address dilemmas related to patient care, such as fairness, transparency, and privacy. As technology advances, AI and robotics in healthcare raise new ethical concerns regarding responsibility, safety, and human interaction. The ethical principles governing the use of AI in healthcare focus on ensuring the responsible development and implementation of AI technologies while safeguarding fundamental human rights and promoting well-being. A core principle is autonomy protection, where AI systems must support, rather than replace, human decision-making in healthcare contexts, ensuring human oversight and safeguarding privacy and informed consent (Wang & Siau, 2018). Furthermore, human well-being must be prioritized, with AI technologies requiring adherence to rigorous safety, accuracy, and efficacy standards before deployment. Continuous monitoring is necessary to mitigate any potential harm to patients (Blanchard & Peale, 2011). Additionally, transparency and explainability are crucial; AI systems should be designed to be understandable by both healthcare providers and patients, with regular updates and public engagement to ensure accountability and reliability (Markkula Center for Applied Ethics, 2015). Clear frameworks for accountability and responsibility are essential to determine liability in cases of harm caused by AI technologies, whether by developers or clinicians (Yu,

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1998). Inclusivity and equity are also vital, as AI must be accessible to diverse populations and free from biases that may exacerbate healthcare disparities. This requires a careful approach to data representation and diversity to ensure fairness in AI applications (Wang & Siau, 2018). Lastly, AI systems should be responsive and sustainable, with continuous assessments to ensure alignment with evolving healthcare needs, technological advancements, and ethical standards (Nalini, 2019). These principles collectively provide a framework to ensure that AI in healthcare benefits society while minimizing risks and promoting equity.

The physician-patient relationship has evolved from ancient Egyptian magical practices to Greek humanism and medieval religious dominance. The French Revolution introduced patient-centered care, while 18th century advancements returned to paternalism. In the late 19th century, Balint and Freud emphasized psychological factors, advocating for a collaborative approach in healthcare (Kaba & Sooriakumaran, 2007). The physician-patient relationship today is challenged by the rapid evolution of medical technology, which often reduces personal interaction. While scientific advancements are vital, the art of medicine, which includes empathy and understanding human nature, remains essential for effective healing. The traditional paternalistic approach is increasingly seen as insufficient, prompting the need for a new model of physician-patient interaction that balances technology with human connection (Murphy et al., 2001; Hellin, 2002). The focus is on redefining these interactions to meet the evolving needs of modern healthcare (Chin, 2002).

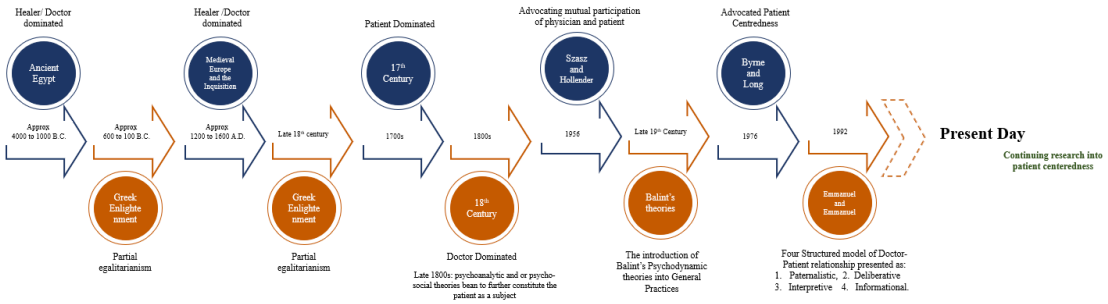

Figure 1: The evolution journey of the Physician-patient relationship

Szasz and Hollender (1956) proposed three models of the physician-patient relationship: activity-passivity, where the doctor holds full control; guidance-cooperation, where the patient cooperates with the doctor's guidance; and mutual participation, which emphasizes equality, collaboration, and shared decision-making, allowing patients more responsibility in their healthcare. Emanuel and Emanuel (1992) delineated four distinct models of physician-patient interaction, each representing varying degrees of physician control and patient autonomy in decision-making. The **paternalistic model** is characterized by the physician exercising complete authority over medical decisions, with the patient passively complying, often due to perceived incapacity to make informed choices. In contrast, the **informative model** grants the patient full autonomy, wherein the physician provides comprehensive information, and the patient independently selects the treatment option, free from physician persuasion. The **interpretive model** shifts the focus to the physician's role in facilitating the

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patient's self-reflection to identify personal values and preferences, ensuring that these factors primarily guide treatment decisions. Lastly, the **deliberative model** embodies a collaborative dynamic, where the physician engages in a dialogical process with the patient, educating and persuading them while retaining the professional prerogative to recommend a treatment path based on clinical judgment. These models collectively underscore the spectrum of interaction between physician influence and patient autonomy, emphasizing the dynamic balance between expert guidance and patient-centered decision-making in clinical practice (Tsai, 2001).

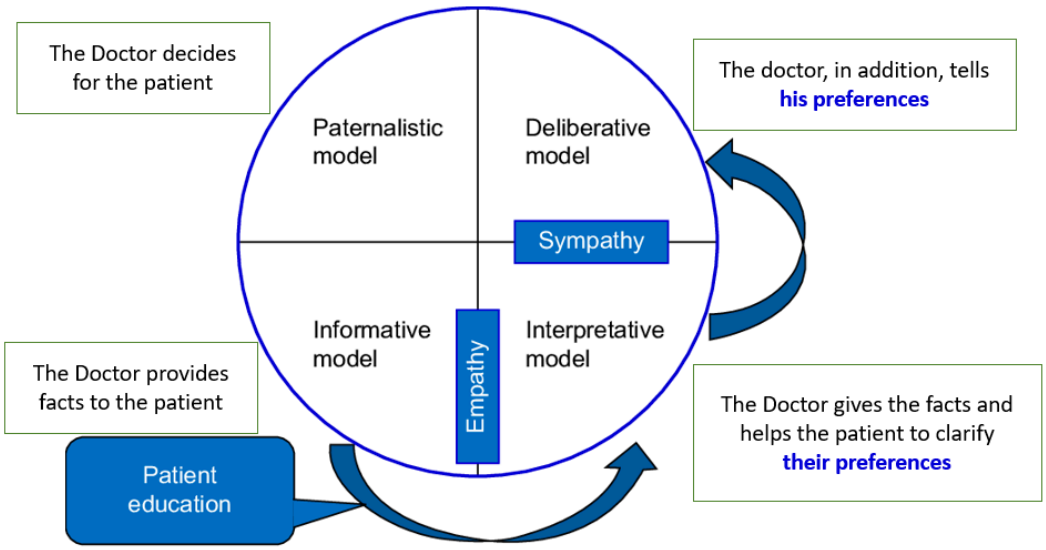

Figure 2: Physician-patient relationship Models (Emanuel and Emanuel, 1992)

The goal of the study was to investigate the consequences of the use of AI and robotic technologies on physician-patient relationship. To operationalize this goal the following research questions (RQ) were defined:

RQ1: How effective are AI and robotic technologies in relation to the physician-patient relationship and healthcare decisions?

RQ2: What ethical asymmetries arise in healthcare decisions due to surveillance practices?

RQ3: How strongly do attitudes toward AI and robotic technologies influence the quality of interpersonal interactions between patients and physicians?

METHODOLOGY

The study utilized a questionnaire-based methodology to identify ethical challenges associated with the integration of AI and robotic technologies in healthcare, with a focus on measurable outcomes while minimizing researcher bias. The target population consisted of participants from a wide range of geographical regions, ensuring diversity. Healthcare professionals were also included in the survey to ensure comprehensibility. Healthcare professionals were also included to ensure clarity and relevance of the survey. Consistent with the introduction of new technological interventions in healthcare, decision-making must be supported by a comprehensive Health Technology Assessment (HTA), integrating interdisciplinary expertise. HTA encompasses the

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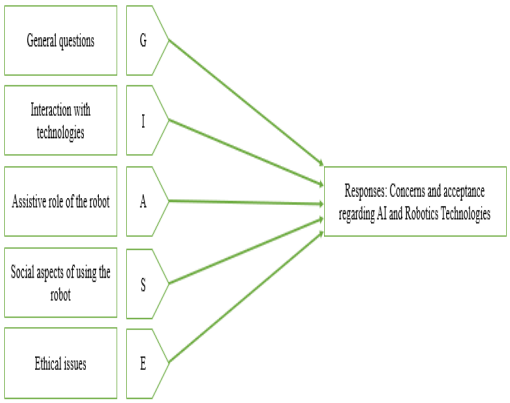
evaluation of treatment effectiveness, cost-effectiveness, and ethical governance, all of which contribute to informed decision-making processes for the implementation of new technologies in complex healthcare systems.



Subsection	Number of questions/ statements
Details on sociodemographic characteristics	6
General information and awareness	4
Evaluation of the respondent's technical affinity	4
AI and robotics technology brings advantages for patient	3
Patient's acceptance of technologies	3
Patients are worried about physicians low AI competence	2
Ethical concern	4

Figure 3: Conceptual framework (Source: Developed by the researcher)

Survey administrations

Data collection was conducted using a structured questionnaire to explore ethical concerns regarding AI and robotics in healthcare, focusing on their impact on the physician-patient relationship. This study followed a positivist paradigm, emphasizing objective, quantifiable data while minimizing researcher bias. The 20-item questionnaire was categorized into five themes: interaction with technology, the role of robots in healthcare, societal impacts, and ethical considerations. Responses were measured using a 5-point Likert scale. The survey was administered online, and 104 participants from Asian and European countries were included. Ethical guidelines and data privacy regulations were strictly followed.

Statistical analysis

The data of the completed questionnaires were digitized, and descriptive statistics were used to analyze demographic variables. Incomplete questionnaires were not imputed. Pearson's Chi-Square test, as implemented in SPSS, was used to assess correlations between variables related to concepts of effectiveness and acceptance.

Notably, participants indicated no significant concern regarding the potential impact of AI on medical treatments, as assessed by their responses to questions on trust in AI. Statistical analysis revealed an asymptotic (2-sided) p-value of 0.001 ($p < 0.01$), suggesting significant results. These findings further demonstrated the applicability and effectiveness of the Technology Acceptance Model in understanding the acceptance of AI technologies in healthcare settings.

RESULTS

The results describe the participation rates of healthcare professionals (82.1%) and non-healthcare professionals (77.6%) in being receptive to using AI for decision-making. In the practice of medical care, 13.9% of participants either utilize or have access to robotics or AI technologies. Another finding of this paper was the fact that a small

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number of 1.9% of respondents refer to ethical considerations as the primary rationale behind their reluctance to engage with AI-based services, as long as physicians are always enrolled and data protection is guaranteed.

In the 'General Information and Knowledgebase' section (Questions 1 to 4), over 45% of participants reported encountering AI in their work, and 20% agreed that technological innovations improve healthcare accessibility. However, 13% of participants aged 60+ strongly disagreed with the notion that AI reduces costs and increases accuracy compared to healthcare professionals. Healthcare professionals, in general, showed more support for AI's benefits compared to non-healthcare participants. In the 'Usage of Technical Devices and Self-Estimated Technical Affinity' section (Questions 5 to 8), 54% of participants aged 60+ accepted the idea of humanoid robots for consultations, while 46% of participants in the 18-30 age group also supported the concept. However, 12% of participants in the 30-45 age group and 4% in the 18-30 group disagreed with using surgical robots for specialized surgeries. Concerns regarding data manipulation by external actors, such as hackers, were also noted. Regarding the 'Assistive Role of Robots' (Questions 9 to 12), 41% of participants aged 18-30, 46% of those aged 30-45, and 43% of the 45-60 age group rated AI positively for use in healthcare. Only a small percentage, 2% of those in the 18-30 age group, 3% in the 30-45 group, and 10% in the 45-60 group, had negative opinions. A majority of respondents to the survey agreed that AI should assist healthcare professionals rather than replace them entirely.

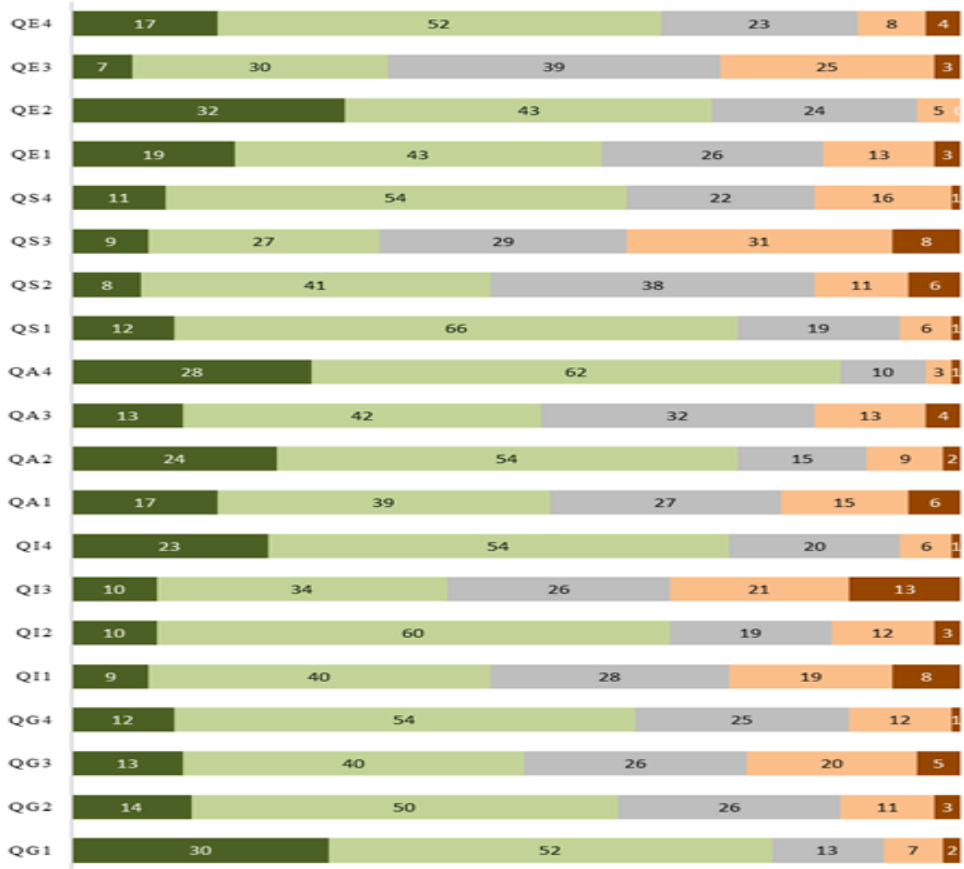

Figure 4. Comprehensive Likert Scale Survey Response

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In the 'Social Impact of Using Robotics Technologies' section (Questions 13 to 16), 60% of participants aged 60+ agreed that AI could help physicians spend more time with patients. A small percentage of participants in the 18-30 (3%) and 30-45 (7%) age groups strongly disagreed with the idea of robotic physicians. Overall, respondents remained neutral, acknowledging the potential social benefits of AI while expressing hesitation about fully replacing human physicians. Finally, in the 'Ethical Issues' section (Questions 17 to 20), concerns over the ethical implications of AI in healthcare were expressed by 22% of participants aged 18-30, 23% of those aged 45-60, and 27% of those aged 60+. Issues related to data privacy and AI's accountability in decision-making were prevalent, with a majority of participants (30%) agreeing that physicians should retain final control over AI-driven healthcare decisions.

CONCLUDING REMARKS – IMPLICATIONS

The rapid integration of artificial intelligence (AI) and robotics into healthcare systems presents both opportunities and challenges in the physician-patient relationship. AI technologies have the potential to enhance clinical decision-making, improve diagnostic accuracy, and streamline healthcare delivery by processing vast amounts of data and performing complex analyses. However, their widespread use raises concerns about the potential erosion of the humanistic aspects of patient care, which is central to the physician-patient relationship. While AI can supplement medical practice by assisting with tasks such as diagnosis, treatment recommendations, and administrative duties, the degree to which it can replace human clinical competence remains debatable. The future of the physician-patient relationship may evolve into a more collaborative model, with AI as a tool to support healthcare professionals rather than replace them entirely. Despite the advancements in technology, it is unlikely that AI will fully replace human expertise in healthcare in the immediate future. Instead, new models of care delivery must be developed that integrate AI and human physicians, ensuring a balance between technological efficiency and the ethical, compassionate aspects of healthcare.To safeguard the moral integrity of the physician-patient relationship, rigorous regulatory frameworks should be established, addressing the ethical implications of AI in healthcare. These frameworks will be crucial in ensuring that patient care remains patient-centered while embracing technological innovation.

Proposed Physician-Patient relationship model - **Instructive Model**

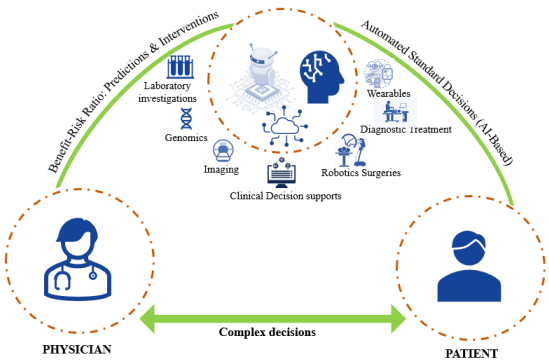

Figure 5: Instructive Model of Physician-Patient Relationship

ISBN: 978-618-5630-22-5

The integration of AI-automated technologies in healthcare is poised to significantly enhance care quality by streamlining diagnoses, increasing access to healthcare services, and improving overall efficiency. The proposed "**Instructive Physician-Patient Relationship Model**" envisions a future where physicians act as orchestrators, prescribing diagnostic tests, seeking specialized expertise, and utilizing Autonomous Algorithmic Decision-Making Systems (AADMS) within the regulatory framework of the General Data Protection Regulation (GDPR) to ensure patient rights and confidentiality. This system aligns with the *Fourth Industrial Revolution*, which aims to harness technological advances to optimize healthcare delivery. However, the integration of AI and robotics in healthcare presents both opportunities and challenges. While these technologies can offer precise diagnoses and enhance access, they may also introduce risks, such as exacerbating healthcare disparities due to uneven technology deployment across regions. Moreover, AI decision-making processes are often opaque, raising concerns over transparency, informed consent, and trust. The use of decontextualized patient data may undermine the human, emotional aspects of care, potentially weakening physician-patient relationships. Additionally, privacy concerns surrounding patient data usage for AI development further emphasize the need for a careful balance between technological advancement and safeguarding patient confidentiality. Addressing these challenges is vital to ensuring that AI technologies in healthcare enhance patient care while preserving core values like trust, equity, and empathy.

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HEALTH MANAGEMENT AND BUSINESS INTELLIGENCE

ADVANCING JOB SATISFACTION AND DIGITAL TRANSFORMATION IN HEALTHCARE THROUGH INNOVATIVE METHODOLOGIES

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ABSTRACT

In the healthcare sector, job satisfaction is vital for ensuring high-quality patient care and the sustainability of healthcare systems. This study examines the intricate relationship between organizational culture and job satisfaction within healthcare settings, focusing on innovative strategies to enhance employee well-being and care quality. Recognizing that satisfied employees are essential for superior patient service, the research emphasizes the need for healthcare organizations to prioritize streamlined work processes and supportive environments.

The study highlights that an organizational culture emphasizing employee well-being can significantly improve job satisfaction (Ayodele et al., 2020). By reducing workplace stress through operational improvements and minimizing bureaucratic obstacles, healthcare organizations can create conditions that foster employee satisfaction (Bhatnagar & Srivastava, 2012). Key factors influencing job satisfaction, such as work environment quality, compensation structures, recognition initiatives, and opportunities for professional development, are examined in detail (Bussing et al., 1999). The research also identifies prevalent challenges in healthcare, including long work hours, increased stress levels, and emotional labor, which negatively impact job satisfaction (Khamlub et al., 2013).

Additionally, the study introduces the integration of Green Lean Six Sigma (GLSS) methodologies as an effective strategy for enhancing job satisfaction while driving digital transformation in healthcare environments (Zhu et al., 2018). GLSS combines Lean and Six Sigma principles with a commitment to environmental sustainability, offering a comprehensive framework for improving operational efficiency, employee engagement, and technological advancement. By systematically eliminating non-value-added activities and involving staff in problem-solving, GLSS empowers healthcare professionals and enhances their sense of ownership and participation in their work (Sreedharan et al., 2018). This empowerment is crucial for enhancing job satisfaction.

Moreover, GLSS supports the digital transformation of healthcare by streamlining processes and incorporating advanced digital tools (Narayanamurthy et al., 2018). This transformation not only improves efficiency and accuracy but also reduces administrative burdens, enabling healthcare workers to focus more on patient care and professional development (Lasalvia et al., 2021). Aligning digital strategies with GLSS

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principles ensures a smooth transition to user-friendly systems, further boosting job satisfaction.

The 'green' aspect of GLSS adds another dimension of job satisfaction by aligning organizational processes with sustainability goals. In an era increasingly focused on ecological balance, healthcare professionals find motivation and pride in working for organizations committed to minimizing their environmental impact. This alignment with personal values fosters a stronger connection to the organization, enhancing job satisfaction (Babapour Chafi et al., 2021; Hoxha et al., 2024).

In summary, this study contributes to the fields of health, well-being, and sustainability by exploring the mechanisms of job satisfaction in healthcare settings. It aims to cultivate a research community focused on refining innovative approaches and recognizing the significant influence of organizational culture on successful initiatives. By optimizing GLSS strategies within supportive environments, the research offers practical implications for creating healthier, more efficient healthcare systems. The findings underscore the critical role of job satisfaction in enhancing healthcare quality and organizational effectiveness, ultimately benefiting healthcare professionals and improving patient care. Key recommendations for healthcare organizations include implementing GLSS strategies to enhance job satisfaction and overall performance.

Key Words: Job Satisfaction in Healthcare, Digital Transformation, Green Lean Six Sigma (GLSS), Healthcare Quality, Organizational culture, Environmental sustainability.

INTRODUCTION

In the healthcare sector, job satisfaction is a vital component that influences not only employee well-being but also the quality of care provided to patients and the overall sustainability of healthcare systems. This study examines the intricate relationship between organizational culture and job satisfaction in healthcare settings. It also highlights innovative strategies to enhance employee satisfaction while improving healthcare quality. By understanding the key elements that contribute to job satisfaction and addressing systemic challenges, healthcare organizations can foster environments that benefit both employees and patients.

Organizational Culture and Job Satisfaction in Healthcare

Organizational culture plays a significant role in shaping job satisfaction in healthcare settings. A culture that prioritizes employee well-being can significantly impact morale and productivity (Ayodele et al., 2020). Healthcare organizations face unique challenges, including long work hours, emotional labor, and high stress levels, which can negatively affect job satisfaction (Khamlub et al., 2013). To combat these challenges, it is essential to create supportive environments where employees feel valued and recognized.

Workplace stress, often exacerbated by bureaucratic inefficiencies and operational challenges, is a primary barrier to job satisfaction. Streamlining processes, reducing unnecessary administrative tasks, and fostering transparent communication can

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mitigate stress and improve employee engagement (Bhatnagar & Srivastava, 2012). Additionally, the study emphasizes key factors influencing job satisfaction, such as fair compensation, opportunities for professional growth, recognition programs, and a positive work environment (Büssing et al., 1999). These factors collectively contribute to an atmosphere where employees can thrive both personally and professionally.

Green Lean Six Sigma (GLSS) as a Solution

Green Lean Six Sigma (GLSS) is a methodology that combines the principles of Lean and Six Sigma with a focus on environmental sustainability. Its integration in healthcare settings offers a comprehensive approach to improving operational efficiency, reducing waste, and enhancing employee engagement. By systematically identifying and eliminating non-value-added activities, GLSS empowers employees to actively participate in problem-solving processes, fostering a sense of ownership and involvement in their work (Sreedharan et al., 2018).

GLSS not only enhances operational efficiency but also supports the digital transformation of healthcare systems. The methodology emphasizes the use of advanced digital tools and technologies to streamline processes and improve accuracy (Narayanamurthy et al., 2018). This digital integration reduces the administrative burden on healthcare workers, enabling them to focus more on patient care and professional development. By aligning digital strategies with GLSS principles, healthcare organizations can create user-friendly systems that further enhance job satisfaction.

The environmental sustainability aspect of GLSS introduces an additional layer of motivation for healthcare professionals. Many employees take pride in working for organizations committed to reducing their ecological footprint. This alignment between organizational goals and personal values strengthens employees' connection to their workplace, fostering greater job satisfaction (Babapour Chafi et al., 2021; Hoxha et al., 2024).

Addressing Systemic Challenges

The healthcare industry is characterized by unique challenges that can negatively impact job satisfaction. Prolonged work hours, increased workloads, and emotional exhaustion are common issues faced by healthcare professionals (Khamlub et al., 2013). These challenges not only affect individual well-being but also compromise the quality of care provided to patients. To address these systemic problems, healthcare organizations must adopt innovative strategies that prioritize employee satisfaction.

Improving the work environment is a critical step in addressing these challenges. A supportive organizational culture that promotes open communication, collaboration, and recognition can significantly enhance job satisfaction. Additionally, providing opportunities for professional growth and implementing fair compensation structures are essential for retaining skilled healthcare professionals (Büssing et al., 1999). Recognizing the importance of these factors, this study underscores the need for healthcare organizations to create environments where employees feel valued and supported.

ISBN: 978-618-5630-22-5

Digital Transformation and Job Satisfaction

Digital transformation in healthcare has the potential to significantly enhance job satisfaction by streamlining workflows and reducing administrative tasks. The integration of advanced technologies, such as electronic health records and automation tools, can improve efficiency and accuracy, allowing healthcare professionals to focus on patient care (Lasalvia et al., 2021). This shift not only improves operational outcomes but also reduces the stress associated with manual and repetitive tasks.

By incorporating GLSS principles into digital transformation efforts, healthcare organizations can ensure a seamless transition to more sophisticated systems. This alignment creates a harmonious balance between technological advancement and employee engagement, fostering a work environment that supports both innovation and well-being. Employees are more likely to embrace digital tools when they perceive them as enhancing their workflow and reducing unnecessary burdens.

Environmental Sustainability and Employee Engagement

The 'green' aspect of GLSS adds a unique dimension to job satisfaction by aligning organizational processes with environmental sustainability goals. In an era where ecological balance is a growing concern, many healthcare professionals find motivation in working for institutions that prioritize sustainability. This alignment with personal values fosters a deeper sense of purpose and connection to the organization (Babapour Chafi et al., 2021; Hoxha et al., 2024).

Sustainability initiatives can include reducing energy consumption, minimizing waste, and adopting environmentally friendly practices. These efforts not only contribute to the organization's sustainability goals but also enhance employees' pride in their workplace. The integration of environmental considerations into operational strategies reinforces the importance of holistic well-being, encompassing both personal and planetary health.

Practical Implications and Future Directions

This study highlights the critical role of job satisfaction in enhancing healthcare quality and organizational effectiveness. By adopting GLSS methodologies within supportive and adaptive organizational cultures, healthcare organizations can create healthier and more efficient environments. The findings emphasize the importance of prioritizing employee well-being through strategies that address systemic challenges, integrate advanced technologies, and align organizational goals with sustainability principles.

The implications of this research extend beyond individual organizations, contributing to the broader field of health, well-being, and sustainability. By fostering a research community dedicated to exploring innovative approaches, this study aims to inspire ongoing efforts to improve job satisfaction in healthcare settings. Future research should continue to investigate the mechanisms that influence job satisfaction, with a focus on refining GLSS strategies and exploring their impact on healthcare professionals and patient outcomes.

CONCLUSION

Job satisfaction is a cornerstone of effective healthcare systems, directly influencing employee well-being, organizational performance, and patient care quality. This study

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underscores the importance of organizational culture in shaping job satisfaction and highlights the potential of GLSS methodologies to address systemic challenges. By optimizing work processes, integrating digital technologies, and prioritizing environmental sustainability, healthcare organizations can create supportive environments that enhance job satisfaction. Ultimately, these efforts contribute to the well-being of healthcare professionals and the delivery of superior patient care, ensuring the sustainability and effectiveness of healthcare systems in the long term

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INTEGRATING HEALTHCARE AND TOURISM FOR SUSTAINABLE GROWTH IN CENTRAL MACEDONIA / GREECE

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ABSTRACT

The rapid growth of medical tourism, fueled by socio-economic factors and a focus on sustainability, has emerged as a pivotal segment in the global tourism sector (Ile & Țigu, 2017; Vrana, 2023). This paper provides a thorough examination of medical tourism strategies with a specific emphasis on the Region of Central Macedonia (RCM) in Greece, seeking to optimize this sector for sustainable growth. Employing a combination of traditional methodologies, such as Systematic Literature Review (SLR) and primary quantitative research, this study also integrates insights from Green Lean Six Sigma (GLSS) principles to foster sustainability within medical tourism practices.
Medical tourism, which merges healthcare and tourism, presents significant economic advantages while necessitating careful consideration of its environmental and social implications (Suess, 2018; Tsekouropoulos et al., 2023). Recognizing the intricate nature of this integration, the research addresses the varied conceptual frameworks and definitions prevalent in the field. The primary aim is to construct a strategic framework that promotes sustainable medical tourism in RCM, capitalizing on the region's unique attributes to attract both local and international medical travelers.
The methodology employed consists of a detailed literature review that establishes a solid theoretical framework, incorporating GLSS principles. This methodology blends Lean and Six Sigma approaches to improve efficiency, optimize processes, reduce waste, and enhance quality, all while embedding sustainable practices that minimize environmental impact. In addition, quantitative research methods, including surveys and statistical analyses, yield insights into factors affecting medical tourism and its repercussions on local healthcare systems, with a pronounced focus on efficiency and sustainability (Kaswan & Rathi, 2021; Pagan & Horsfall, 2020).
Findings indicate that RCM possesses substantial strengths, such as its thermal springs and advanced healthcare facilities, which serve as key attractions for medical tourists. However, it also faces challenges, including the urgent need for improved infrastructure, enhanced service quality, and focused marketing strategies. The research underscores sustainability factors—such as environmental conservation and economic viability—as critical components in formulating an effective medical tourism strategy (Tsekouropoulos et al., 2023; Zhu et al., 2018).
Strategic recommendations for RCM include establishing a medical tourism cluster that facilitates stakeholder collaboration, developing targeted marketing campaigns, and incorporating GLSS principles to maximize resource efficiency and minimize environmental harm (Swarnakar et al., 2021). Specific steps for implementation involve creating partnerships among healthcare providers, tourism operators, and local governments, conducting market research to identify target demographics, and launching campaigns that highlight the region's unique offerings. Additionally, policies advocating sustainable practices, community engagement, and long-term growth are recommended to align with the United Nations' Sustainable Development Goals (SDGs).

ISBN: 978-618-5630-22-5

In conclusion, this research enhances the understanding of medical tourism by proposing a comprehensive strategy that weaves together sustainability principles and insights from GLSS methodologies. It offers valuable guidance for policymakers, healthcare providers, and tourism operators seeking to leverage the economic potential of medical tourism while promoting sustainable development in Central Macedonia. The study emphasizes the importance of interdisciplinary approaches and innovative practices in realizing a sustainable medical tourism sector that benefits both the region and its visitors.

Key Words: Medical tourism, Health tourism, Central Macedonia, Sustainable growth, Green Lean Six Sigma (GLSS), Economic opportunities

INTRODUCTION

The rapid expansion of medical tourism, driven by socio-economic changes and a growing emphasis on sustainability, has become a critical segment of the global tourism industry (Ile & Țigu, 2017; Vrana, 2023). This study delves deeply into the strategies necessary to optimize medical tourism for sustainable growth, with a focus on the Region of Central Macedonia (RCM) in Greece. By integrating traditional research methodologies such as a Systematic Literature Review (SLR) with primary quantitative research and principles of Green Lean Six Sigma (GLSS), the paper seeks to provide a framework that promotes sustainability and efficiency within the medical tourism sector.

Medical tourism, which represents a fusion of healthcare and tourism, offers notable economic benefits but also poses environmental and social challenges (Suess, 2018; Tsekouropoulos et al., 2023). It requires a careful balance between generating economic opportunities and mitigating negative impacts. The study acknowledges the complexities of integrating healthcare services with tourism and evaluates the diverse conceptual definitions that exist in the field. The primary objective is to develop a strategic framework tailored to RCM's unique resources and characteristics, enhancing its appeal to both domestic and international medical tourists.

To construct this framework, the research begins with a comprehensive review of existing literature, building a robust theoretical foundation for understanding medical tourism in the context of sustainability. Central to this foundation is the application of GLSS principles, which combine the Lean approach—focused on efficiency and waste reduction—with Six Sigma's emphasis on quality improvement. By embedding sustainability into these practices, GLSS provides tools to optimize medical tourism operations while reducing their environmental footprint (Kaswan & Rathi, 2021; Pagan & Horsfall, 2020). These insights are complemented by quantitative research, which includes surveys and statistical analyses to explore the key factors influencing medical tourism and its impact on local healthcare systems.

The findings reveal that RCM boasts several strengths that position it as a potential leader in medical tourism. Its thermal springs and modern healthcare facilities are major attractions for medical travelers. However, these advantages are tempered by

ISBN: 978-618-5630-22-5

challenges such as inadequate infrastructure, inconsistent service quality, and the absence of targeted marketing strategies. These obstacles highlight the need for a strategic, coordinated approach to capitalize on the region's assets while addressing its shortcomings.

Sustainability emerges as a cornerstone in developing a successful medical tourism strategy for RCM. This includes not only economic viability but also environmental stewardship and social responsibility. Conservation of natural resources, promotion of green practices, and community engagement are identified as essential components. The integration of GLSS principles is particularly relevant, as these methodologies ensure resource efficiency, reduce waste, and promote high-quality services that are aligned with sustainability goals (Tsekouropoulos et al., 2023; Zhu et al., 2018).

One of the central recommendations of the study is the establishment of a medical tourism cluster in RCM. Such a cluster would encourage collaboration among various stakeholders, including healthcare providers, tourism operators, local authorities, and policymakers. By fostering partnerships, the cluster would streamline operations, promote knowledge-sharing, and enhance the region's competitiveness. Targeted marketing campaigns are also proposed, aiming to highlight RCM's unique offerings, such as its thermal springs, state-of-the-art medical facilities, and cultural heritage. These campaigns would focus on specific demographics and markets, showcasing RCM as a premier destination for medical tourism.

Another critical recommendation is the implementation of policies that advocate sustainable practices in both healthcare and tourism. These policies should be aligned with the United Nations' Sustainable Development Goals (SDGs), ensuring long-term benefits for the region. For instance, promoting renewable energy sources, encouraging waste reduction initiatives, and enhancing the environmental awareness of stakeholders and visitors alike are key measures. Community engagement is equally vital, as the success of medical tourism depends on the support and participation of local populations. Training programs, public consultations, and employment opportunities in the sector can strengthen community involvement and foster a sense of shared ownership.

The study also emphasizes the need for continuous research and evaluation. Conducting regular market studies to identify emerging trends, monitoring the effectiveness of implemented strategies, and adapting to changing demands are crucial for maintaining the sustainability and competitiveness of medical tourism in RCM. Furthermore, leveraging technological advancements, such as digital platforms and data analytics, can enhance the efficiency of operations and improve the overall visitor experience.

By integrating these recommendations, RCM can transform its medical tourism sector into a model of sustainable development. The application of GLSS principles ensures that resources are used efficiently, processes are streamlined, and quality standards are consistently met. These improvements not only benefit medical tourists but also have positive ripple effects on the local economy, healthcare system, and environment.

In conclusion, this research offers a comprehensive strategy for advancing medical tourism in the Region of Central Macedonia. By combining sustainability principles

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with insights from GLSS methodologies, the study provides actionable recommendations for policymakers, healthcare providers, and tourism operators. The proposed framework highlights the importance of interdisciplinary approaches and innovative practices in creating a medical tourism sector that is economically viable, environmentally sustainable, and socially inclusive. These findings underscore the potential of RCM to become a leading destination for medical tourism, benefiting both the region and its visitors while contributing to broader global sustainability goals.

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TRANSFORMING HEALTHCARE WITH GREEN LEAN SIX SIGMA: CHALLENGES AND OPPORTUNITIES IN THE DIGITAL ERA

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ABSTRACT

In the healthcare sector, operational efficiency is essential for patient well-being and organizational sustainability. Green Lean Six Sigma (GLSS) has emerged as a powerful approach to drive positive change by combining Lean principles, which focus on eliminating non-value-added activities, with Six Sigma's data-driven problem-solving techniques. This integrated approach helps healthcare organizations improve performance, enhance sustainability, and deliver higher-quality care (Hines et al., 2004; Kaswan & Rathi, 2021; Farrukh, 2020).

This study provides a comprehensive review of literature on GLSS in healthcare, employing qualitative and narrative synthesis methodologies (Denyer & Tranfield, 2006). It explores the key requirements, challenges, and impacts of GLSS implementation, focusing on how it enhances environmental performance, operational efficiency, and quality of care. The review covers publications from 1990 to 2024, with particular emphasis on the post-2023 surge in GLSS research, driven by the global shift toward sustainability following the COVID-19 pandemic (Swarnakar et al., 2021; Tsekouropoulos et al., 2023; Kaswan et al., 2023).

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Key findings indicate that the *TQM Journal* is a leading source for GLSS-related publications, with substantial contributions from scholars such as Antony and others. The United States leads in publication volume, particularly through institutions like the VA Medical Center. Organizational culture is identified as a critical factor for successful GLSS implementation, with management commitment, employee engagement, and teamwork being essential. A culture that promotes continuous improvement and sustainability is vital to overcoming resistance and embedding GLSS into everyday operations.

Some practical recommendations for healthcare organizations implementing Green Lean Six Sigma (GLSS) include fostering a culture of sustainability and continuous improvement, promoting staff training in GLSS methodologies, and investing in digital tools to enhance data-driven decision-making. Successful case studies demonstrate that GLSS can significantly improve operational efficiency, as seen in U.S. healthcare systems where patient wait times were reduced, and care quality was enhanced (Antony, 2015; Chugani et al., 2017).

Despite significant progress in GLSS research, gaps remain, particularly in developing digital tools to streamline implementation and in formalizing best practices for key processes, such as patient handoff. Future research should focus on creating comprehensive guidelines and advancing digital innovations that can further enhance GLSS adoption in healthcare (Henrique et al., 2021; Al-Balushi et al., 2014; Lawal et al., 2014).

GLSS aligns with broader sustainability goals by reducing waste, improving resource management, and fostering a culture of continuous improvement. These objectives have become more urgent due to the economic and operational pressures exacerbated by the COVID-19 pandemic. By adopting GLSS, healthcare units can address these challenges while supporting their mission to deliver high-quality care (Kaswan & Rathi, 2021).

In conclusion, this study underscores the strategic potential of GLSS for healthcare organizations and highlights the need for further investigation into digital innovations and readiness factors. Implementing GLSS can significantly enhance both operational efficiency and sustainability, positioning healthcare organizations to better navigate future challenges (Zhu et al., 2018; Sfakianaki & Kakouris, 2019).

Key Words: Green Lean Six Sigma (GLSS), Healthcare Units, Sustainability, Digital Tools, Organizational Culture, Continuous Improvement.

INTRODUCTION

In the healthcare sector, operational efficiency plays a pivotal role in ensuring both patient well-being and organizational sustainability. Achieving these goals requires a structured approach to optimizing processes, reducing waste, and improving outcomes. Green Lean Six Sigma (GLSS) has emerged as a transformative methodology that combines the waste-reduction focus of Lean principles with the data-driven problem-solving framework of Six Sigma. By integrating these approaches, GLSS enables

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healthcare organizations to improve their operational performance, advance sustainability initiatives, and deliver higher-quality care (Hines et al., 2004; Kaswan & Rathi, 2021; Farrukh, 2020).

This study provides an in-depth review of the literature on GLSS in healthcare, utilizing qualitative and narrative synthesis methodologies to explore its requirements, challenges, and impacts. Specifically, it highlights how GLSS contributes to environmental performance, operational efficiency, and patient care quality. The analysis covers publications spanning from 1990 to 2024, with a particular focus on the rapid growth of GLSS research following the global emphasis on sustainability in the wake of the COVID-19 pandemic (Swarnakar et al., 2021; Tsekouropoulos et al., 2023; Kaswan et al., 2023).

Advancements in GLSS Research and Applications

The Total Quality Management (TQM) Journal emerges as a leading platform for publishing research on GLSS, with notable contributions from scholars such as Antony and colleagues. The United States leads in publication volume, driven by initiatives within prominent institutions like the VA Medical Center. This prominence reflects a growing recognition of GLSS as a critical strategy for achieving sustainable healthcare improvements.

Key findings emphasize the importance of organizational culture in successfully implementing GLSS. A culture that fosters continuous improvement and sustainability is essential for embedding GLSS practices into daily operations. Factors such as strong management commitment, active employee engagement, and effective teamwork are critical to overcoming resistance and achieving long-term success. Without these elements, the integration of GLSS can face significant barriers.

Practical Insights for GLSS Implementation

For healthcare organizations looking to adopt GLSS, several practical recommendations stand out. First, fostering a culture of sustainability and continuous improvement is imperative. Organizations must train their staff in GLSS methodologies and invest in digital tools to enhance data-driven decision-making. Case studies from U.S. healthcare systems demonstrate the tangible benefits of GLSS implementation, such as reduced patient wait times and improved care quality (Antony, 2015; Chugani et al., 2017). These examples underline the methodology's potential to address inefficiencies and elevate overall performance.

However, challenges persist. A major hurdle involves developing digital tools that streamline GLSS implementation and formalizing best practices for critical processes like patient handoffs. Addressing these gaps is crucial for enabling healthcare organizations to fully leverage the benefits of GLSS.

Addressing Research Gaps and Future Directions

Despite significant advancements, there remain areas for further exploration in GLSS research. One key area is the development of comprehensive digital tools that support real-time data analysis and decision-making. Digital innovations, such as predictive analytics and AI-driven process optimization, have the potential to revolutionize GLSS adoption in healthcare. Additionally, more work is needed to formalize guidelines and

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frameworks that healthcare organizations can use to implement GLSS effectively across diverse settings (Henrique et al., 2021; Al-Balushi et al., 2014; Lawal et al., 2014).

Future research should also focus on readiness factors, such as organizational infrastructure and stakeholder alignment, which are critical for successful GLSS integration. As the healthcare sector continues to evolve, these research efforts will help bridge existing gaps and advance the practical application of GLSS.

GLSS and Sustainability Goals in Healthcare

GLSS aligns closely with broader sustainability goals by minimizing waste, optimizing resource management, and promoting a culture of continuous improvement. These objectives have gained heightened importance due to the economic and operational pressures brought on by the COVID-19 pandemic. By adopting GLSS, healthcare organizations can not only address these challenges but also support their mission of delivering high-quality care in a resource-constrained environment (Kaswan & Rathi, 2021).

The emphasis on sustainability within GLSS also extends to environmental considerations. Through waste reduction initiatives, better energy management, and resource-efficient practices, GLSS helps healthcare units minimize their ecological footprint. This dual focus on environmental and operational sustainability positions GLSS as a strategic tool for achieving long-term resilience in the healthcare sector.

Strategic Potential and Conclusion

The findings of this study underscore the strategic potential of GLSS for healthcare organizations. By integrating Lean and Six Sigma principles with sustainability objectives, GLSS offers a holistic framework for addressing the multifaceted challenges faced by the healthcare sector. From improving operational efficiency to enhancing environmental performance, GLSS enables organizations to deliver better patient outcomes while achieving their sustainability goals.

Nevertheless, the full potential of GLSS remains untapped, particularly in the areas of digital innovation and readiness factors. Future research should prioritize these domains to create more robust guidelines and tools for GLSS implementation. As healthcare organizations continue to navigate a rapidly changing landscape, adopting GLSS will be critical for ensuring both operational excellence and sustainability (Zhu et al., 2018; Sfakianaki & Kakouris, 2019).

In conclusion, GLSS represents a powerful approach for driving positive change in healthcare. By addressing current challenges and focusing on future opportunities, healthcare organizations can unlock the full potential of GLSS, positioning themselves to better navigate future challenges while delivering high-quality, sustainable care.

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ENHANCING MEDICAL TOURISM FOR SPECIAL NEEDS AND ELDERLY PATIENTS THROUGH DIGITAL INNOVATION AND GREEN LEAN SIX SIGMA

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ABSTRACT

The intersection of medical tourism and digital innovation presents unique opportunities for enhancing the travel experience and healthcare services for people with special needs and the elderly (Ribeiro et al., 2018; Li et al., 2022). This paper explores through a Literature Review how advanced technologies can be harnessed to create an inclusive, efficient, and comfortable medical tourism experience for these demographic groups. It delves into several key areas where digital innovations can make significant impacts: telemedicine, accessible online platforms, customized travel planning, enhanced communication tools, smart healthcare facilities, data analytics, integrated health, travel insurance, training, education, and feedback systems.

Telemedicine and virtual consultations are fundamental in providing preliminary healthcare assessments, enabling patients to interact with healthcare providers from either the comfort of their homes before making travel arrangements, or during their traveling and vacations. Remote monitoring tools provide continuous health updates, ensuring that any medical issues are promptly addressed (Gogia, 2019; Chauhan et al., 2024).

Accessible online platforms and apps are crucial for facilitating easy access to information and services. Websites and mobile applications designed with accessibility features such as voice commands, larger text options, and intuitive navigation ensure that people with disabilities can easily plan and manage their medical travel. AI-powered tools can generate personalized itineraries, while VR tours of medical facilities and accommodations help in making informed decisions (Chang et al., 2016).

Communication is another critical area where digital innovation can make a difference. Real-time translation services and AR tools help overcome language barriers and provide on-the-spot guidance, making the travel experience smoother and more enjoyable for patients and their companions (Shaw et al., 2020; Nambisan et al., 2017).

Integrated health and travel insurance plans specifically designed for people with special needs and the elderly provide comprehensive coverage, including emergency services and medical evacuations. Digital claims processing systems streamline the insurance process, making it more accessible and less stressful for patients (Harris, et al. 2019).

Education and training for the professionals in the tourism industry are essential for maintaining high standards of care and service. Online training programs ensure they are well-equipped to meet the unique needs of these groups regarding travel logistics, and support services (Awad et al., 2021).

Finally, digital feedback systems enable continuous improvement by collecting and analyzing patient feedback. AI-powered surveys can identify areas for enhancement, ensuring that services evolve to meet the changing needs and expectations of patients Moreover, integrating Green Lean Six Sigma (GLSS) principles into these innovations ensures sustainability and efficiency (de Freitas et al., 2017; Bhat et al., 2020; Farrukh et al., 2020):

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- Process Optimization: Apply Lean Six Sigma techniques to streamline processes, reduce waste, and improve service delivery in medical tourism.
- Sustainability Initiatives: Implement green practices in healthcare facilities, such as energy-efficient systems and waste reduction programs, to create eco-friendly medical tourism options.
- Continuous Improvement: Use GLSS methodologies to continuously monitor, analyze, and improve healthcare services, ensuring they remain effective and efficient for special needs and elderly patients.

In conclusion, integrating digital innovation and Green Lean Six Sigma into medical tourism can significantly improve the accessibility, efficiency, and overall experience for people with special needs and the elderly. By leveraging advanced technologies and sustainable practices, medical tourism providers can offer safer, more personalized, and higher-quality services, ensuring that these vulnerable groups can fully benefit from the opportunities of medical travel.

Key Words: Medical tourism, digital innovation, special needs, elderly, healthcare accessibility, Green Lean Six Sigma (GLSS).

INTRODUCTION

The intersection of medical tourism and digital innovation offers transformative potential in enhancing the healthcare travel experience for individuals with special needs and the elderly. As global populations age and accessibility concerns rise, integrating advanced technologies becomes imperative for creating inclusive, efficient, and comfortable medical tourism experiences (Ribeiro et al., 2018; Li et al., 2022). This paper, through a comprehensive literature review, examines how digital tools and methodologies can address the unique needs of these demographic groups, focusing on telemedicine, accessible platforms, tailored travel planning, communication tools, smart healthcare, data analytics, integrated insurance, training, and feedback systems.

Telemedicine and Remote Monitoring: Pioneering Accessible Healthcare

Telemedicine has revolutionized the way healthcare is delivered, particularly in medical tourism. Virtual consultations allow patients to interact with healthcare providers from the comfort of their homes, eliminating geographical barriers before their travel. Such preliminary assessments enable informed decision-making and reduce uncertainties, ensuring a smoother healthcare journey (Gogia, 2019; Chauhan et al., 2024).

Remote monitoring technologies further enhance this process, offering real-time health updates and alerting patients or their caregivers to potential medical issues while traveling or on vacation. This constant oversight ensures timely intervention when necessary, minimizing health risks and adding a layer of safety for elderly patients or those with chronic conditions.

Accessible Platforms and Custom Travel Planning

Online platforms and mobile applications with built-in accessibility features are crucial for empowering individuals with disabilities or reduced mobility. Features like voice-activated commands, larger text options, and intuitive navigation ensure seamless

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access to essential information and services. AI-powered platforms further enhance personalization by creating tailored itineraries based on the user's medical and travel needs (Chang et al., 2016).

Virtual reality (VR) tools add another dimension to decision-making. Prospective medical tourists can explore hospitals, clinics, accommodations, and even transportation options through VR tours, helping them choose options that align with their unique preferences and requirements.

Enhanced Communication Through Real-Time Technology

Communication plays a pivotal role in ensuring smooth medical tourism experiences. Advanced digital tools, such as real-time translation services, enable patients to overcome language barriers when interacting with healthcare professionals or navigating unfamiliar locations. Augmented reality (AR) systems provide on-the-spot guidance in real-world settings, such as airports, hotels, or healthcare facilities, offering step-by-step navigation and accessibility assistance (Shaw et al., 2020; Nambisan et al., 2017).

Such technologies significantly reduce stress and confusion for both patients and their companions, fostering a sense of confidence and independence throughout their journey.

Integrated Insurance and Stress-Free Claims Management

Medical tourists with special needs or elderly individuals often require comprehensive health and travel insurance. Tailored plans that integrate health and travel coverage offer peace of mind by addressing emergencies, medical evacuations, and unforeseen complications. Digital innovations simplify the insurance process through automated claims management systems, reducing administrative burdens and making the experience less stressful for patients and their families (Harris et al., 2019).

The efficiency of such systems ensures that individuals can focus on their health and recovery without unnecessary distractions or delays.

Training and Education for Tourism Professionals

To maintain high standards of service, training for professionals in the medical tourism industry is essential. Online training programs tailored for hospitality staff, healthcare providers, and travel coordinators can equip them with the knowledge and skills necessary to address the specific needs of special populations (Awad et al., 2021).

Training modules can cover areas like handling assistive devices, managing mobility constraints, and ensuring cultural sensitivity. Such efforts contribute to creating a more inclusive environment across the medical tourism landscape.

Digital Feedback Systems for Continuous Improvement

Feedback systems powered by digital technologies play an essential role in the ongoing improvement of medical tourism services. AI-powered surveys collect and analyze patient feedback, identifying trends and areas for enhancement. By understanding the evolving needs of patients with special requirements, service providers can refine their offerings to deliver higher-quality, more tailored experiences.

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Feedback loops also allow patients to voice concerns, suggest improvements, and highlight success stories, ensuring that their perspectives directly influence service evolution.

Green Lean Six Sigma: A Framework for Sustainability and Efficiency

Integrating Green Lean Six Sigma (GLSS) principles into medical tourism complements digital innovation by fostering sustainability and efficiency (de Freitas et al., 2017; Bhat et al., 2020; Farrukh et al., 2020).

Process Optimization

Lean Six Sigma techniques can streamline medical tourism processes, eliminating inefficiencies and reducing waste. For example, optimizing appointment scheduling or travel coordination minimizes delays and ensures smoother experiences for patients.

Sustainability Initiatives

GLSS emphasizes eco-friendly practices, which are increasingly relevant in the healthcare sector. Hospitals and medical tourism providers can adopt energy-efficient systems, minimize waste through advanced recycling programs, and design sustainable travel packages that appeal to environmentally conscious travelers.

Continuous Improvement

A hallmark of GLSS is its commitment to continuous improvement. By systematically monitoring and analyzing healthcare processes, providers can adapt to the changing needs of patients with special requirements. This ensures that medical tourism services remain not only effective but also innovative in meeting the demands of a dynamic global market.

Bridging Innovation and Accessibility

The convergence of digital innovation and GLSS principles in medical tourism has the potential to transform how services are delivered to individuals with special needs and elderly populations. By harnessing advanced technologies such as telemedicine, accessible online platforms, and AI-powered tools, and by adopting sustainable practices, medical tourism providers can offer inclusive and high-quality experiences.

These efforts not only improve the accessibility and efficiency of medical tourism but also promote the well-being and satisfaction of vulnerable groups. Through a commitment to innovation and sustainability, the industry can ensure that people with special needs and the elderly fully benefit from the opportunities medical travel offers, paving the way for a future where healthcare is universally accessible and inclusive.

CONCLUSION

The integration of digital innovation and Green Lean Six Sigma principles into medical tourism offers transformative opportunities for enhancing accessibility, efficiency, and patient satisfaction for individuals with special needs and the elderly. Technologies such as telemedicine, accessible platforms, AI-driven personalization, and smart healthcare solutions ensure a seamless, inclusive experience, while GLSS principles foster sustainability and continuous improvement. Together, these advancements pave the way for safer, more personalized, and eco-friendly medical travel, ensuring that these vulnerable groups can access high-quality healthcare while enjoying the benefits of global mobility.

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DIGITAL INNOVATION IN HEALTHCARE GOVERNANCE: OPPORTUNITIES AND HUMAN RIGHTS CHALLENGES

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ABSTRACT

Digital innovation, involving Artificial Intelligence (AI), is reshaping for the better multiple sectors of the economy and human society, involving the healthcare sector, by creating multiple opportunities. Indeed, it is claimed that AI innovation can be a tremendous force for good, assisting societies in overcoming a number of significant challenges of the current time. Particularly, in healthcare processes and settings, digital innovation, including AI technologies, has the potential to facilitate universal health coverage and thus the realization of the right to health for all. Nevertheless, such advancements are not without risks and can raise significant human rights challenges which may intensify existing health inequalities and/or even trigger new ones and pose new governance challenges in the absence of proper security and regulatory action as well as human oversight. Without any doubt, the expansion of AI in healthcare governance and its ensuing human rights challenges underscore the urgency of rethinking traditional approaches and as such, they demand States to ensure that digital innovation, involving AI technologies, in healthcare processes and settings will work for all members of the society. Thereto, in an age increasingly influenced by AI, the present paper aims to delve into the intersection of AI and healthcare governance and examine the dual nature of AI in healthcare governance underlying both its transformative potential and critical challenges. Drawing on existing evidence, this paper seeks to examine the value of digital innovation in healthcare governance and particularly how healthcare governance can harness AI's benefits while upholding human rights principles and fostering inclusive and equitable innovation in the digital era by identifying a regulatory framework for addressing the complex human rights challenges stemming from the use of AI.

Key Words: Artificial Intelligence, Digital Innovation, Governance**,** Healthcare, Human Rights

INTRODUCTION

Digital innovation, involving Artificial Intelligence (AI), becomes increasingly prominent with the potential to impact every sector of the economy and society in the coming decade, including the healthcare sector (Organization for Economic Co-operation and Development, 2024b). In this regard, it is claimed that digital innovation, and particularly AI, in healthcare governance is redefining and reshaping the right to

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health and as such AI offers immense opportunities for improving the availability, accessibility, acceptability and quality of healthcare services, while at the same time entailing serious human rights challenges that demand urgent and concerted regulatory action (United Nations General Assembly, 2023). Within this context, the United Nations (UN) High Commissioner for Human Rights cautioned that: "[N]o other technological development of recent years has captured the public imagination more than artificial intelligence (AI), in particular machine-learning technologies. Indeed, these technologies can be a tremendous force for good, helping societies overcome some of the great challenges of the current time. However, these technologies can also have negative, even catastrophic, effects if deployed without sufficient regard to their impact on human rights" (United Nations Human Rights Council 2021: para 2).

Without any doubt, the expansion of AI in healthcare governance and its ensuing human rights challenges underscore the urgency of rethinking traditional approaches and demand States to ensure that digital innovation, involving AI technologies, in healthcare settings and processes will work for all members of the society. Thereto, in an age increasingly influenced by AI, the present paper aims to delve into the intersection of AI and healthcare governance and examine the dual nature of AI in healthcare governance underlying both its transformative potential and critical challenges. Against this backdrop, drawing on existing evidence, this paper seeks to examine the value of digital innovation in healthcare governance and particularly how healthcare governance can harness AI's benefits while upholding human rights principles and fostering inclusive and equitable innovation in the digital era by identifying a regulatory framework for addressing the complex human rights challenges stemming from the use of AI. The findings from this paper can contribute to the achievement of an equitable digital transformation in healthcare governance.

RESEARCH METHODS

The paper is based on a systematic legal analysis of international and regional human rights regimes, literature research and document analysis, towards identifying a regulatory framework required for upholding the right to health for all in the digital age. The literature-scientific research included publicly available documents, reports, peer-reviewed studies and other publications primarily of human rights bodies at the United Nations level. These sources are published in English and they tend to provide useful interpretation material for the issue under examination.

RESULTS AND DISCUSSION

3.1. Unraveling the intersection of AI and healthcare governance

During the COVID-19 pandemic state organizations and private companies largely invested in digitalization and extensively used digital tools to address health needs due to the increased demand for healthcare services delivery, associated with the increased isolation, the so-called working from home arrangements, and reduced physical capacity, enforced to counter COVID-19 crisis (Davis 2020: 41, Sun, Esom, Dhaliwal, Amon 2020: 22, United Nations General Assembly 2023: paras. 5 and 28). Digital health tools were adopted in the healthcare sector as a means of enhancing access to information, in diagnostics, telemedicine, monitoring and health surveillance (United

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Nations General Assembly 2023: para. 5). In 2020 the UN Secretary General in a report on the role of new technologies for the realization of economic, social and cultural rights pointedly noted that digital innovation provides the opportunity to enhance universal health coverage and thus the realization of the right to health for all, while also encompassing important risks in potentially exacerbating existing inequalities related to age, gender identity, sexual orientation, cultural identity, ethnicity, and race, (digital) literacy, disability and (mental) health status, economic status, among others and in triggering new ones (United Nations Human Rights Council 2020: para. 19). Notably, according to the Organization for Economic Co-operation and Development (2024a: 15) AI is poised to revolutionize the healthcare ecosystem and affect all corners of health systems. From personalised treatment plans, early disease detection, prevention, diagnosis and prognosis of health conditions (involving cardiovascular diseases and certain types of cancer) and telehealth platforms to automating administrative tasks for decreasing operational costs, AI, when used in healthcare settings and processes, can provide immense opportunities for optimizing efficiency and for enhancing healthcare service delivery towards achieving universal health coverage (Organization for Economic Co-operation and Development 2024a: 23, Organization for Economic Co-operation and Development 2024b: 3, Santamaria Echeverria 2023: 387-392, The Physiological Society 2023: 17, United Nations General Assembly 2023: paras. 52 and 83, United Nations Human Rights Council 2020: paras. 19-20). In this regard, it is important to note that the United Nations 2030 Agenda for Sustainable Development highlights the significance of universal health coverage in the Sustainable Development Goal 3 by explicitly emphasizing States' obligation to 'achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all" (United Nations General Assembly 2015: 16). In view of the above, it is asserted that digital technologies, including AI systems, can be used for a number of aspects of healthcare, healthcare systems, public health and clinical practice and they tend to provide several benefits when designed and deployed in an accountable way, involving the rapid processing of vast amounts of health data, the automation of healthcare processes with potentially less cost, while ultimately facilitating universal health coverage (Malik, Solaiman 2024: 21-28, Organization for Economic Co-operation and Development 2024b: 3, The Physiological Society 2023: 12, United Nations General Assembly 2023 para.: 27). In practice, the expansion of digitalization, like AI systems, in healthcare governance has the potential, inter alia:
(i) to transform patient care through the development of personalized treatment plans and to help patients better understand their medical records through AI-powered tools,
(ii) to help patients, especially those who live in remote or resource-constrained areas where healthcare service delivery is often obstructed due to healthcare staff shortages, to satisfy their pressing and complex health needs through remote patient e-monitoring and the development of more personalized treatment and drugs, and accessible e-processes,

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(iii) to help trace healthcare systems inequities (for example underserved populations), identify geographic areas requiring assistance, and support workforce retention,
(iv) to enable the automated scanning and analysis of massive amounts (population-scale) of patient datasets, involving physiological datasets, data from medical images and signals, alongside the most current scientific literature, for prediction, forecasting, producing results and making recommendations rapidly and at scale, as such allowing for proactive clinical decision-making and prevention of adverse medical conditions (for example early detection of certain types of cancers, prediction of infectious disease outbreaks),
(v) to meaningfully affect public health by helping in rapid drug discovery and vaccine development and predict the best preventive and chronic care management opportunities,
(vi) to detect fraud and health sector corruption in procurement processes,
(vii) to allow healthcare professionals to devote more time on their patients, reduce medical errors and focus on direct patient care through the automation of their administrative tasks, namely the integration of data into clinical workflow by AI systems, which can serve as a documentation assistants (Alexiadou 2022, Organization for Economic Co-operation and Development 2024a: 21-23 and 29, Organization for Economic Co-operation and Development 2024b: 3, Sun, Esom, Dhaliwal, Amon 2020: 22, Santamaria Echeverria 2023: 387-392, The Physiological Society 2023: 6 and 12, Wahl, Cossy-Gantner, Germann, Schwalbe 2018, Zardiashvili, Fosch-Villaronga 2020: 48).
Nevertheless, as with any innovation, the digitalization in healthcare settings and processes is accompanied by several human rights challenges and risks. The deployment of digital technologies, including AI systems in healthcare processes, poses several challenges for health care professionals and healthcare policy makers as well as human rights risks related to governance issues. Notably, without proper design, enhanced security and human oversight, these systems may become especially intrusive and thus violate the right to health for all and ultimately threaten universal health coverage. For instance, when an AI system used in healthcare processes is trained on inaccurate, non-inclusive or biased patient dataset, it may unintentionally lead to biases and algorithmic discrimination and exclusion thus adversely affecting universal health coverage (Organization for Economic Co-operation and Development 2024a: 19). Evidence indicates that when designing and deploying AI in healthcare processes, it must be ensured that data used to build the AI system are representative of the target population that will benefit from this system, while promoting transparency about the nature of the data used in its construction (Organization for Economic Co-operation and Development 2024a: 19). Another worrying issue relates to privacy and security concerns regarding the treatment of personal (sensitive) patient information, given that AI technology and service providers collect, store, use and manage increasing amounts of information for training AI systems, augmenting concerns for data exploitation or privacy breaches by cyberattacks and thus also affecting the right to privacy, which is protected, inter alia, in Article 17 of the International Covenant on Civil and Political

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Rights (1966) (Organization for Economic Co-operation and Development 2024a: 19-20, Raso et al. 2018). In parallel, the "black box" nature of AI algorithms can make the rationale behind specific AI driven outputs difficult to explain, which may lead to a lack of trust in AI systems when accompanied by the risk of biased data and algorithmic discrimination (Organization for Economic Co-operation and Development 2024a: 20).

3.2 Standard setting and regulatory actions

From the perspective of the preceding discussion it can be discerned that the human rights challenges and risks stemming from the design and deployment of digital (AI) systems in healthcare processes and settings are contrary to the nature of human rights law according to which all individuals possess inherent dignity and an equal entitlement to all human rights. Article 1 of the Universal Declaration of Human Rights (1948) declares that "[A]ll human beings are born free and equal in dignity and rights", while Article 25 of the Universal Declaration of Human Rights recognizes everyone's right to health as integral part of the right to an adequate standard of living (Eide, Barth Eide 1999: 523). Significantly, the International Covenant on Economic, Social and Cultural Rights (1966) represents the first legally binding instrument that enshrines health as a right and as such it provides a global standard for ensuring health for all. Specifically, the International Covenant on Economic, Social and Cultural Rights acknowledges in Article 12, read in conjunction with Article 2 paragraph 2, the right of everyone to health without discrimination and mandates States to take specific steps for its realization. Within this context the United Nations Committee on Economic, Social and Cultural Rights, the body responsible for overseeing States' compliance with the International Covenant on Economic, Social and Cultural Rights, has adopted in its General Comment No. 14 the so-called AAAQ framework which requires health facilities, goods and services be available, physical and economically accessible to all without discrimination, acceptable, namely respectful of the culture of individuals, minorities and communities, gender sensitive and sensitive to life-cycle requirements and of quality (United Nations Committee on Economic, Social and Cultural Rights 2000: para. 12). At this point, it is important to emphasize that the AAAQ framework can operate as a guidepost for the design, deployment and eventually for the assessment of health AI systems by requiring: to be available (i.e., counter the digital divide across social groups), to be physically and economically accessible as well as accessible on the basis of non-discrimination and information accessibility, to be acceptable (i.e., incorporate cultural, gender and racial diversity), and to be of good quality (Sun, Esom, Dhaliwal, Amon 2020: 25, United Nations Committee on Economic, Social and Cultural Rights 2000: para. 12, United Nations General Assembly 2023: para. 29) . In fact, in 2020, the United Nations Committee on Economic, Social and Cultural Rights required States to adopt policies and measures that expand the AI's benefits, while at the same time minimizing the risks (United Nations Committee on Economic, Social and Cultural Rights 2020: para. 74)

In parallel, the United Nations Convention on the Rights of the Child (1989) under Article 24 affirms the right to health of every child. Article 24 of the Convention on the Rights of the Child sets an important foundation for promoting healthcare for all

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children in the digital era given its interrelation to other substantive principles and rights recognized in the Convention on the Rights of the Child, including the right to non-discrimination (Article 2), the child's best-interests principle (Article 3), the right of the child to be heard (Article 12). Equally important, the right to health in conjunction with the equality and non-discrimination principles is also recognized in other legally binding international human rights instruments that focus on specific vulnerable population groups, such as, the International Convention on the Elimination of All Forms of Racial Discrimination (1965) in Articles 2(1) and 5(e)(iv), the Convention on the Elimination of All Forms of Discrimination against Women (1979) in Articles 2 and 12, and the United Nations Convention on the Rights of Persons with Disabilities (2006) in Articles 4(1), 5 and 25. These provisions discern a set of prohibitions and entitlements that are also applicable when addressing the risks stemming from the use of digital systems, like AI systems, in the health sector.

Meanwhile, at the United Nations level, added to the aforementioned general legal standards, by building upon the work of the United Nations Special Rapporteur on the right to health and the United Nations High Commissioner for Human Rights, certain parameters, that should hold a center place throughout the life cycle of AI systems in healthcare processes and settings, can be discerned, involving, inter alia: (i) the application of fundamental principles, such as equality and non-discrimination, participation and accountability, principles that also hold the Sustainable Development Goals and the Guiding Principles on Business and Human Rights, (ii) the introduction of effective judicial and non-judicial remedies for those who suffer human rights violations and abuses relating to the use of AI in healthcare delivery, (iii) the establishment of data privacy frameworks and the review and/or adoption of a broader range of laws to address the challenges of AI in a rights-respecting way, (iv) the implementation of stricter legal requirements for the use of AI technology when the risks for human rights in sectors, like healthcare, are higher, (v) the systematic exercise of comprehensive human rights due diligence throughout the life cycle of AI systems, as well as prior big data held about individuals, are shared or used, (vi) the regular implementation of comprehensive health rights impact assessments, a significant element of human rights due diligence, (vii) the promotion of transparency around the use of AI in the healthcare sector by developers, marketers, operators and users of AI systems, while enabling independent and external auditing of automated systems, and (viii) the promotion of participation of all stakeholders in decisions on AI development, deployment and use, in particular affected individuals and groups (United Nations Human Rights Council, 2021, United Nations General Assembly, 2023).

At the same time, in the context of the Council of Europe, the European Convention on Human Rights (ECHR) (1950) encompasses several provisions of relevance for ensuring individual's protection in healthcare processes and settings from AI-related abuses, including an obligation to respect human rights (ECHR, 1950, Article 1), the right to respect for private and family life that involves a right to personal (sensitive) data protection (ECHR, 1950, Article 8; see e.g., European Court of Human Rights, 2008), the right to freedom of expression (ECHR, 1950, Article 10), the right to an

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effective remedy (ECHR, 1950, Article 13), the prohibition of discrimination (ECHR 1950, Article 14; Protocol 12 to the ECHR, 2000, Article 1), and the prohibition of abuse of rights (Article 17 ECHR). Meanwhile, at the European Union (EU) level, the Charter of Fundamental Rights of the European Union contains certain provisions for fostering inclusive and equitable AI innovation in healthcare processes and settings, involving the general requirements of human dignity (Article 1), equality (Article 20) and non-discrimination (Article 21) in the enjoyment of the rights protected, involving the right of everyone to healthcare under Article 35. Notably, at the EU level, the Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonized rules on AI ("EU AI Act"), which is the first binding worldwide horizontal regulation on AI, introduces a common set of binding rules for the design and deployment of AI systems in the EU. As regards to the health sector, based on the intensity and scope of the risks that AI systems can generate, the regulation identifies certain AI systems in healthcare processes as high-risk systems such as the emergency healthcare patient triage systems given that these systems make decisions in very critical situations for the life and health of persons (Regulation (EU) 2024/1689, recital 26, recital 58 and Annex III). Moreover, it is noteworthy that the regulation includes several provisions of significant relevance to the regulation of AI systems in healthcare processes, such as obligations for risk management (Regulation (EU) 2024/1689, Article 9) and obligations for human oversight (Regulation (EU) 2024/1689, Article 14), transparency obligations (Regulation (EU) 2024/1689, Articles 13 and 50), obligations of providers and deployers of high-risk AI systems, including the performance of fundamental rights impact assessment for high-risk AI systems (Regulation (EU) 2024/1689, Articles 16-27) as well as establishes the right to obtain from the deployer clear and meaningful explanations of the role of the a high-risk AI system in the decision-making procedure and the principal elements of the decision taken (Regulation (EU) 2024/1689, Article 86). These provisions aim to ensure human rights respect by reducing the risks stemming from the lifecycle of AI systems. Here it is also important to emphasize that AI literacy concerning the operation and use of AI systems with due consideration of the context the AI systems are to be used in and the persons or groups of persons on whom the AI systems are to be used constitutes a significant prerequisite for harnessing AI's benefits, while upholding human rights principles (Regulation (EU) 2024/1689, Article 4).

LOOKING AHEAD

In light of the preceding discussion it must be conceded that the promotion of "design justice" is urgently required pursuant to which AI systems are designed through diverse and inclusive processes towards fostering an equitable digital transformation in healthcare governance (United Nations General Assembly 2023 para.: 44). Essentially, States need to establish a comprehensive framework to regulate the lifecycle of AI systems, involving high-risk systems, deployed in the health sector in a rights respecting way with emphasis on accountability and transparency requirements, accompanied by proper enforcement mechanisms, while countering human rights challenges and risks in the digital age. Within this context human rights impact

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assessments correlated with health technology assessments can constitute useful administrative tools for ensuring that AI systems in healthcare processes and settings will operate in a manner consistent with right to health obligations that would lead to better and safer AI benefits realization (Organization for Economic Co-operation and Development 2024a: 29). This also demands the meaningful participation of the healthcare users (and their representative organizations) in the decision-making processes which can be reinforced through the promotion of digital literacy of users and subjects of digital technologies so as their specific needs and concerns become an integral part of the design and deployment of AI systems in the health sector, combined also with continuous oversight on the part of the States (United Nations General Assembly 2023 para.: 76).

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PRIVACY CHALLENGES IN DIGITAL HEALTH GOVERNANCE: ETHICAL IMPLICATIONS

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ABSTRACT

Introduction: Digital health is a rapidly expanding medical field grounded on the accessibility of ever augmenting amounts of data about people's lifestyles, habits, clinical histories and pathophysiological features. From wearable devices to telehealth and telemedicine platforms, mobile health (mHealth), health information technology (IT) and personalized medicine, digital health innovations provide unprecedented opportunities to improve patient care, results, and access to medical services. Though, the defining trait of digital health relates to data rather than technology. In this regard, what is interesting about digital health, is that through wearable, portable, ingestible or implantable devices, it invokes a "seamless flow of critical medical data between patients, their families and their physicians". However, the rapid application of digital technologies raises ethical issues and privacy challenges that must be addressed in order to assure responsible and secure data use.
Methodology: The paper draws on existing literature research and applies a systematic document analysis/a systematic review. Electronic databases such as Web of Science (WoS), Scopus, Pub Med and Google Scholar, as well as documents by the European Commission (EC), the Official Journal of the European Union, the World Health Organization (WHO) etc. regarding issues, inter alia, of digital health technologies, data and privacy protection and governance, as well as the ethical values to foster ethical digital health, will be extensively searched based on the search strategy pertaining to the purpose of this paper.
Discussion: From the extensive review of the existing scientific literature, it is well established that there is an exigent need for ethical boundaries that need to be placed which determine a principal ethical framework predominantly targeted to individual action, responsibility and overall conduct in relation to the digitalization of health governance, primarily encompassing respect for human dignity, individuals' autonomy, decision making and individual privacy rights. From a practical perspective, it is claimed that this framework puts forward six ethical values involved in digital health, which are i. justice: equity in access, exclusion, equal treatment, non-discrimination, non-stigmatization, data ownership, empowerment; ii. autonomy: freedom of choice, informed consent, awareness of data collection and use, right to (not) know results; iii. privacy: data protection, confidentiality, data sharing, intended/unintended uses of data;

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iv. security: data storage, safety of information, protection against unauthorized access and use of data; v. responsibilities: trust, balance of power, relation between stakeholders, benefits and benefit sharing, data ownership; vi. procedural values: transparency, accountability, inclusiveness.
Conclusion: Against this backdrop, digital health technologies offer immense opportunities to transform health systems governance by broadening health coverage and spreading health information and literacy. Moreover, healthcare costs can potentially be curtailed and efficiency can be reinforced. Yet, digital health technologies also provoke challenges with regard to digital illiteracy, data governance and privacy human rights bringing about inequities in access and informed consent, which need to be addressed. Hence, it is crucial for all stakeholders, especially digital health providers, to ensure that digital health technologies are designed, deployed, implemented and governed in an ethical, fair, equitable, appropriate and human centered way. Establishing these regulations is a presupposition for ensuring that digital health technologies will be fit for the purpose of serving the public good.

Key words: Digital Health, Digital Ethics, Data Governance, Privacy Challenges

INTRODUCTION

The digital revolution provides huge opportunities to improve private and public life, and our environments, from health care to smart cities and global warming. Unfortunately, such opportunities come with significant ethical challenges. In particular, the extensive use of increasingly more data—often personal, if not sensitive (Big Data)—the growing reliance on algorithms to analyze them in order to shape choices and to make decisions (including machine learning, AI, and robotics), and the gradual reduction of human involvement or oversight over many automatic processes, pose pressing questions about fairness, responsibility, and respect of human rights (Floridi et al, 2019). Digital health is a rapidly expanding medical field grounded on the accessibility of ever augmenting amounts of data about people's lifestyles, habits, clinical histories and pathophysiological features. From wearable devices to telehealth and telemedicine platforms, mobile health (mHealth), health information technology (IT) and personalized medicine, digital health innovations provide unprecedented opportunities to improve patient care, results, and access to medical services. However, the rapid application of digital technologies raises ethical issues and privacy challenges that must be addressed in order to assure responsible and secure data use (Vagena et al., 2018).

METHODOLOGY

The paper draws on existing literature research and applies a systematic document analysis/a systematic review. Electronic databases such as Web of Science (WoS), Scopus, Pub Med and Google Scholar, as well as documents by the European Commission (EC), the Official Journal of the European Union, the World Health Organization (WHO) etc. regarding issues, inter alia, of digital health technologies, data and privacy protection and governance, as well as the ethical values to foster ethical

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digital health, will be extensively searched based on the search strategy pertaining to the purpose of this paper.

THE SCOPE OF DIGITAL HEALTH

Digital health, entails connecting health-related data, including data generated by patients themselves, and harnessing the medical potential of technological tools of common usage, such as smartphones, wellness bands, apps, social media and sensing devices disseminated in our dwelling environment. Most of these tools are not initially conceived for medical use and are not marketed as medical devices. Notably, however, some prominent digital health technologies already cut across the rigid distinction between licensed and ordinary gadgets, and the latter have also started to receive official designation as medical devices. But digital health is not limited to ordinary technology, nor to ordinary-turned-medical technologies. Certain digital health tools present entirely novel features, as in the case of digital pills that, thanks to a microcircuit activated upon contact with liquids in the patient's stomach, can tell an external sensor whether and when a patient has taken his or her medication. The defining feature of digital health, however, has to do with data rather than technology. What is distinctive about digital health in this respect, is that – typically through wearable, portable, ingestible or otherwise implantable devices – it generates a "seamless flow of critical medical data between patients, their families and their physicians" (Eisenstein, 2012, 1013-4). The ambition of digital health is therefore aptly described as generating a circulation of data from patients (patient-generated data), to devices and/or health professionals (who analyze and make sense of the data), and then back to devices that eventually provide the patient with information regarding their health status and how to manage it. (Vagena et al., 2018).

POLICY AND PRACTICE INITIATIVES TO FOSTER ETHICAL DIGITAL HEALTH

The purposes and utilizations of digital health are to monitor, prevent, screen, diagnose and treat health-related issues on the healthcare and public health level. This ongoing digital transformation within health and medical care could be termed as "Health 4.0", highlighting the importance of adjusting existent practice and governance structures to meet the challenges implicated by digital health, as for instance how data should be stored and accessed by whom, who can benefit from digital health and who is at risk of being excluded, and which types of informed consent should be employed. In view of this change of cultural environment, it is important to carefully consider the chances and challenges from an ethical perspective in order to establish and frame a sound and fair approach for digital health. In view of the magnitude of ethical issues emerging with the application of digital health technology, policy initiatives are needed, which specifically address those concerns. Recently, the ethical dimension gained increasing attention in the policy field as moral questions of Artificial Intelligence and underlying algorithms were publicly discussed and the need for regulation was expressed (Brall et al., 2019).

Particularly, at the EU level, this was met when the "Ethics Guidelines for Trustworthy AI" were published in April 2019 by the independent high-level expert group set up by

ISBN: 978-618-5630-22-5

the European Commission. It puts forward seven premises or values to be met by AI technologies to be trust-worthy, which are (i) human agency and oversight, (ii) technical robustness and safety, (iii) privacy and data governance, (iv) transparency, (v) diversity, non-discrimination and fairness, (vi) societal and environmental well-being and (vii) accountability (AI-HLEG, 2019). With regard to digital health specifically, the WHO concurrently released the "Recommendations on Digital Interventions for Health System strengthening", which assess the benefits, harms, acceptability, feasibility, resource use and equity considerations of digital health interventions. Whereas the WHO pronounces that "digital health interventions are not a substitute for functioning health systems, and that there are significant limitations to what digital health is able to address" (WHO, 2019, p. 13). Digital health interventions should complement and enhance health system functions through mechanisms such as accelerated exchange of information, but will not replace the fundamental components needed by health systems such as the health workforce, financing, leadership and governance, and access to essential medicines (WHO, 2019). WHO also implemented the "Digital Health Atlas", a website-based technology registry for systematically tracking national digital health activities, in order to equip governments, technologists, implementers and donors to better regulate implementations, as well as supervise their functionality and geographical growth (WHO, 2019, p. 33).

Also, in the related field of regulating health data—often referred to as big data—criteria and proposals were developed. In 2024, the OECD "Recommendation on Health Data Governance" pertains to the access to, and the processing of, personal health data for health-related public interest purposes, such as improving health care quality, safety and responsiveness; minimizing public health risks; identifying and assessing new diagnostic tools and treatments to improve health outcomes; governing health care resources efficiently; contributing to the progress of science and medicine; improving public policy planning and evaluation; and reinforcing patients' participation in and experiences of health care (OECD, 2024, p.4).

Whereas the EU "General Data Protection Regulation – GDPR" (2016) can be seen as a first binding legal step toward protecting data privacy. Establishing regulations to manage the handling of digital health technologies and big data not only fosters users' trust in digital health and thus adoption of it, but it can also contribute to a fair, ethical, equitable application and implementation of digital health. As long as digital health can be offered in a fair manner, its opportunities can exceed the challenges (Brall et al., 2019; EU – GDPR, 2016).

ETHICAL AND POLICY IMPLICATIONS IN DIGITAL HEALTH

From the extensive review of the existing scientific literature, it is well established that there is an exigent need for ethical boundaries that need to be placed which determine a principal ethical framework predominantly targeted to individual action, responsibility and overall conduct in relation to the digitalization of health governance, primarily encompassing respect for human dignity, individuals' autonomy, decision making and individual privacy rights. From a practical perspective, it is claimed that this framework puts forward six ethical values involved in digital health, which are i.

ISBN: 978-618-5630-22-5

justice: equity in access, exclusion, equal treatment, non-discrimination, non-stigmatization, data ownership, empowerment; ii. autonomy: freedom of choice, informed consent, awareness of data collection and use, right to (not) know results; iii. privacy: data protection, confidentiality, data sharing, intended/unintended uses of data; iv. security: data storage, safety of information, protection against unauthorized access and use of data; v. responsibilities: trust, balance of power, relation between stakeholders, benefits and benefit sharing, data ownership; vi. procedural values: transparency, accountability, inclusiveness (Brall et al., 2019, p.20; Royakkers et al., 2018).

i. Privacy and security

As more data sources become available and advanced analytics can be applied for various purposes, protecting privacy is undoubtedly a complex challenge. Data security has also been a challenge, with cyber-attacks, hacking of databases and data kidnapping. In this context, people need to be convinced that robust security measures are mandated and enforced through coherent policies. Concerns can be addressed with the adoption of appropriate technologies, monitoring and evaluation of security systems, transparency and accountability mechanisms;

ii. Trust

Public trust in health data uses is of paramount significance. However, trustworthy digital health activities require more than privacy protection. Components of trust include transparency, accountability, benefit sharing and undoubtedly more clarity about data ownership and data control. What is important is that trust cannot be achieved by promoting only one of the above mentioned components, but rather through a concerted effort to promote all of its components. Therefore, trustworthiness cannot merely be attained by innovative consent models offering more or less control of data uses. Rather, consent innovation has to also be accompanied by transparency on how individuals and societies will benefit from digital health developments, by oversight mechanisms that safeguard public interests and by accountability mechanisms that can maintain public scrutiny;

iii. Accountability

With automated data mining for decisions of clinical or public health relevance becoming one of the most promising features of digital health, accountability is of critical importance. Particularly, the employment of these new tools involves pertinent adaptations in existent accountability standards. In addition, mobile technologies can be used to target specific populations with health-related information that can help contain the spread of infectious diseases. These new developments can reinforce the speed and accuracy of health monitoring, contributing to more focused and effective interventions. It is expected that medical practice will increasingly be enhanced by AI algorithms for diagnosis, treatment decisions and surgical procedures. Progress in such areas is expected to greatly improve the quality of healthcare provision for patients. Such tools can vary from providing assistance to health care providers to possibly one day being fully autonomous from human supervision. Nevertheless, as more AI-guided

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tools become autonomous, fewer human operators are able to supersede their decisions and actions. (Vagena et al., 2018, p. 3-4).

The field in which ethical issues in digital health accumulate is multifaceted: i. it is determined by the distinct phases of digital health usage, for instance before accessing digital health technologies, during, as well as after usage; ii. different stakeholders from the medical and non-medical, public and private sector are involved, setting new challenges with regard to governance structures, emphasizing the need for reconsidering responsibilities; iii. challenges are bound to technical issues, such as how to protect data (i.e. secure storage, firewalls, etc.), as well as to aspects associated to general governance (i.e. accountability and transparency) (Brall et al., 2019, p.18-19).

i. Access

The first phase of digital health usage is before users actually access such technologies and applications, where ethical considerations inherently arise in line with aspects related to access. They specifically relate to logistic and resource-related aspects, including equitable access to digital health services in terms of affordability of and access to technological equipment. It remains crucial to safeguard fairness and equity in access already when developing such digital health approaches. Integrating such ethical considerations in the planning phase is, mostly in the field of AI for health (Brall et al., 2019, p.18-20). The above arguments imply that ethics and AI are associated at several levels: (i) Ethics by Design: the technical - algorithmic embodiment of ethical reasoning capabilities as part of the behavior of artificial autonomous system, (ii) Ethics in Design: the methods, the scope of regulation and engineering that sustain the analysis and evaluation of the ethical implications of AI systems as these incorporate or substitute traditional social, moral, legal structures and (iii) Ethics for Design: the codes of conduct, standards and certification processes that ensure the integrity and credibility of developers and users as they research, design, construct, employ and manage artificial intelligent systems (Dignum 2018; Sekiguchi & Hori 2018). Thus, the developers of digital health interventions have a moral responsibility to design and develop such technologies in a way that take into account ethical considerations, for instance when designing algorithms for AI, that represent all parts of the population and leave no ground for bias and resulting discrimination. However, digital health technologies offer opportunities for inclusion of population groups which experience barriers to access conventional healthcare provision due to geographical distance to reach medical settings in general or specified healthcare professionals or due to physical inability to travel to the medical sites on a regular basis. Furthermore, possible increases in coverage contribute to improve global health and can be evaluated as a measure to enhance equality of opportunity (Brall et al., 2019, p.18-20);

ii. Truthful information, empowerment and informed consent

In order to make people competent to actually employ the opportunities offered to them if they wish, truthful information about the benefits and risks of engaging in digital health methods has to be provided to the individual users. Hence, users should be motivated and entrusted to be involved in digital health technology. For this reason, open communication, technical training and education should be available. Moreover,

ISBN: 978-618-5630-22-5

users of digital health technology should be cognizant that their data are being collected for health-related purposes, for instance in the case of location tackers, which can give information about an individual's health. However, there is always the peril of digital health constituting a "surveillance society". Concerning truthful information, informed consent has a leading role. While, traditional models of informed consent aimed to inform patients and research subjects and primarily paid attention to avoid harm to the individual in the course of the procedure, new patterns of informed consent for digital health have to be regarded. Specifically, the new patterns should not only recognize intended and unintended uses of data provided by aware users, but should also examine the larger time dimension, when data are stored and potentially used for a substantial amount of time (Brall et al., 2019, p.18-20);

iii. Storage, access, sharing and ownership of data

Implementing digital health technologies and also thereafter, challenges of ethical concern arise with regard to storage, access, sharing and ownership of data as well as return of results. Apart from specifying relevant ethical considerations in accord with security, privacy, confidentiality, discrimination, unintended uses of data and right to know or not to know results about sometimes incidental findings, these aspects also have implications for an ethical, fair and just application of digital health. Most importantly, data have to be stored in such a way that no unauthorized access through hacking or other fraud is facilitated that tolerates discrimination and stigmatization, when confidential information is being abused. Additionally, when data collectors grant access to other stakeholders, various considerations regarding fairness emerge: What is the purpose of accessing and using the data? Are users aware of the uses of their data? And are these data only used for intended purposes or also unintended uses? These queries are relevant to address as they not only refer to the ethical issues of autonomy, informed consent and right to privacy, but are also closely interrelated with justifiable uses of data basing on the individual's right to determine for what his or her personal information is used for. A fair use of data should be guaranteed as regards ownership of data, circling around questions to be answered as regards to who owns the data and who is responsible for guarding data, namely data collectors, users themselves, governments, public organizations, etc. (Brall et al., 2019, p.18-20);

iv. Dignity and Autonomy

Digital health tools should only be adopted when the dignity of the patient can be protected. For instance in the case of using telemedicine in hospital settings, the conveyance of potentially bad news to the patient should be in accordance to upholding dignity of the patient and therefore distant technologies (through using screens) should be refrained from when delivering news which put the patient in a vulnerable situation. Instead, personal and face-to-face communication is preferred to protect dignity of patients in vulnerable situations. In this case, however, autonomy—in terms of patients' choice of the communication channel—can tailor the delivery of healthcare to patients' needs. Conversely, patients who do not want to be institutionalized, can stay at home longer and be better supported in their home environment by means of telemedicine.

ISBN: 978-618-5630-22-5

Consequently, their quality of life and dignity can be ameliorated through the application of such technologies (Brall et al., 2019, p.18-20).

CONCLUDING REMARKS

The new wave of digitization prevails on public values. Digital technologies (services and products) are not plain gadgets, they are having a radical impact on societies. It is time to identify the implications and to ensure that people's values and fundamental rights are protected in the new digital era. Such an awareness is imperative in that issues regarding ethics, informed consent, privacy and data governance etc. can be pro-actively addressed, that is, be anticipated, reflected upon, deliberated with the public and other stakeholders, and be responded to (Kizza, 2013; Stahl et al. 2017). For other ethical issues concerning digitization such as discrimination, autonomy, human dignity and unequal balance of power, the supervision is hardly organized. Besides, civil society organizations and citizens are not sufficiently aware of the new digital developments, nor do they realize how they will be affected; the possibilities to defend themselves are too restricted. The need to focus on the effects of digitization is underlined by the fact that the central ethical themes relate to important values set down in international treaties and national constitutions. Issues, such as privacy and justice reflected in the right to respect for private life, the right to equal treatment and the right to a fair trial. Human dignity is mentioned in international treaties such as the Charter of Fundamental Rights of the European Union (EU Charter) "Human dignity is inviolable. It must be respected and protected" (article 1) and the Universal Declaration of Human Rights (UDHR) "Everyone who works has the right to just and favourable remuneration ensuring for himself and his family an existence worthy of human dignity, and supplemented, if necessary, by other means of social protection." (article 23, para.3). Values such as autonomy, equal power relationships and control over technology are not explicitly named in the treaties but can be seen as part of or following from these fundamental and human rights (Royakers et al., 2018, p. 139-140).

Against this backdrop, digital health technologies offer immense opportunities to transform health systems governance by broadening health coverage and spreading health information and literacy. Moreover, healthcare costs can potentially be curtailed and efficiency can be reinforced. Yet, digital health technologies also provoke challenges with regard to digital illiteracy, data governance and privacy human rights bringing about inequities in access and informed consent, which need to be addressed. Hence, it is crucial for all stakeholders, especially digital health providers, to ensure that digital health technologies are designed, deployed, implemented and governed in an ethical, fair, equitable, appropriate and human centered way. Establishing these regulations is a presupposition for ensuring that digital health technologies will be fit for the purpose of serving the public good (Brall et al., 2019).

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QUALITY ASSURANCE IN HEALTH UNITS

THE IMPACT OF INTERNAL AUDITS ON UPGRADING INFORMATION SYSTEMS IN GREEK PUBLIC HOSPITALS: ADDRESSING CORRUPTION AND TECHNOLOGICAL DEFICIENCIES

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ABSTRACT

Corruption and mismanagement are at the center of discussions regarding public hospitals in Greece. With the 4025/2011 Greek legislative ordinance, internal audit was instituted with the aim of minimizing these phenomena and ensuring better quality health services. The purpose of our study is to demonstrate that internal audit contributes to the maximum extent to the upgrading of the existing information systems of Greek hospitals. For the preparation of this study, a database of results from recent internal audits (2022-2023) of a representative sample of 48 out of 131 secondary hospital structures in the country's health regions was used. Particular emphasis was placed on evaluating and auditing the processes of independent departments such as IT, accounting, and control mechanisms – security safeguards across the entire IT infrastructure of the hospital services. From the results of the survey, malfunctions and lack of security in the operation of the information systems of hospitals were found in a large part of our sample, along with insufficient use of medical and informatics technologies. Specifically, in 27.08% of the hospital structures in the sample, cases were observed where either no IT application existed or it was not adequately utilized by hospital staff. Furthermore, some other problems hospital structures identified regarding the interconnection/interoperability of the information systems were related to the inability of certain clinics to announce electronically the patient to their insurance provider, failure to adhere to electronic referrals and lack of updates to the National Insurance Capability Registry. In 19% of hospital structures, there were no safeguards for network protection and equipment, such as address security controls, nor were there access-level classifications to the internet based on the employee's position, aimed at ensuring overall process security. The new developments in hospital administration

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highlight the significant role of technology, leading to a redefinition of their goals and revealing dysfunctions that contribute to mismanagement, corruption, and resource waste. However, as the study results have shown, a large part of the studied hospital structures are at a moderate level of information system organization, not meeting the requirements expected of a modern Health Unit within the Information Society. Underfunding and poor administration of hospitals actively contribute to an unfavorable framework for the implementation of reform proposals in key areas such as information systems. Given the circumstances and the institutionalization of internal audit, the provision of services in several cases has been upgraded, enhancing the operation of information systems. In this way, appropriate guarantees are provided to hospital staff for the exercise of good governance.
Key Words: internal audit, public hospitals, health information systems, health system.

INTRODUCTION

The new Information and Communication Technologies (ICT) and the capabilities they provide have penetrated every aspect of our daily lives (education, work, public administration, entertainment, etc.) including healthcare. Hospitals gather and process significant information about citizens' health. IT solutions are being adopted and implemented for recording and efficiently managing the large volume of data (medical and administrative-economic operations). From this perspective, ICT offers significant advantages to healthcare units (e.g., workload reduction, improvement of working conditions, etc.), simplifying hospital operations as a whole. However, in Greece, they have not experienced corresponding development. As a result, management errors that incur costs (e.g., bureaucracy, corruption, and lack of transparency) are observed, impacting the state budget and the quality of provided services. With the institutionalization of internal audits in healthcare institutions, an effort was made to mitigate these issues through better utilization of information systems (Koutoupis A.C., 2009).

The Information Systems of Healthcare Units and Their Components

The needs of modern times make the development of new methods for hospital management and the adaptation of existing ones to the demands of the new era imperative. Information systems serve this purpose and represent both innovation and a challenge in the field of healthcare service management, particularly in Greece, which has faced years of dysfunction due to various crises (economic crisis, pandemic). Specifically, a Hospital Information System (HIS) is a computational system that ensures the integration and communication of external and internal information flows within a hospital, as well as a unified operational approach to applications within the hospital (Giavrami K., 2013). The goal of an HIS is to improve the quality of care provided and optimize patient service. Therefore, optimizing the quality of services (Karastamati E., 2012) and delivering accurate information results in better healthcare planning, improved diagnoses, and increased access to healthcare services for more patients across an entire country.

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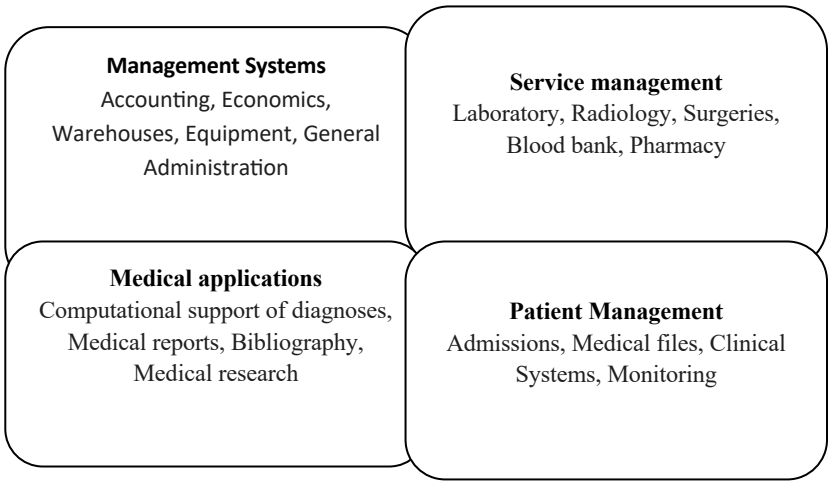
Hospital Information Subsystems

The information subsystems of a hospital constitute an Integrated Hospital Information System, which is divided into the following subsystems (Vangelatos A. & Sarivougioukas I., 2001): the administrative/financial subsystem, the medical subsystem, the laboratory subsystem, and the management subsystem (see Figure 1).

Figure 1

Hospital Information System



Source: Karastamati, E. (2012)

Problems in the Implementation of Hospital Information Systems

When Hospital Information Systems (HIS) are implemented optimally, they yield significant benefits. However, due to unforeseen factors, implementation challenges often arise. Adopting and implementing reliable hospital information systems can be difficult to achieve due to various constraints (Giavrami K., 2013). The primary reason for failed development or adoption lies in the particularly high cost of such investments. Additional reasons include the lack of clearly defined system objectives and the selection of inappropriate technology for implementation. Further challenges stem from miscalculations of development costs or the financial impact of the system, insufficient data processing, and the users' lack of knowledge regarding ICT or the specific application.

Purpose of the study

The purpose of this study was to examine the processes of a representative sample of hospitals within the Greek Health System and to identify the operational risks associated with their various activities and functions. Particular emphasis was placed on the evaluation and assessment of the processes of independent IT departments and the control mechanisms—safeguards—across the entire scope of the computerized structure of hospital services.

DATA AND METHODS

This study utilized the results of internal audits conducted during the period 2022–2023 by an internal auditing firm on 48 out of the 131 largest hospitals within the Health

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Regions (H.R.) of the country. The aim was to evaluate the implementation of Hospital Information Systems (HIS) and their impact on the operation of hospital units as applied thus far in Greece. The primary objectives of the audit focused on reviewing the Independent Departments of Organization and IT, the operation of computerized systems, the interconnection of Information Systems, and the hardware. Additionally, emphasis was placed on network and equipment security, the review of the Security Policy and Disaster Recovery Plan, adherence to backup protocols, staff training needs and processes, software usage audits, and equipment inventory procedures. Furthermore, particular attention was given to user access to the network and data security, network equipment maintenance, the preparation of Annual IT Equipment Needs, the lack of goal-setting processes or annual departmental plans, the management and monitoring of maintenance contract agreements, the systematic recording and tracking of tasks, the assignment of unrelated duties to staff, and finally, the staffing levels of IT Departments. Based on the internal audits conducted on a reliable sample of healthcare institutions, the hospitals were categorized into high-risk (H), medium-risk (M), and low-risk (L) institutions.

RESULTS

The adoption and integration of information systems in hospitals, combined with their effective impact on all operations, provide a new "technological identity" and transform them into a strategic resource fully integrated into the overall operational strategy of the healthcare institution. However, as revealed by the internal audit conducted, it was determined that these systems are at a moderate level of information organization, failing to meet the requirements demanded by the structure of a modern Health Unit within the Information Society (Stamoulis M. et al., 2009). The research findings for all hospitals within the Health Regions are presented in Table 1 below:

Table 1

Results of Internal Audit Research in Hospitals of the Health Regions

Health Regions		Total Number of Hospitals	Sampled Hospitals	High-Risk Hospitals	Medium-Risk Hospitals	Low-Risk Hospitals
1	1st Health Region (Attica)	28	12	2	9	1
2	2nd Health Region (Piraeus and Aegean)	22	11	2	7	2
3	3rd Health Region (Macedonia)	17	8	2	5	1
4	4th Health Region	16	8	1	7	0

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	(Macedonia and Thrace)					
5	5th Health Region (Thessaly & Central Greece)	13	5	3	2	0
6	6th Health Region (Peloponnese, Ionian Islands, Epirus, Western Greece)	27	3	2	1	0
7	7th Health Region (Crete)	8	1	1	0	0
Total:		131	48	13	31	4

Source: Our processing of Data

Specifically, the hospitals that participated in the study were categorized into high, medium, and low risk based on internal control standards. From our sample, the majority of the hospitals (31 out of 48) are classified as medium risk, reflecting functional malfunctions in the internal control processes, while 13 out of 48 hospitals fall into the critical high-risk category. Positive results are observed in 4 hospitals in our sample located in the two Health Regions of Attica (Attiko, Thriassio, Onassis) and Papageorgiou in Thessaloniki, specifically in the 3rd Health Region. Most of the hospital structures under study are in a moderate state of administrative risk; however, there is significant potential for improvement, provided that the recommendations of internal auditors are taken into consideration by the management of the healthcare institutions. The findings of the internal audits conducted in public hospitals by specialized and certified auditors, and the categorization of these hospitals into high-risk (H), medium-risk (M), and low-risk (L) are presented below. The results of the audits are detailed below.

High-risk hospitals

In the high-risk category, it was found that 27.08% of the studied sample falls into this group, which corresponds to 13 out of 48 hospitals in the country. Of these, 6 hospitals are located in the 5th, 6th, and 7th Health Regions, 4 hospitals in the 1st and 2nd Health Regions, and 3 hospitals in the 3rd and 4th Health Regions. Specifically, in hospitals of this category, several tasks have been outsourced to private IT companies, with "HDIKA" handling the majority of hospital applications (interconnection between their IT systems). However, there have been instances where either no IT application exists, or it is not sufficiently utilized by hospital staff. Additionally, some issues regarding the interoperability of IT systems have been identified, such as the inability to notify certain clinical departments about the electronic notification of the patient to "EOPYY" (due

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to the inability to recognize "EOPYY"), the failure to comply with electronic referral issuance (due to "HDIKA"), and the incomplete updating of the National Insurance and Coverage Registry "ATLANTIS" (even though there is an existing connection). However, there are no security mechanisms for network access, and there is no accessibility classification on the internet per workstation/employee, aiming at the overall security of the process. Backups (backup) are maintained in all servers at the hospitals in our sample, located within the hospital buildings in specially secured areas (computer rooms) that have the necessary security measures for emergency situations (e.g., fire, theft, etc.). Additionally, backups are also stored on Network Attached Storage. Nevertheless, in case of natural disasters (e.g., earthquakes), the security of hospital data is not ensured, as no backup is kept on servers outside the hospitals.

Medium-Risk Hospitals

In the medium-risk category, it was found that 64.58% of the studied sample i.e., 31 out of the 48 hospitals in the country, fall into this category. Of these, 16 are distributed across the 1st and 2nd Health Regions, 12 across the 3rd and 4th Health Region, and 3 across the 5th, 6th, and 7th Health Region. Specifically, in hospitals of this category, the hardware equipment is significantly modern. Only 15% of the computers are outdated, frequently encountering issues related to failures and maintenance. Additionally, only 20% of these computers have a central processing unit dating back to 2016 or earlier, rendering their processing power inadequate to efficiently handle most modern programs and applications. Furthermore, issues were identified concerning the security policy (absent in the form of an official document) despite the pilot implementation of relevant practices, as well as the disaster recovery program (also absent). The level of IT knowledge among the staff in the IT departments is generally very low. Additionally, there are no established training procedures for hospital unit staff conducted by the IT department employees on topics relevant to their specialties (e.g., browsers, internet, Word, Excel, etc.), except when new applications are installed or during significant customizations in each department by IT companies. In cases of queries, informal training or assistance is provided by the IT department on a case-by-case basis to individual employees.

Regarding software usage controls in each hospital, installing new programs on the hospital's computers is impossible unless the user has administrator rights. This is because access rights are granted by IT departments to employees at a 'restricted' user level, except for 5% who are power users. These individuals have limited access rights due to the nature of their work (e.g., medical laboratories). To support the functionality of hospital departments and save resources, free software from the internet can be installed on the computers of health units. Although a documented process for recording and monitoring the hospital's entire equipment inventory is absent, this task is largely ensured as IT department staff maintain a detailed Excel file tracking installed computers and printers (both on and off the network within the hospital premises). However, some equipment has not been included in the hospital inventory, rendering the file incomplete. Unfortunately, in most cases, labeling tags with serial numbers for all equipment are not used, although tracking is conducted based on the computer name

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(a unique and descriptive name) provided by the Organization and IT Department. Regarding user access to the internet, it is governed by strict security levels tailored to the responsibilities and duties of each hospital department or clinic, at the program level. To facilitate employee functionality, simultaneous log-ins of the same user on multiple computers are observed. In rare cases, a security password is provided to certain employees, along with password changes to ensure process security. The IT applications at the medium-risk level are supplemented by some additional elements. With changes in management, detailed equipment lists and related documents were prepared and shared, analyzing the needs of the departments. Furthermore, regarding the monitoring of maintenance contracts between hospitals and IT companies, preventive maintenance visits are included without additional costs, as well as the resolution of problems/malfunctions within a specified timeframe in most contracts. Concerning the systematic recording and monitoring of activities, while the time of user access and the point in the system from which users log in are recorded and tracked by the Organization and IT Departments of the hospitals, exception reports (e.g., unusual user access such as changes to static patient or staff data) are not generated. IT department employees were often found to be occupied with unrelated tasks (e.g., internet postings, general computer usage issues), which, combined with understaffing, gradually hinder the department's and the hospital's overall functionality.

Low-Risk Hospitals

In the low-risk category, it was found that 8.33% of the studied sample, i.e., 4 out of the 48 hospitals in the country, fall into this category. Of these, 3 are located in the 1st Health Region and 1 in the 3rd Health Region. Specifically, the Organization and IT Departments are capable of providing significant support to the individual departments and clinics of these hospitals in matters related to equipment repairs and/or replacements.

DISCUSSION AND CONCLUSIONS

Discussion about the new developments in hospital management highlight the significant role of technology, leading to a redefinition of their objectives and uncovering dysfunctions that contribute to phenomena of mismanagement, corruption, and resource wastage.

For hospitals categorized as high-risk, the operation of the independent IT departments is further complicated due to the lack of goal-setting processes and annual plans for these departments. Specifically, there are no measurable (and objective) goals, making it impossible to carry out actions with a specific direction/strategy in combination with the evaluation of the contribution of the departments and their employees. Therefore, it is difficult to design future actions of the departments, which is compounded by unforeseen events and changes in the regulatory framework. A series of actions is proposed to improve their effectiveness. Some of these include enhanced computerized coverage using updated software programs, full utilization of existing equipment, intensified communication with "EOPYY" (National Organization for Healthcare Services Provision) and the "ATLAS" registry, conducting a cost-benefit analysis of the IT Department in collaboration with management while prioritizing needs to establish

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an Internet accessibility hierarchy process (per job position), creating a backup server outside hospital premises (to prevent data loss in case of natural disasters), and drafting an annual plan with measurable and objective goals and directions.

Regarding medium-risk hospitals, most IT departments and other specialized administrative staff are understaffed, particularly in regional hospitals outside Athens, leading to problems in the daily operation of departments and healthcare units as a whole (Antonoglou D. & Rontos K., 2024). Suggested to conduct a thorough evaluation and prioritization of needs for cost-benefit analysis, drafting a Security Policy study and a Disaster Recovery Plan, reinstating hospital information systems (HIS) in emergencies (disaster recovery site), compiling a formal document of IT Security Policy, recording staff training needs, maintaining existing security safeguards along with regular monitoring (to prevent illegal computer use, potential civil, criminal, or administrative penalties), and assessing departmental and clinical needs of hospitals. It is also recommended to consider acquiring Volume Licensing Programs, setting individual profiles for each employee, securing access for all employee profiles, and regularly changing user passwords (Rodakos H.P., 2015). Additionally, a documented report on existing needs, IT infrastructure expansion requirements, potential replacements, promotion of HIS security or software legalization, annual consumable tracking, monitoring of maintenance contracts with documented compliance checks, and communication between the Organization and IT Support Departments with IT contractors to explore generating exception reports from HIS to track and review unusual user accesses are advised to ensure further process security. Consolidating staff responsibilities to align with their designated roles within the hospital's organization (Koutoupis A.C., 2009) is also encouraged.

Finally, about low risk hospital, the organization and IT Departments are capable of providing significant support to the individual departments and clinics of these hospitals in matters related to equipment repairs and/or replacements (often resolving the majority of malfunctions). However, due to the volume and severity of the malfunctions, the insufficient knowledge of department staff, and the required time, the hospitals have entered into maintenance contracts with external partners.

To conclude, this study captured the actual state of internal audit processes in public hospitals nationwide based on results obtained from internal auditors tasked with carrying out this work. If internal audit results for (131) public hospitals in the country were available, a comprehensive assessment of the overall situation in each Health Region and hospital could be made, allowing a comparison of the effectiveness of their respective administrations.

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HUMAN RESOURCES AND HEALTHCARE: FLIPPED TEACHING PRACTICES FOCUSED ON SOCIALIZATION OF WORKERS IN HEALTHCARE UNITS

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ABSTRACT

This research examines the implementation of flipped teaching practices in the healthcare sector, focusing on their impact on staff socialization and professional development. The flipped teaching strategies, known as Flipped Learning, can promote active participation and interaction, thereby improving interprofessional collaboration and the quality of healthcare services. By meaningfully integrating digital tools and interactive experiences, employees improve their problem-solving skills and develop skills critical to the quality of patient care. The research highlights the need for innovative educational approaches that adapt to the ever-changing needs of the healthcare sector. The results suggest that flipped teaching practices in the healthcare sector, contribute to the creation of a supportive learning environment, where employees become more engaged and efficient. Integrating educational practices into the workplace through carefully designed training programs can significantly improve organizational effectiveness and the quality of healthcare services provided. This strategic combination of flipped teaching practices with knowledge management models such as the SECI model improves employee socialization and organizational culture, promotes innovation and continuous professional development of staff, and

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emphasizes the importance of continuous training to improve professional skills. capabilities and improving the overall performance of the organization.

Key Words: Flipped Classroom, SECI Model, HRM, Health Units

INTRODUCTION

Modern healthcare relies heavily on effective collaboration and successful communication between healthcare professionals. The quality of patient care is directly related to the efficiency and participation of employees in the healthcare units. However, the continuous developments and increasing demands in this area require the introduction of innovative teaching strategies that contribute to the training process and professional development of staff. Among the most promising innovations in education are inverted teaching practices – also known as flipped classrooms or inverted learning – which have gained ground in recent years. In this model, students (or in this case staff) prepare for the course in advance by studying material provided online. The workspace is then used for knowledge application and collaborative learning activities. Such an approach allows participants to focus on topics that interest them most, encouraging active participation and interaction among themselves. The incorporation of a similar method in the training of health workers is a response to the needs of modern healthcare where rapid and continuous training is essential. Although traditional lecture-based training has gained wide recognition, it appears to pose challenges in terms of active participation. And this is because new flipped teaching practices promote an environment of learning innovation where employees are encouraged to actively participate in the learning process and develop important skills necessary for their professional development (Latorre–Cosculluela et al., 2021; Nichat et al., 2023; Zhang et al., 2023). Socialization of employees in healthcare units is an essential factor in the success of healthcare organizations. Socialization strengthens relationships and cooperation among group members, contributing to understanding of group roles and trust. However, HRM challenges such as workplace stress and pressure, need to be overcome by implementing strategies that promote employee collaboration and support. The SECI model (Socialization, Externalization, Combination, Internalization) provides a useful framework for understanding the process of knowledge management and knowledge diffusion by integrating the process of socialization into discrete phases of transfer of explicit and tacit knowledge of the organization. Its application in combination with flipped teaching practices can promote the development of a culture of knowledge that favors professional development and interaction between employees (El Mawas & Muntean, 2018).

THE CURRENT STUDY

The study investigates the role of flipped teaching practices in the socialization and professional development of healthcare workers, focusing on improving collaboration and knowledge management, thus enhancing effectiveness and overall efficiency in the workplace. Exploring case scenarios highlights the imperative need for knowledge sharing and knowledge diffusion, especially for new entrants to the healthcare field.

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Through the recognition of challenges and emerging opportunities, this research seeks to develop innovative educational methodologies, with the ultimate goal of improving the quality of care and services provided to patients. The main problem concerns the socialization of workers in health units, which is recognized as a critical factor for their professional development and the success of health organizations. The research hypothesis speculates that the application of Flipped Learning can enhance this socialization process by promoting collaboration and knowledge sharing among employees. Research examines how this educational-in-the-field approach affects the development of critical professional skills and the overall quality of care provided. In order to function well in the area of health units, it is apparent that good interpersonal relationships, effective communication, rules of conduct, awareness of incident response protocols and professional redefinition are required in the modern environment and in "ba" (Attard et al., 2021) as a holistic position of a learning community and the individual learner who collaboratively delivers all the distinct phases of the SECI model to the group. "ba", defined as a common environment, comes from Japanese and means "place". It is a spatiotemporal relationship, establishing the correlation of space and time, which can unify physical space, cyberspace and thought space, as a model of knowledge creation, a place where knowledge is shared (Hu et et al., 2023). As a new space-time work, according to SERVQUAL (Amponsah & Agyekum, 2021) the formation of a framework that will focus on the continuous professional development of health workers through more innovative educational practices is required. The literature particularly emphasizes the importance of Flipped Learning for the socialization of healthcare work (McLaughlin et al., 2014). According to Zhang (2023), the use of online tools is drastically changing health education and providing opportunities to develop critical thinking and problem-solving skills (Zhang et al., 2023). Others also emphasize that the flipped classroom is of interest because it can promote collaborative learning environments (Alshebami & Seraj, 2022).

The purpose of the study was to examine the effect of Flipped Learning on the process of socialization and professional development of workers in health units. Specifically, it focused on how this educational approach improves collaboration and knowledge management in healthcare as other researchers have examined (Shahmoradi et al., 2017), but it goes deeper, according to the model of transfer of explicit and tacit knowledge in organizations. This model known as SECI (socialization, externalization, combination and internalization) was developed by Nonaka and Takeuchi (1995).

Investigative Questions:

1. How does flipping learning affect employee socialization?
2. What impact does Flipped Learning have on professional development and critical thinking skills?
3. How does Flipped Learning help improve collaboration and knowledge management among employees?

The present study examines the impact of flipped teaching practices on the social and professional development of healthcare workers, using a mixed methodological framework to highlight the benefits of critical thinking and collaboration through the

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SECI model. The results are expected to provide valuable insights for improving self-learning strategies and improving knowledge management and interaction in high-pressure environments.

METHODS

The research questions were answered through a qualitative and quantitative analysis of the participants' experiences, collected through interviews and questionnaires based on the RGT tool. Operational definitions include variables that assess employees' socialization, knowledge management skills, critical thinking, and professional development. The variables were measured using the qualitative and quantitative RGT (Repertory Grid Technique) approach tool, which allows comparing participants' perceptions before and after applying Flipped Learning (Figure 1). These observations provided information about social dynamics and improving professional behavior.

The study used a mixed methods approach with a representative sample of 22 workers from a regional health center in Crete, selected through purposive sampling to ensure representation of different professional roles and experiences, thus enabling the emergence of polyphony in the health sector. Group A, 14 employees, with no knowledge of digital technology, worked together using the Delphi method, while Group B, 8 employees, prepared a week of Flipped Learning. The application of authentic learning and the integration of Flipped Learning, combined with the use of the SECI levels, improved collaboration and organizational effectiveness in Group B, while Group A showed deficiencies in socialization and internalization of knowledge, which negatively affected management and organization. First, interviews were conducted with staff, followed by observations of problem- solving practices. Participants' personal perceptions and experiences were revealed through authentic learning materials for assessment. This material was distributed for flipped study and contributed to deepening understanding and critical analysis. This approach contributed to the evaluation of the empirical data and the formation of consensus conclusions. The combination of these methods expanded scientific knowledge and academic debates. The workers informed about the SECI phases (Nonaka et al., 2000) participated in focus group discussions in which they analyzed case studies and applied authentic learning to real-world problems in professional practice over the following week. The paradigm problematization that focused on the increase in mental health problems due to stress in HRM provided the framework for the application of their knowledge. Additionally, ICT professionals used to engage in Flipped Learning outside of work, expanding their skills through design thinking PBL techniques. The eight ICT specialists participated in online sessions and flip learning activities to deepen their knowledge and strengthen their critical thinking.

RESULTS

The research questions examined the effects of Flipped Learning on employee socialization, professional development, critical thinking skills and collaboration. It examined how this approach to learning and individual engagement improves knowledge management and collective interaction in the workplace.

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The observation of problem-solving practices was accompanied by interviews in which employees' personal perceptions and experiences during employee training were recorded. By using Flipped Learning, Team B improved the SECI process at all stages and promoted participation and collaboration. In contrast, Group A demonstrated weaknesses in socialization and internalization of knowledge, resulting in less effective management and organization. This research project demonstrates the value of incorporating modern educational approaches to improve organizational knowledge and effectiveness. Specifically, employees gave the following answers to solve the problem of "Increase in mental health problems due to pressure on HRM".

Group A (Delphi):

S: Meetings with employees to understand their psychological needs.
E: Creation of support programs.
C: Synthesis of the elements for the development of intervention programs.
I: Training for the implementation of the programs.
--S: Reduced interaction and recognition of psychological needs.
--I: Limited application of support programs.

Group B (Flipped Learning):

S: Creating online courses about mental health.
E: Workshops where employees will be able to share their experiences.
C: Gathering experiences to improve programs.
I: Application of knowledge in real scenarios.
++S: Online courses that encourage open discussion.
++I: Application of knowledge in real support scenarios.

1	Flipped Classroom	lectures	job training	interdisciplinarity	digital tools	5
socialization						+socialization
sense of community						+sense of community
PBL skills						+PBL skills
professional development						+professional development
knowledge management						+knowledge management
organizational efficiency						organizational efficiency

Figure 1: RGT the views of employees

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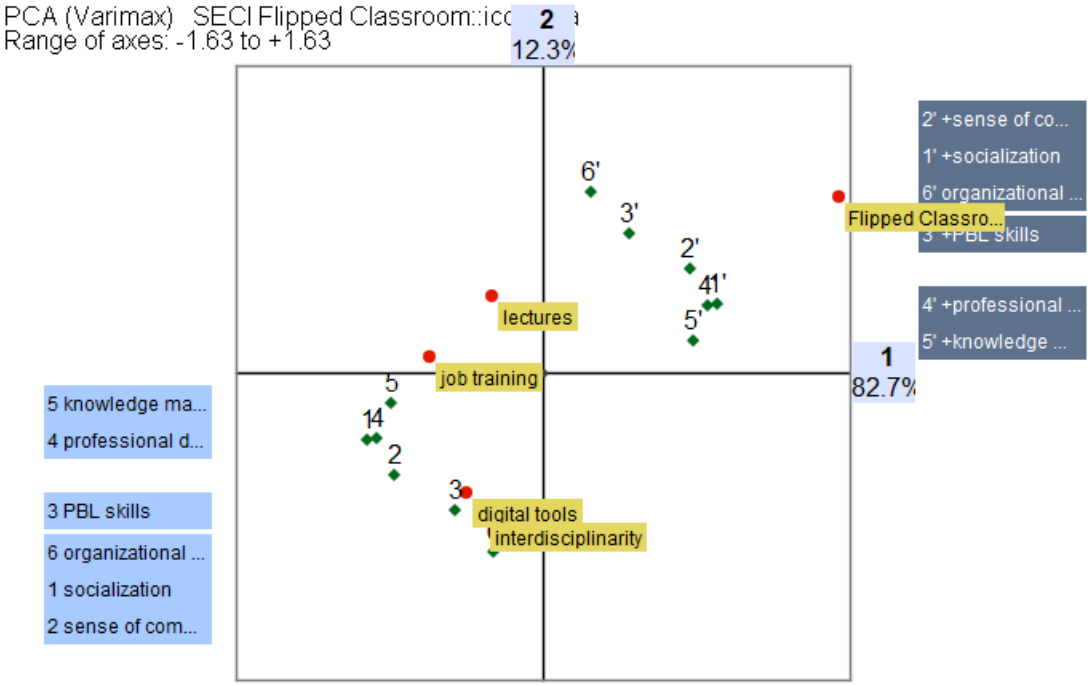

Figure 2: PCA Analysis

In the present study, a combined quantitative and qualitative analysis was applied to examine the two groups of employees using principal components analysis and George Kelly's Theory of Personal Constructs (Wheatley et al., 2020). Group A adopted the Delphi method, while Group B applied Flipped Learning, aiming to assess indicators such as socialization, sense of community, professional development, knowledge management, PBL skills, and organizational effectiveness. The results of the analysis were highlighted by the PCA structure coefficients, with the two principal axes explaining 82.7% and 12.3% of the total variance (Figure 2).

The first principal component (PC1) explains 82.7% of the variance and is positively related to socialization and sense of community with a structure coefficient of 0.95. In contrast, organizational effectiveness is negatively related to the same axis (-0.91), suggesting that the emphasis on social interactions may limit the rigor of organizational functioning. The second principal component (PC2), explaining 12.3% of the variance, is associated with professional development and PBL skills with coefficients of 0.94 and 0.84, respectively, and promotes active learning strategies. The negative correlation of knowledge management (-0.25) with PC2 suggests that standardized knowledge may be undermined in experiential learning environments.

Comparison of Groups A and B

The comparative analysis of Groups A and B shows the superiority of the flipped Group B Learning approach in supporting the SECI process. Group B focused on socialization and knowledge integration through online sessions and authentic learning scenarios, optimizing Phases S and E of SECI. This approach promoted the use of innovative methods in realistic environments and increased efficiency in Phases C and I. In contrast, Group A, which used the Delphi method, did not achieve similar levels of

ISBN: 978-618-5630-22-5

socialization and knowledge sharing due to the emphasis on structured communication restricts collective culture and knowledge integration in the S and I phases. The analysis shows that the Delphi method does not offer incentives that promote collegiality and a substantial internalization of knowledge.

The use of Flipped Learning led to a significant improvement in socialization and a sense of community among employees and promoted collaboration. Participants experienced gains in critical thinking and problem-solving skills while gaining a deeper awareness of the need for professional development and awareness. At the same time, improvements in knowledge management and organizational effectiveness are helping to improve the quality of patient care, according to employees. By recognizing the phases of the SECI model, workers' cognitive ability was increased and their cognitive load increased. Strengthening community engagement was critical to addressing authentic learning challenges while successfully integrating good professional development practices into the organization.

DISCUSSION

The research questions focused on the effect of Flipped Learning on the social and professional dimensions of employees with three objectives: We examined how the method using the SECI model affects the socialization of individuals in the workplace, potentially offering new opportunities for interaction. We examined how Flipped Learning contributes to professional development and emphasized strengthening critical thinking skills. Finally, we analyzed how Flipped Learning can improve collaboration and effective knowledge management between employees, thereby contributing to the creation of a more dynamic and connected work environment. The study highlighted the positive relationship between flipped classroom practices and the socialization and professional development of health workers. Participants reported improved collaboration and interaction, increasing trust and mutual support within teams. These practices promote teamwork and communication strategies and facilitate knowledge transfer and the development of critical thinking and problem- solving skills. The use of modern technologies improves the learning experience, provides continuous feedback and encourages participation. Socialization proves fundamental to understanding roles and responsibilities and creating a positive work environment. The PCA analysis revealed two main components: socialization and organizational effectiveness, which confirmed productivity growth. Overall, flipped teaching practices contribute to individual development and improving the quality of nursing services and are recommended to be integrated into the educational design of the health sector. Knowledge transfer between phases of the organizational model proved crucial, as staff perceived in focus group discussions, with improvements in patient service practices through more effective communication. Socialization, as described in the SECI model, requires speed and adaptability (reversibility of planning for decision-making and rapid implementation of actions), especially in crises such as the pandemic, where lifelong learning and workforce retraining were highlighted. This dynamic change highlighted the need for immediate innovation and flexibility in organizational environments and underscored the value of continuous training and adaptation to new data.

ISBN: 978-618-5630-22-5

Therefore, the research highlights the effectiveness of flipped model learning in improving social interaction and critical thinking skills. Through this pedagogical approach, a strengthening of social bonds and the promotion of a sense of community is observed while improving cooperation between participants. In addition, the model contributes to the development of problem-solving and knowledge management skills, making professionals more aware of their job requirements and continuous learning.

Adopting a social ontology that understands the processes of socialization and learning as social constructions highlights the importance of organizational context for professional development. With its adaptive and collaborative character, Flipped Learning promotes collaborative work and the exchange of experiences and makes subjective perceptions visible and an integral part of the research process. Through qualitative and quantitative analysis, participants examined the role of socialization and knowledge management, highlighting the influence of social context on their personal and professional perceptions. The results capture the personal perspectives of the participants and highlight the importance of communication and shared understanding in the educational environment. The emphasis on collective learning and subjectivity promotes a deeper understanding of each employee's professional development. The research paper highlights the importance of flipped teaching practices for the socialization and professional development of health workers. Implementing these practices further promotes collaboration and knowledge within teams and strengthens the sense of community, which, as other researchers have emphasized, is crucial for the smooth functioning of health units (Attard et al., 2021). Also according to the views of Ødegaard et al. (2021), flipped teaching practices lead to active participation and dynamic interactions, which are essential for building positive relationships between employees (Ødegaard et al., 2021). The importance of socialization proves to be a factor that increases the effectiveness of work groups and knowledge management as employees develop cooperation and communication skills (McLaughlin et al., 2014). These skills become even more important in environments where leadership, rapid decision-making and high-quality care are required. The summary of the results of the study shows that the application of the SECI model (Socialization, Externalization, Combination, Internalization) contributes to the reversal of traditional learning approaches and promotes a more participatory culture (Nonaka et al., 2000). Combining the research findings with previous studies suggests that integrating digital tools and online platforms implies promoting employee interaction and cognitive engagement (Zhang et al., 2023). However, the research also highlights the challenges associated with adopting these practices. Employees often express concerns about the time required to participate in online training activities. This adaptation to new forms of learning may initially be met with resistance due to the demands of daily work and the associated burden in the healthcare sector, as other researchers emphasize (Alshebami & Seraj, 2022). The need for ongoing training and support is a critical factor in the success of implementing reverse practices. Healthcare organizations must ensure that employees receive the appropriate knowledge and skills to adapt to new learning conditions (Alderaibi & Bugis, 2023): All of this points to the need for differentiated

ISBN: 978-618-5630-22-5

educational strategies that incorporate interaction and practical application of learning. Feedback from the interviews also highlights the importance of ongoing evaluation of training programs to meet the evolving needs of the field, as others have noted (Kowalewski & Ruschoff, 2019).

LIMITATION

The case study focuses on the implementation of flipped teaching practices in healthcare, with particular emphasis on staff socialization. Due to their requirements and challenges, health units require, on the one hand, constantly improved competence of human resources, and on the other hand, strong cohesion and cooperation between employees. The implementation of practices such as teaching flipping is combined here with the SECI model to support the socialization process, promote professional development and thus ensure the improvement of healthcare services.

CONCLUSION

The upgraded organizational culture, promoted through Flipped Learning, plays a key role in enhancing the quality of health services. Incorporating these practices can usher in a new era of professional development, providing tools and strategies vital to meeting today's HR challenges. The developed framework and exemplary research scenarios can be a valuable resource for HRM and researchers. The study shows that flipped teaching practices, combined with the SECI model, enhance socialization and professional development in the health sector, and their integration into educational processes can improve collaboration, increasing the quality of patient care and satisfaction of the workers. However, success depends on the ongoing support and evaluation of these strategies.

Suggestions: A question was raised whether the SECI model could contribute to concrete examples of knowledge transfer between departments, e.g. Description of jobs for newcomers (job description) and job changes for reasons of empathy (job rotation), workload and the development of mutual support. From the perspective of participants, it was reported that "clear job description steps in all departments required explicit recording and knowledge of prior experience knowledge." Therefore, similar exemplary research scenarios can be a valuable resource for healthcare educators, practitioners, and researchers. From the experiential involvement of the workforce, it is clear that the need for employee training through the SECI model is crucial for the transfer of innovative organizational practices. Online technologies enable Flipped Learning, the improvement of educational processes and the professional development of employees and are considered necessary tools for this. However, participants need to be motivated to share knowledge as traditional protocols often do not promote innovation and the development of professional learning communities. Examples such as recognizing the response to an emergency –an incident with "unknown protocol"– highlight the importance of timely categorization and intervention, particularly in situations such as outbreaks of unknown cause. On the other hand, external evaluation by department heads or independent teams can improve knowledge transfer and problem solving in the workplace.

ISBN: 978-618-5630-22-5

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E-HEALTH POLICIES

THE NEED TO IMPLEMENT THE DIGITAL HEALTH SYSTEM IN THE PENINTIARY SYSTEM IN ALBANIA: A CROSS-SECTIONAL STUDY.

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ABSTRACT

Background: The introduction of telemedicine services in prisons offers a notable opportunity to enhance healthcare access for prisoners, thereby improving the realization of their right to health (Tian et al., 2021; Gunn et al.,2020; Mateo et al.,2019; Kinner et al.,2018; Oh et al.,2005). The healthcare system in Albania, as part of the National Strategy and Development 2030, is currently experiencing significant transformations and process reengineering in response to rising patient expectations and increasingly complex challenges concerning health, cost containment, and the enhancement of care quality. In Albania, the healthcare landscape is characterized by a multitude of changes, particularly those associated with technological advancement and digitalization, as well as the fortification of human resources. Key elements driving these changes include healthcare policies, financial reforms, and innovations within the healthcare framework.

Objective: The objective of this study is to offer a thorough examination of e-health interventions in the penitentiary system in Albania.

Methodology: This research employs a qualitative, cross-sectional approach through a literature review and a comparison of e-health implementation in Albanian prisons and at the European Union level. The tools employed to accomplish this aim consist of a questionnaire designed for penitentiary professionals, alongside a comparative analysis of relevant literature and political strategies about digital implementation within the prison system. This questionnaire was specifically developed by the author for this research and was directed towards the heads of five prisons in Albania. The questionnaire metric properties underscore its reliability, with this study revealing Cronbach's alpha and McDonald's Omega values of $\alpha = 0.871$ and $\omega = 0.80$, respectively.

Results: The cross-sectional results indicate that while the legal framework is well-established, justice stakeholders encounter challenges in implementing it in prisons for three primary reasons. Firstly, establishing and maintaining e-health services incur high costs. Secondly, utilizing telehealth to link inmates with healthcare providers hinders the traditional human evaluation and treatment process. Thirdly, while telehealth can

ISBN: 978-618-5630-22-5

alleviate the strain of recruiting on-site healthcare professionals, they requires extensive training and support for technical infrastructure, which is currently lacking in Albania. **Conclusions:** In conclusion, despite the presence of remote healthcare initiatives in the Medical and Juridical Masterplans, the interest in adopting telemedicine in Albania and the Western Balkans remains limited (Qosaj et al.,2024; Tresa et al.,2022; De Oliviera et al.,2021; Mehta& Pandit,2018; Mackenbach et al.,2013). Moreover, the efforts in this field lack sufficient backing, presenting a significant barrier to their incorporation into standard healthcare protocols.

Keywords: telemedicine, legal reform, prisons, advancement, human rights

INTRODUCTION

The effective development of fundamental rights for the incarcerated population constitutes a significant challenge impacting the structuring of penitentiary systems in contemporary society (Cliquennois, 2021). Among these rights, the right to health occupies a particularly prominent position, the efficacy of which is "institutionally" undermined by the status of deprivation of personal liberty (Lines,2008).Notwithstanding the legal framework, the formal statutes assert that detained individuals possess the same rights as free citizens to receive effective and appropriate preventive, diagnostic, therapeutic, and rehabilitative services, the disparities inherent within the penitentiary system, compounded by deficiencies within the healthcare system the law engenders "multiple discrimination" that adversely affect detainees' access to health services (Lines,2008). The transition of responsibilities from the Ministry of Health to the Ministry of Justice concerning the organization and provision of healthcare services within penal institutions and consequently, the safeguarding of the right to health for the incarcerated populace appears to have left several challenges, particularly about the treatment of individuals experiencing health and mental health issues. In this context, it is imperative to underscore that, in conjunction with infectious diseases, mental health conditions are significantly more prevalent within the prison population compared to individuals at liberty (Cunha et al.,2023). As a result, it can be inferred that, at least in certain domains, the demand for healthcare services within prisons exceeds that observed in the general population. Another element that warrants examination in this context is the demographic shift within the prison populace, which results in a pronounced escalation in the demand for health care services within correctional facilities (MacDonald, 2018). Beyond merely posing a challenge to the structuring of health care provisions, the demographic transition of the prison population significantly influences the associated financial expenditures. In this context, it has been seen that "*older prisoners incur health care costs that are two to three times greater than those of their younger counterparts*" (MacDonald,2018). Nevertheless, it should be noted that the phenomenon of aging is not the sole contributor to the persistent rise in these expenditures (Moschetti et al.,2018).The living conditions endured by incarcerated individuals are inferior to those experienced by non-incarcerated citizens, thereby rendering them more susceptible to

ISBN: 978-618-5630-22-5

the social determinants of health (Yesuf et al.,2024). Moreover, the preservation and enhancement of the physical, mental, and social well-being of prisoners appear to be severely obstructed by the insufficiency and inadequacy of available services, both within and outside of penitentiary systems, which, in turn, leads to a further deterioration of their living conditions (Favril et al.,2024). This pathogenic spiral shows the irrevocable deterioration of the right to health within the prison context, with detrimental consequences that may persist long after the completion of the prison term, adversely impacting individuals throughout their entire lifespan, akin to an authentic stigma (Favril et al.,2024;Beaudry et al.,2021).The severity of the health management was enforced by the proliferation of COVID-19 has once more brought in focusthe pressing concern regarding the efficacy of the right to health in prisons, particularly emphasizing the necessity forpreventative measures, which are frequently overlooked by a penitentiary system. Although several measures have been taken to reduce the effect of overcrowding in prisons,including several amnesties, these measures did not bring prevention measures to a better management of spaces as recommended by the WHO in the ad hoc recommendations issued during the health emergency (Heaty et al., 2023).This paper delineates the prospective implications that the integration of telemedicine services within prisons may exert on the efficacy of the right to health for incarcerated individuals in Albania. A comprehensive review of the existing literature on this subject will be introduced from a distinct dichotomy that arises between the American context, where telemedicine services are typically available to the incarcerated population, and the European and the Western Balkans context, where, conversely, such services encounter significant challenges in becoming a standard aspect of healthcare provision. Then a section that describes the progression of this phenomenon within Albania will be analyzed. Before reaching any conclusions, the principal challenges associated with this form of technological advancement are highlighted, the characteristics of which are inherently challenging. This necessitates the development of an appropriate policy framework that is informed by an "ethical perspective," ensuring that telemedicine can genuinely enhance the accessibility and quality of healthcare within correctional settings, thereby facilitating the effective realization of fundamental rights for the incarcerated population.

The Rationale for Telemedicine in Prisons

The necessity for the implementation of telemedicine within prisons emerges from the distinctive obstacles encountered in the provision of healthcare services to incarcerated individuals since the pandemicscs (Yesuf et al.,2024). Conventional methods of healthcare delivery frequently face substantial barriers, such as logistical complexities linked to the transportation of inmates for medical evaluations, the restricted availability of specialized healthcare due to workforce limitations, and the increased security threats associated with such transfers. Literature revealed that telemedicine presents a practical alternative by enabling remote medical consultations, thus diminishing the necessity for transportation, and improving access to specialized medical care while upholding security measures. (J. Turner, 1998; Tian, 2021). The benefits related to this particular modality of technological advancement have been

ISBN: 978-618-5630-22-5

positively acknowledged by the different literature and studies, which have emphasized the significance of emerging technologies as tools for facilitating "*remote monitoring and specialist consultation through the electronic transmission of tests, data, and images to centers of excellence, without the necessity of confronting the myriad issues, including the associated costs and delays, involved in the transportation of inmates or medical professionals*". From this viewpoint, the implementation of telemedicine services has been regarded as a prospective catalyst for transformation within the entire correctional system, thereby potentially enablinga diminishment of the prevailing social perception of incarceration, rendering it "*an element of the endeavor to adapt to the advancement of society towards the marginalized groups*."

The State of the Art of Telemedicine in Penitentiary Contexts

Although the advantages are linked to the implementation of telemedicine services within prisons, it is imperative to acknowledge that minimal interest has been documented to date concerning this subject, both at the national and international levels. A thorough review of the extant international literature on the subject provides a more comprehensive understanding of the current advancements and the accessibility of telemedicine services designed to benefit the incarcerated population. In his article, Shaver (2022)reveals a notable predominance of experimental initiatives and research studies conducted in the United States compared to the European ones, which has subsequently led to the coining of the term ***correctional telemedicine***. Among the numerous advantages of telemedicine within the prisons, the literature in the United States has emphasized the critical benefit of eliminating the need to transfer inmates from the penitentiary to medical care facilities. The inmates perceive such transfers themselves as a significant source of distress and inconvenience. Moreover, it has been noted that this experience could be characterized as "*remarkably stigmatizing due to the imposition of handcuffs and the obligatory presence of correctional officers*". The reduction in transportation of inmates also aligns with the potential for realizing substantial economic savings.

Hewson et al. (2024) found in their comprehensive review of healthcare interventions aimed at addressing chronic non-communicable diseases within the prison population and among individuals recently released from incarceration, that the prevalence of health disparities and chronic illnesses in this demographic underscorethe urgent need for effective healthcare strategies. These target group, according to the authors, face heightened risks of multimorbidity, premature mortality, and diminished quality of life. Their systematic literature review encompassed a wide array of databases, yielding 19,061 articles, from which 65 studies involving 18,311 participants were ultimately included. Most of these studies were characterized as quasi-experimental and displayed varying quality levels, indicating a need for stringent research methodologies in future investigations. The interventions identified ranged from chronic disease screening and telemedicine to health education and integrated care systems. Notably, the provision of enhanced primary care and support from community health workers significantly contributed to improved health outcomes for individuals recently released from prison. However, the review reveals a significant challenge in comparing the effectiveness of

ISBN: 978-618-5630-22-5

different interventions due to clinical heterogeneity among the studies. As a result, while several interventions demonstrated positive impacts on clinical and cost-effectiveness, the variability complicates the establishment of a clear best practice. The authors conclude that further research is imperative to identify the most efficacious strategies for managing chronic non-communicable diseases in prison settings, particularly addressing the complexities of multimorbidity.Sethuran et al. (2022) in their comprehensive scoping review, examined the utilization and evidence for electronic consultations (eConsult) within prisons globally. Conducted through a meticulous analysis of three academic databases such as MEDLINE, Embase, and CINAHL, it identifies relevant literature published between 1990 and 2020. The review process included a thorough examination of both published articles and grey literature, ensuring a broad understanding of the subject matter. A total of 226 records were initially retrieved, culminating in 22 studies that met the inclusion criteria, thereby focusing predominantly on adult male offender populations across diverse correctional environments. The findings reveal the existence of 13 unique eConsult services across six countries, with a notable variance in service structure; six of these services encompassed multiple medical specialties, while the remaining were single-specialty initiatives. The results are categorized into five thematic areas: feasibility, cost-effectiveness, access to care, provider satisfaction, and clinical impact. The evidence indicates that eConsult is a beneficial approach that mitigates the need for unnecessary transportation of inmates, demonstrating feasibility and cost-effectiveness while enhancing access to healthcare services. Furthermore, the implementation of eConsult has shown a positive clinical impact and high provider satisfaction rates. However, the authors acknowledge existing gaps in the literature, particularly concerning patient satisfaction, as well as the barriers and enablers to effective implementation for marginalized groups including women, youth, and transgender individuals. The study emphasizes the importance of eConsult as a timely and effective tool for delivering high-quality healthcare to incarcerated populations, advocating for further research to optimize these services for diverse offender demographics.Cerezo-Ruiz et al. (2021) show that the implementation of telemedicine within penitentiary centers (PCs) has emerged as a significant advancement in the quest to enhance access to specialized medical care for incarcerated individuals. This approach not only facilitates secondary prevention strategies but also effectively mitigates the financial burdens associated with transporting inmates to external healthcare facilities for physical consultations. A notable initiative stemming from the Community Health Service was the introduction of gastroenterology teleconsultations in a specific PC, which commenced in late 2020. This innovative telemedicine project complements an existing hepatology consultation service that has been operational since 2015, conducted on a monthly or as-needed basis. The integration of teleconsultation services in penitentiary settings is particularly relevant given the unique challenges faced by the healthcare system within these institutions, including limited access to specialists and the logistical difficulties of inmate transportation. By leveraging telemedicine, healthcare providers can ensure that inmates receive timely and appropriate medical attention while simultaneously

ISBN: 978-618-5630-22-5

conserving resources. The ongoing development of telehealth initiatives not only reflects a commitment to improving health outcomes for this population but also underscores the growing recognition of telemedicine as a viable solution to address the healthcare disparities that often exist in prisons. This strategic use of technology for the authors demonstrates the potential for telemedicine to transform the landscape of healthcare access in penitentiary environments.In their systematic review Titan et al. (2021) reveal that the implementation and efficacy of telehealth interventions within prison systems, an area that has received limited scholarly attention compared to telehealth applications in rural and remote communities. The rationale of the authors stem from the recognition that traditional healthcare delivery in prisons is often hampered by various barriers, leading to the exploration of telehealth as a viable alternative. The methodology employed in this review adhered to established best practices for systematic reviews, including a comprehensive literature search and the application of the modified McMaster Critical Appraisal Tool to evaluate the methodological quality of the studies included. A total of twenty-nine quantitative studies were analyzed, revealing considerable variability in the types of healthcare services offered through telehealth, as well as in the implementation processes and intervention parameters. However, the review noted significant methodological concerns, including issues related to the rigor of data collection and analysis, as well as the psychometric properties of the outcome measures utilized in the studies. The findings of this review are characterized by mixed evidence regarding the effectiveness of telehealth in prison settings. While some studies indicated positive outcomes, suggesting that telehealth can be as effective as conventional healthcare and may enhance patient satisfaction, the review emphasizes the necessity of understanding local contexts and the multitude of factors that may influence the delivery of telehealth services. The authors underscore that addressing these contextual factors is crucial for the successful implementation and sustainability of telehealth interventions within correctional facilities.The study of Jimnez et al. (2019) investigates the implementation of telemedicine as a viable strategy for the eradication of hepatitis C virus (HCV) within a Spanish prison. Recognizing the pressing need for HCV intervention in prisons, as highlighted by the Spanish Health Ministry Strategic Plan, the research addresses the significant barriers to specialized healthcare access for incarcerated populations. The initiative commenced on February 3rd, 2015, in large penitentiary housing approximately 1,200 inmates, with the program designed as an open-label intervention that provided direct-acting antiviral (DAA) treatment via telemedicine, thereby circumventing the logistical challenges of in-person referrals to specialists. Preliminary assessments revealed a prevalence concerning HCV viremia prevalence of 12.4% among inmates prior to the program's initiation. Throughout the intervention period from 2015 to 2018, a total of 131 patients underwent DAA treatment, with a notable 42.74% of these individuals also living with HIV, thereby complicating their treatment regimen. Remarkably, the program achieved a sustained virological response (SVR) rate of 97%, and subsequent treatment protocols successfully addressed cases of non-response. By the conclusion of the program, HCV prevalence within the facility had

ISBN: 978-618-5630-22-5

been reduced to zero. In terms of participant feedback, a significant majority of inmates (67%) and all participating healthcare providers expressed high levels of satisfaction with the telemedicine approach. The findings underscore the effectiveness of telemedicine in ensuring equitable access to specialized care for HCV elimination in correctional settings, suggesting its broader application in similar environments. Finally, as Turner (1988) discusses in his paper, the transformative potential of videoconferencing technologies in the realm of healthcare delivery, particularly within the prison system, has a significant social and economic impact. It highlights the economic efficiencies that telemedicine can introduce by facilitating clinical consultations between healthcare professionals and incarcerated individuals, thereby addressing a critical gap in medical access for this population. However, the authors emphasize that the successful integration of such technologies extends beyond mere technical infrastructure; it necessitates the cultivation of strong interpersonal relationships among participants in the telemedicine network. Drawing on a comprehensive 18-month case study that connected an academic medical center with a prison hospital and a maximum-security prison, the paper elucidates various lessons learned throughout the implementation process. Central to the discussion is the concept of "tele-competence," which refers to the adept use of telecommunications technologies to forge virtual connections that are not only functional but also relationally meaningful. The findings suggest that fostering trust and rapport among healthcare providers, prison staff, and patients is crucial for the efficacy of telemedicine initiatives. This research underscores the importance of a comprehensive approach to telemedicine, where both technological and relational dimensions are prioritized to enhance the quality of healthcare delivery in challenging environments such as prisons. Through these insights, the paper contributes significantly to the ongoing discourse on the future of healthcare technology in correctional settings.

A summary of the key Findings from Telemedicine Implementations in the literature is given below:

a). Economic Efficiencies and Cost Reduction

Several studies highlight the economic efficiencies realized through telemedicine in penitentiaries. For instance, the implementation of a hepatology and gastroenterology teleconsultation program demonstrated a marked reduction in costs associated with transporting inmates to hospitals for physical consultations. This not only alleviated the financial burden on prisons but also optimized resource allocation (Cerezo-Ruiz et al., 2021). Similarly, the systematic review by Tian et al. synthesized evidence from multiple studies indicating that telehealth interventions could be as effective as traditional healthcare delivery while achieving high levels of patient satisfaction (Tian, 2021).

b). ImprovedAccess to Specialized Care

Telemedicine significantly enhances access to specialized healthcare services for inmates. The systematic review by Hewson et al. underscored the prevalence of chronic non-communicable diseases among the prison population and emphasized the role of telemedicine in managing these conditions effectively (Hewson T, 2024). Furthermore,

ISBN: 978-618-5630-22-5

studies such as those conducted by Galán et al. (2019) revealed that telemedicine played a pivotal role in the treatment of Hepatitis C, achieving a sustained virological response in 97% of treated patients, which illustrates its effectiveness in managing specific health conditions within correctional settings (Galan et al.,2019).

c). *Patient Satisfaction and Acceptance*

High levels of patient satisfaction with telemedicine services have been consistently reported across various studies. For example, in the teleconsultation program focusing on HIV and HCV management, a remarkable 99% acceptance rate among patients was noted, which reflects the willingness of inmates to utilize telemedicine as a viable healthcare delivery method (Labisi et al.,2022). Additionally, the study conducted by Cerezo-Ruiz et al. reported favorable outcomes in terms of patient satisfaction in gastroenterology consultations, further reinforcing the positive reception of telemedicine in penitentiary healthcare (Cerezo-Ruiz A, 2021).

d) *Challenges and Limitations*

Despite the evident benefits, the implementation of telemedicine in prisons is not without its challenges. One significant barrier is the need for robust technical infrastructure and tele-competence among healthcare providers and inmates alike. Turner introduced the concept of tele-competence, emphasizing the importance of effectively implementing telecommunications technologies to create virtual connections, which is crucial for the success of telemedicine initiatives (Turner, 1998).Moreover, local context and specific implementation of drivers influence the effectiveness of telehealth interventions significantly. Factors such as staff training, inmate engagement, and technology accessibility can affect the overall success and sustainability of telemedicine programs in prisons (Tian, 2021).

The stance in Albania

Regarding the provision of healthcare services within correctional institutions, the General Directorate of Prisons in Albania has drafted a new General Regulation (**No. 209, of 6.4.2022**) which delineates the entitlements and responsibilities of incarcerated individuals (see CHAPTER IV, Article 21 (RIGHTS OF PRISONERS AND LIVING CONDITIONS IN THE INSTITUTION). Although onlinecommunication is not a common form of meetings and visits, it still represents a significant tool in economics, patient´ satisfaction and acceptance and overall improvement. In the Western Balkans and Albania, the interest in the advancement of telemedicine services (external to correctional facilities) has steadily increased over the past ten years, particularly due to the initiatives undertaken by the need to be competitive and in the same step with the Region market which has commenced the provision of innovative remote services as an alternative to traditional assistance methods, notwithstanding the lack of specific regulatory frameworks governing such practices(Qosaj et al.,2024).In this context, it should be noted that the onset of the pandemic served as a significant catalyst for growth in this domain, resulting in an expansion of telemedicine services nationwide, not solely for the management of patients afflicted by COVID-19—but also prompting some "tentative" efforts to formulate a comprehensive strategy by the Government.In the case of Albania, this very first effort established the context for facilitating the legal and

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economic parity of remote services with conventional ones and fostering their integration within the National Health Service in Albania (NHSA).In December 2010, the International Virtual E-Hospital Foundation (IVeH), in conjunction with the Ministry of Health and with the backing of USAID Albania, completed the initial phase of the integrated telemedicine and electronic health program (PITSHE) within Albania. This inaugural phase involved the full operationalization of the Temporary National Telemedicine Center situated in Tirana, alongside the establishment of five temporary regional telemedicine centers located in proximity to the regional hospitals of Kukës, Shkodër, Durrës, Korce, and Vlorë.The advancement of information technologies within the healthcare sector was already incorporated into the broader e-Health Information Strategy established by the Ministry of Health in 2010. Moreover, the National Health Strategy 2021-2030 further reinforced the importance of these technologies to promote a transformation of the organizational framework of the National Health Service toward the Sustainable Development Goals. In Policy Goal 9, the Strategy states: *Digital Health Context and issues to be addressed. The objective of the Digital Health Policy within the National Health Strategy for the years 2021-2030 is to expedite the reforms of the healthcare system, thereby fostering a superior quality, efficient, and patient-centric methodology. Digital Health has been acknowledged by the World Health Organization as an essential foundational element for Universal Health Coverage (UHC) and the health-related Sustainable Development Goals (SDGs). Furthermore, a well-administered digital health system will bolster national capacities for the management of the healthcare system by improving the availability of information and augmenting the skills required to process, analyze, and report on care processes and health outcomes. Over the past seven years, Albania has witnessed a substantial increase in eHealth, characterized by significant investments in the digital transformation of health. Nevertheless, the digital healthcare market in Albania remains fragmented and necessitates further consolidation, as each patient must receive a uniform level of support from digital services nationwide, irrespective of their location when engaging with a healthcare provider(pp.79).*

The current research

METHOD

This study adopts a qualitative, cross-sectional methodology through an extensive literature review and an analytical comparison of the implementation of e-health initiatives within Albanian correctional facilities.

Variables of the study.

In terms of independent variables that may elucidate the feasibility of telemedicine deployment within correctional institutions, the investigation identified economic expenditures, interpersonal dynamics, and personnel training as critical factors.As the dependent variable, the research scrutinized the potential for telemedicine implementation in correctional settings. Demographic factors such as Gender and Age were excluded as variables in this analysis due to the lack of adequate data, which stemmed from the reluctance of respondents to provide the necessary information.

ISBN: 978-618-5630-22-5

Instruments

A constructed questionnaire intended for penitentiary professionals, in conjunction with a comparative analysis of pertinent literature and political frameworks concerning digital implementation within the correctional system, was utilized for the current investigation. The objective of this analysis is not to conduct a comprehensive examination of the system; rather, it seeks to gauge and obtain insights from professionals about the state of telemedicine across five penitentiaries in Albania. The metric properties of the questionnaire highlight its robust reliability, with the current study demonstrating Cronbach's alpha and McDonald's Omega coefficients of $\alpha = 0.871$ and $\omega = 0.80$.

Sample

The present studyincluded 300 prison staff from five penitentiaries in Albania (medical staff and psychosocial staff) medical staff in an age- range from 22 to 40 years old, with a mean age of 25 years (M=25) who served in a low-security prison in Albania. It was impossible to access higher security facilities for the researcher, so the research was employed in this kind of correction facility.

Quantitative data processing was conducted with the SAS JMP software.

Ethical Considerations

In the execution of the present investigation involving student subjects, the research team diligently ensured adherence to ethical principles, which encompassed the following:

Provision of approved information and consent from subjects. Through the platform utilized for the completion of questionnaires, a comprehensive outline was provided detailing the objectives, conditions, and methodologies of the study, along with an explanation of the nature of participants' involvement. Subjects were informed of the voluntary aspect of their participation in the study and the option to withdraw at their discretion should they choose not to engage.

Upholding the confidentiality and anonymity of subjects, whereby participants were apprised of the protocols regarding the handling of personal data of minors, and that the gathered data would solely be employed for research objectives, thereby aligning with the principles of anonymity and confidentiality as stipulated by the European Data Privacy Protection Act.

RESULTS

The majority of participants (70%) in the present research indicate that the complete implementation of telemedicine in Albania is highly improbable.

Given that all examined variables are qualitative in nature, the Chi-square test was employed to assess the interdependence among them. The Chi-square analysis yielded a positive and consistent value with a calculation of $X2 = 15.453$ for $p < .001$. In the examination of the relationship between the chi-square test and "telemedicine" in conjunction with economic costs, which is not presented here, it was determined that the substantial expenses associated with implementation and maintenance significantly hindered the utilization of digital health within penitentiary settings (F=3; SM=.819; df=2), while the training of personnel exerted a considerable influence (F=4; SM=.941;

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df=2). The significance of interpersonal relationships appears to exert a lesser effect on the perceptions of the respondents (F=2; SM=561; df=3).

CONCLUSIONS

The health crisis instigated by the proliferation of COVID-19 has markedly expedited the shift towards digitalization of a substantial portion of social and professional interactions (Shaver,2022). These dynamics further exacerbate the sense regarding the apparent lack of attention exhibited by successive administrations over the past twenty years concerning the subject of telemedicine within the correctional system. Notwithstanding its inherent limitations and the ethical dilemmas, it invokes, the implementation of telemedicine in prisons would have constituted a valuable instrument for enhancing healthcare services for the incarcerated population. Specifically, telemedicine would have streamlined screening processes within correctional institutions, thus facilitating timely triage for inmates. Concurrently, the deployment of remote services would safeguard the health of all personnel, both healthcare providers and others, who, in various capacities, interacted with the infected inmates.More broadly, in consideration of the arguments presented in this paper, it can be asserted that the principal impediment to the advancement of telemedicine services in prisons as a viable alternative to traditional healthcare lies in the absence of a coherent and effective comprehensive policy framework. Such a framework is essential for identifying and addressing the critical challenges associated with the utilization of these services, as well as securing the financial resources requisite for promoting their integration by correctional institutions. The formulation of this policy necessitates an "overall vision," which ensures that technological advancements are tailored to the actual needs of prisoners, thereby relying on a preliminary needs assessment—and which does not disrupt the pre-existing organizational framework, or more specifically, which does not undermine the right of each inmate to receive care from a "flesh-and-blood" physician, even if this necessitates their transfer outside the facility. In this context, it is indeed pertinent to recall that the National Committee for Ethics and Bioethics should be established within correctional settings to provide an extensive examination of the healthcare challenges in correctional settings. The policy advocating for telemedicine must be grounded in ethical principles in this line, given that, as previously articulated, this mode of technological advancement possesses an inherently "ambivalent" nature. Consequently, the advantages derived from this innovation, both on a theoretical and practical dimension, are frequently accompanied by various risks, which, if not adequately mitigated, may result in a (further) decline in the quality of healthcare within prisons. Specifically, considering the dichotomy between opponents and proponents of telemedicine, the implementation of telemedicine services within prisons ought to be accompanied by a series of safeguards designed to prevent and/or alleviate the hazards associated with the lack of physical interaction between healthcare provider and patients. Amongst these safeguards, for instance, a reference of the establishment of inclusion (or exclusion) criteria, ensuring that only those individuals who, following a preliminary evaluation, are identified as capable of benefiting from such services are permitted access to remote care. An even more concerning scenario

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would involve telemedicine services entirely supplanting traditional methods of care, rather than serving as a complementary approach. In this context, it is evident that the proliferation of telemedicine within correctional institutions must not culminate in exacerbating the existing "dual track" disparity between the incarcerated population and those at liberty concerning the safeguarding of the right to health. In other terms, it is imperative to ensure that telemedicine within prisons does not become an exclusive privilege for the incarcerated, which diminishes the right to health of detainees to a mere "viewing" and "being viewed" by healthcare professionals via digital screens.Finally, this form of innovation must be economically viable, meaning it should be executed in a manner that avoids substantial financial burdens on public institutions or the State, a risk that is particularly salient given that the operation of telemedicine relies on advanced technologies whose management and upkeep may incur highly variable costs, especially considering the economic motivations of private entities engaged in this sector. In summary, it can be argued that the implementation of telemedicine services in prisons is a multifaceted challenge, influenced by a variety of interests and a diverse array of stakeholders. The necessity to "ensure the safety" of inmates often emerges as a central concern in the context of delivering telemedicine services, particularly in certain environments or for specific groups of incarcerated individuals. Furthermore, it is crucial to recognize that while technological advancements should not be viewed as a comprehensive solution to the health issues prevalent in correctional settings when tailored to meet the genuine needs of the inmate population and aligned with established healthcare quality standards, the introduction of telemedicine could herald a transformative phase in the recognition of prisoners' rights. This shift may foster a "culture" that perceives incarceration primarily as a restriction of personal freedom, while simultaneously upholding all other fundamental rights.

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EVALUATION OF THE PERFORMANCE LEVELS OF NURSES WORKING IN EMERGENCY AND INTENSIVE CARE UNITS REGARDING ADVANCED CARDIAC LIFE SUPPORT

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ABSTRACT

The low survival rates following cardiac arrest indicate the ongoing need for the development and maintenance of advanced life support skills during Cardiopulmonary Resuscitation (CPR) training. Emergency department and intensive care nurses are crucial healthcare professionals responsible for rapidly and effectively intervening in critical situations within hospital settings, with critical roles in advanced life support practices. Simulation-based training is widely used for CPR trainings of healthcare providers. This study aimed to compare the performance of nurses who received "Cardiopulmonary Resuscitation Training" within the scope of in-service training according to their departments.

A retrospective and descriptive research design was conducted with 1543 nurses who received CPR training at the CASE Simulation Center between April 2014 and March 2021. A pretest, scenario based performance exam, and a posttest were conducted." Data were collected using the "Advanced Life Support (ALS) Scenario Control Form" and an Observation-Based Performance Evaluation checklist. Analyses were performed

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using the MedCalc Statistical Software version 12.7.7 (MedCalc Software bvba, Ostend, Belgium; http://www.medcalc.org; 2013) program".

Participants consisted of 39% nurses working in Inpatient Wards, 35.5% in Intensive Care Units, 13.7% in Emergency Departments, and 11.9% in other outpatient units, with no significant differences found between groups in pre-test results. Statistically significant differences were observed between simulation pre-test and post-test results in all groups, with higher post-test averages across all groups. At the end of the training, no statistically significant difference was observed between groups in the scenario based performance exam scores.
Simulation-based advanced life support training has been found effective in enhancing nurses' knowledge and skill levels. Conducting more frequent and updated training sessions for nurses working in intensive care units and emergency departments will lead to improved clinical performance.

Key words: Nurse, Simulation Training, Cardiopulmonary Resuscitation

INTRODUCTION

Cardiovascular diseases are an important cause of mortality and morbidity in the world and in our country (Davis, Storjohann, Spiegel, Beiber, Barletta, 2013; Kelly and Rachel, 2021; Arıcı and Turan, 2023; Civek and Akman, 2023), according to World Health Organisation (WHO) data, it was reported that 17.9 million people died due to cardiovascular disease in 2019 (Kelly and Rachel, 202; Arıcı and Turan, 2023). Cardiopulmonary resuscitation is a basic practice to save life after cardiac arrest and is a critical link in the life-saving chain. There is a direct link between current knowledge and performance in cardiopulmonary resuscitation practices and poor survival outcomes (Everett-Thomas et al., 2016; Uysal, 2010; WHO, 2021). The low survival rates after cardiac arrest indicate that there is still a need to improve advanced life support skills and maintain competence during CPR (Akbulut, Tülüce and Kahraman, 2016; Everett-Thomas et al., 2016; Taş and Akyol, 2017).
Simulation-based training is widely used in the practical training of all health professionals. Especially in Cardiopulmonary Resuscitation Training, this method is preferred in both pre-graduation and post-graduation trainings (Kelly and Rachel, 2021; Tüker and Tanrıkulu, 2020; Karaduman and Başak, 2020; Terzioğlu, 2015). In the current hospital environment, safety and care culture are prioritised. Therefore, it is preferred to conduct these trainings in safe environments to ensure patient safety.
Emergency and intensive care nurses are important health professionals who have the responsibility to intervene quickly and effectively in critical situations in the hospital environment. The fact that these nurses have resuscitation skills, especially in emergencies and critical illness cases, positively affects the survival of patients. In this context, it is vital for nurses to master current resuscitation protocols and to update these skills regularly.

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Cardio Pulmonary Resuscitation training, especially for Emergency and Intensive Care nurses, should include not only basic life support skills, but also advanced life support skills and strategies for special situations.

With the amendment made to the Nursing Regulation dated 19 April 2011 in Turkey, the duties, powers and responsibilities of intensive care and emergency nurses have been increased and include; 'Provides cooperation with the physician in emergency situations. Makes a code blue call in case of arrest. Participates in basic / advanced life support practices in line with the protocols adopted by the institution (such as oxygen delivery, respiratory support, heart massage, emergency medications, application of medical devices), roles and responsibilities have been added. In this context, if there is no physician in the unit at that time and there is an advanced life support certificate (not expired), it initiates basic and advanced life support practices, applies heart massage, respiratory support, defibrillation and emergency synchronised cardioversion. Reports the cases' (THDER, 2011; Örsal, Boğa and Kersu, 2020; Altındiş and Ergin, 2018). Within the scope of the change in the regulation, especially nurses working in emergency and intensive care have important duties in advanced life support. This creates the need for additional training (Güngör and Tarjan, 2021).

In our country, in line with the Quality Standards in Health and international accreditation standards, regular basic and/or advanced life support training is mandatory for staff, emphasising the importance of continuous skill development and maintenance of healthcare personnel in all healthcare facilities (Güngör and Tarjan, 2021).

In this context, 'Cardiopulmonary Resuscitation Trainings' are given to nurses working in Acıbadem Healthcare Group. Since 2014, 'Cardiopulmonary Resuscitation Trainings' have started to be given in the simulation centre with the simulation-based teaching technique in addition to the classroom environment.

The aim of this study was to compare the performance of nurses who received 'Cardiopulmonary Resuscitation Training' within the scope of in-service training at CASE Simulation Centre between April 2014 and March 2021 according to their departments.

METHOD

Type of Study: Retrospective and descriptive.

Population and Sample of the Study: The sample of the study consisted of 1543 nurses working in Acıbadem Healthcare Group who received Cardiopulmonary Resuscitation Training at Acıbadem Mehmet Ali Aydınlar University Clinical Simulation Centre between April 2014 and March 2021. No sample calculation was used, all data were included in the study. All nurses participating in the study consisted of nurses who received the theoretical training that the Ministry of Health requires mandatory participation every year, and who participated in the advanced life support applied course with simulation-based training method for the first time. The time spent by the nurses in the clinic varies.

ISBN: 978-618-5630-22-5

Data Collection Tools: The 'Advanced Life Support (ALS) Scenarios Control Form' prepared in accordance with the 2021 ERC Guidelines was collected using the Appendix 1 Observation-Based Performance Evaluation checklist.

Education Implementation Steps:

1. Cardiopulmonary Resuscitation Training was given to Acıbadem Healthcare Group nurses in Acıbadem University CASE Simulation Centre with groups of minimum 12 and maximum 24 people under the title of update training to a total of 93 groups consisting of 1543 people between April 2014 and March 2021 within the scope of continuing professional education, The trainers who took part in these trainings were experienced trainers who attended the simulation-based trainer training course.
2.A pre-test consisting of 20 multiple-choice questions was applied to the participants when they came to the training. the questions of this test were prepared in accordance with the European Resuscitation Council algorithm.
3.Participants attended the theoretical session given by the same instructor for 90 minutes
4.Participants were divided into three groups after the theoretical lecture and one trainer was authorised for each group. 60 minutes of relevant skills training (heart massage, monitoring, defibilation, oxygenation) was given. After the instructor demonstration in the skills training, one-to-one participants were allowed to experience the applications and their skills were improved with immediate feedbacks accompanied by the instructor in this process. Skill training was given to all groups (n: 93 groups/1543 people) by the same three trainers.
5. After the skills training, scenario applications were performed in mannequin-based patient simulators in groups of 6-8 people. Scenario applications were carried out by the same three trainers involved in the skills training.
6. Before the scenario practice, 15-20 minutes was given to the people for preparations such as sharing the roles, emergency trolley control, defibilator control and the environment was introduced.
7. During the scenario implementation, observational performance evaluation was performed by three trainers. The performance evaluation of all groups (n: 93 groups/1543 people) was carried out by the same three trainers.
8. At the end of the training, the participants were given a post-test exam consisting of 20 multiple-choice questions.

Data Analysis and Evaluation: Participants' data entries, including pre-test and post-test scores as well as adult and child Advanced Life Support (ALS) scenario control form data, were recorded in Excel. Statistical analysis was performed using SPSS (Statistical Package for Social Sciences) for Windows 22 programme. The conformity of continuous variables to normal distribution was tested by Shapiro Wilk test. Descriptive statistics were used to describe continuous variables (mean, standard deviation, minimum, median, maximum). Descriptive statistics were used to describe categorical variables (frequency, percentage). Repeated Measures ANOVA test was used to compare more than two dependent and normally distributed continuous variables. Comparison of two continuous variables that are dependent and conform to

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normal distribution was made with Paired Samples t test. Comparison of two dependent categorical variables was made with McNemar. Statistical significance level was set as 0.05. Analyses were performed using MedCalc Statistical Software version 12.7.7 (MedCalc Software bvba, Ostend, Belgium; http://www.medcalc.org; 2013).

Ethical Aspects of the Study: "Acibadem University Case Participant Information Form - Consent Form'" consent was obtained from all participants before the training. The ethics committee approval for the research was obtained from the ethics committee of Acıbadem Mehmet Ali Aydınlar University in 2023 with decision number 2023-18/.

RESULTS

The observation-based performance evaluation of simulation-based Cardiopulmonary Resuscitation trainings given to 1543 nurses working in Acıbadem Healthcare Group between 2014 and 2021 within the scope of in-service training was retrospectively analysed. Of the participants, 39% were nurses working on the Inpatient Floor, 35.5% in Intensive Care Units, 13.7% in the Emergency Department, and 11.9% in other outpatient units (Table 1).

Table 1

Distribution of Participants by Departments

Department	N	%
Emergency Service	211	13.7
Other (Outpatient-Polyclinic)	183	11.9
Intensive Care	548	35.5
Inpatient Ward	601	39.0

No significant difference was found between the pre-test and post-test results among the groups. However, a statistically significant difference was observed between the pre-test and post-test within all groups. The post-test mean scores after the simulation were higher in all groups (Paired Samples t-test, $p<0.05$) (Table 2).

No significant difference was found between adult and pediatric scenario applications across all groups. Similarly, no statistically significant difference was observed in the observational performance evaluations between the groups (Table 2).

Table 2

Comparisons Within and Between Groups

	Emergency	Other	Intensive Care	Inpatient Ward	p
Simulation Pre-Test	63,37±15,16 65- (25-100)	60,08±16,57 60- (20-100)	62,63±14,6 65- (0-100)	61,43±15,21 60- (0-100)	0,092
Simulation Post-Test	84,95±9,43 85- (50-100)	84,81±10,47 85- (45-100)	86,57±8,87 85- (45-100)	85,87±9,88 85- (50-100)	0,067
p*	**<0,001**	**<0,001**	**<0,001**	**<0,001**	

ISBN: 978-618-5630-22-5

Adult CPR Scenario Score	349,61±755,61 96- (51-98,6)	247,67±324,86 95- (50-98,5)	334,71±793,84 94- (50-98,6)	287,6±647,77 96- (50-98,6)	0,327
Pediatric CPR Scenario Score	408.06±396,15 98- (45-98,2)	398,15±397,82 99- (57-99,5)	425,86±399,59 98- (45-99,1)	384,99±391,15 98- (45-99,5)	0,379

*One-Way ANOVA test, *Paired Samples t test*

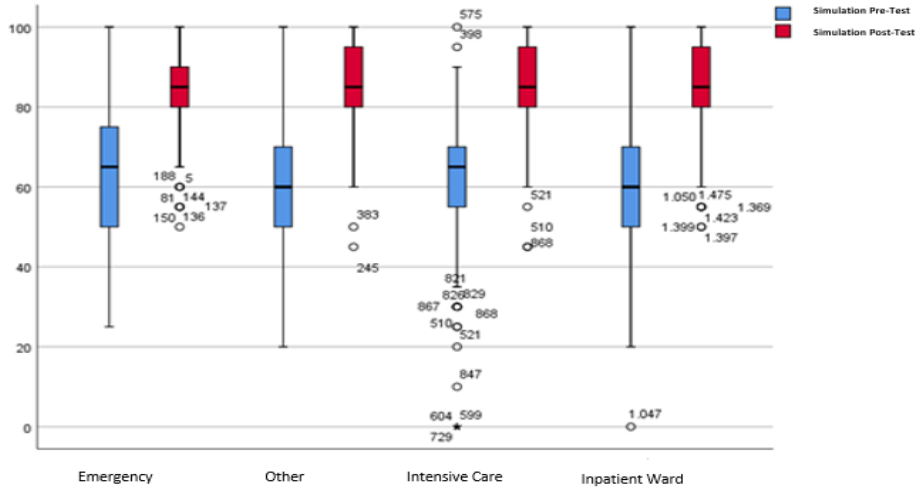

Figure 1

Simulation Pre-Post Test Distributions by Department

In the Other (Outpatient-Clinic), ICU (Intensive Care Unit), and IWP (Inpatient Ward) groups, a weak but statistically significant positive correlation was found between pediatric and adult CPR scores ($p<0.05$).

DISCUSSION

In this study, a retrospective analysis was conducted on the observational performance evaluations of simulation-based Cardiopulmonary Resuscitation (CPR) training provided as part of in-service education. The performance of nurses working in emergency and intensive care units was compared with those working in inpatient wards and other departments.

The analysis revealed no significant difference in both pre-test and post-training performance evaluations between nurses working in emergency and intensive care units, where resuscitation is more frequently encountered, and those working in inpatient wards or other outpatient units.

Participants' pre-test scores were observed to be low, which is consistent with the findings of Santos et al. (2021). Similarly, the study by Rajeswaran et al. (2018) showed that participants' post-training CPR test scores increased, aligning with the results of this study. In the present study, a significant increase was observed in pre-test and post-test scores across all groups. Overall, the low pre-test scores of all participants provide evidence of the necessity of such training programs.

The post-test scores significantly increased across all groups, with no differences observed between them. Similarly, observational performance scores were high in all

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groups, and no significant differences were noted. These findings suggest that the training effectively reached the expected level in a safe environment.

It is believed that key factors contributing to the achievement of expected learning outcomes in all groups include delivering the training with experienced instructors, structuring it according to international standards, and conducting assessments through both written and practical performance evaluations (Guerrero, Castro and Raguini, 2022). Given that new guidelines for Cardiopulmonary Resuscitation (CPR) training are issued every five years, it is essential to update the knowledge and skills of both instructors and healthcare professionals working in clinical settings (Güven and Karabulut, 2018). Therefore, these trainings should be conducted annually on a regular basis (http://www.saglik.gov.tr).

Nurses working in Emergency and Intensive Care Units encounter cardiopulmonary arrest more frequently in their daily practice than those in other departments (Oğuztürk, Turtay, Tekin and Sarıhan, 2011). Therefore, their knowledge and skill levels were expected to be higher. However, this study did not find a significant difference. This may be attributed to the fact that, although they participate in advanced life support teams, the process is primarily led by physicians, limiting their active and decision-making roles (Şener, Güler and Türkan, 2004; Hamilton, 2005; Karahan et al., 2005).

In a study conducted by Kartal in 2021, when test scores were compared across different clinics, a statistically significant difference was found between the clinics. Additionally, in a study by Bukıran on nurses, the success level of emergency nurses in CPR was found to be higher compared to intensive care nurses, and a statistically significant difference was observed (Kartal, 2021). This difference can be explained by the fact that physicians and nurses working in the emergency clinic encounter a greater number of cardiopulmonary arrests.

In the study conducted by Örsal et al. in 2017, which evaluated Cardiac Life Support training for nurses working in Emergency and Intensive Care Units, it was emphasized that these trainings should be updated at regular intervals. The same study also found a significant difference in the evaluation results of nurses working in intensive care units, where resuscitation is performed more frequently, compared to those working in other departments (Örsal, Boğa and Kersu, 2017).

In the study conducted by Munezero et al. (2018), it was determined that there was a statistically significant improvement in the knowledge and skills of all nurses after CPR training. These results are consistent with the findings of our study.

The presence of a weak positive statistically significant correlation between pediatric and adult CPR scores in the Other (Outpatient-Clinic), ICU (Intensive Care Unit), and IWP (Inpatient Ward) groups is significant in terms of CPR training and application because it suggests that CPR performance is similarly affected across different departments. This weak positive correlation implies that the training and resources required to improve CPR application quality could be designed in a similar way for all patient groups. This finding could serve as a guide in the development of training programs and clinical practices and contribute to the effective application of CPR across a wide patient population.

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With the regulations in the 2011 Nursing Regulation, it is essential to enhance the competency of nurses, especially those working in Emergency and Intensive Care Units, in Cardiopulmonary Resuscitation (CPR) (http://www.saglik.gov.tr). To achieve this, interdisciplinary training programs (such as Blue Code teams) are recommended (Şahan and Terzioğlu, 2019).

Effective teamwork is expected in emergency situations; however, team collaboration is not regularly assessed or discussed in clinical practice. It is recommended that those expected to work as part of a team receive effective team training. Both nurses and physicians need to participate in both intra-disciplinary and inter-disciplinary team training to improve patient safety (Michael, Biermann Gröning, et al., 2022). Simulation-based training is now proposed as a method that enables healthcare professionals to understand and raise awareness about the importance of teamwork and the aspects of team performance (Anderson, Secrest, Krein, et al., 2021).

CONCLUSION

Simulation-based advanced life support training has been found to be effective in increasing nurses' knowledge and skill levels. Particularly for nurses working in intensive care units and emergency departments, who encounter situations requiring cardiopulmonary resuscitation more frequently, more frequent and updated training in a safe environment will lead to improvements in their performance. Since teamwork is crucial in critical patient management, there is a need for studies on the use of interdisciplinary training methods, particularly in advanced life support training, and their effectiveness.

LIMITATIONS OF THE STUDY

The sample of the study consists of nurses working in a private healthcare group. The results reflect the outcomes of a single training session. The results of repeated training within professional development courses should also be evaluated.

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EVALUATION OF POST-GRADUATE ORIENTATION PROGRAM FOR SURGICAL NURSING SIMULATION BASED LEARNING EXAMPLE

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ABSTRACT

Objective: The aim of the study was to evaluate the simulation based orientation program in post-graduate surgical nursing.
Methods: The study was performed in a descriptive retrospective design. The data were maintained within the nursing education and development department of a private health group in Turkey between 2017-2019. Totally 1615 nurses who were new at a health institution were included in the study. Orientation program includes 64 hours of theoretical education and 27 hours of simulation based learning. Partial task trainer, medium and high fidelity human patient simulators were used during simulation.
Results: It was determined that nurses mostly worked in the surgical inpatient service (22.3%; n=360) and intensive care units (15.9%; n=257). The nurses' orientation program knowledge level pre-test mean score was 63.8±13.7, and post-test mean score was 81.7±11.6. A statistically significant difference was found between pre-test and post-test scores ($p<0.001$). When the skill point averages of the nurses were evaluated, it was determined that the highest skill level in the basic-advanced life support scenario was in the "Material Management" sub-dimension (95.75%), and the lowest skill level was in the " Patient safety" sub-dimension (74.77%).
Conclusion: Clinical orientation program based on simulation based learning can increase the knowledge level of nurses and can be an effective method in developing competence. Health institutions should use simulation based learning methods in clinical orientation program in accordance with their own conditions and using different

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simulation techniques. It is recommended that post-graduate orientation program can be enriched with different scenario and used in the development of nurses' competencies.

Keywords: Simulation Based Learning, Surgical Nursing, Orientation Program, Postgraduate Education

INTRODUCTION

Continuing education in nursing continues after undergraduate education. It is a planned educational process that develops knowledge, skills, and behavior to meet the changing requirements of the profession (Serbest and Ulupınar, 2010). The undergraduate professional education received by nurses may be insufficient in monitoring and implementing the technology and today's care needs. Obligatory reasons such as increasing scientific knowledge day by day, changes in care methods, differences in working conditions, or forgetting the fundamental knowledge over time have made post-graduate orientation programs compulsory in the nursing profession (Savcı, Şerbetçi and Hacer, 2021). Practicing on the patient without gaining sufficient skills involves both ethical and legal responsibility. In our country, not all nursing students can graduate by learning basic nursing skills and gaining competence. For this reason, it has become important to gain and evaluate the necessary competence in orientation programs.

Post-graduation orientation programs are important in terms of facilitating the professional transition process of newly graduated nurses and supporting their adaptation to their work areas. Orientation programs help newly graduated nurses to develop their clinical skills, learn the functioning processes of the health institution, and get used to the working environment (Fey and Miltner, 2000). Clinical orientation programs aim to improve the clinical practice of newly graduated nurses. In this process, nurses learn clinical skills, practice instructions, medications, and treatment protocols. At the same time, basic skills such as emergency interventions, patient assessment, and patient safety are developed (Strauss, Ovnat, Gonen, Lev-Ari and Mizrahi, 2016). Post-graduate orientation programs support newly graduated nurses to feel safe, develop their professional knowledge and skills, and provide care in accordance with patient safety standards (Baxter, 2010; Park and Jones, 2010).

Although many teaching methods are used in nursing education, one of them is simulation-based learning. Real experiences can be taught interactively with simulation (Terzioğlu, Kapucu, Özdemir, et al., 2012; Gaba, 2007). By experiencing the clinical situation in a realistic learning environment, participants can develop many skills such as clinical decision-making, critical thinking, and communication, and transform their theoretical knowledge into practice (Wilford and Doyle, 2006; Göriş, Bilgi and Bayındır, 2014).

Simulation in orientation programs is an effective method used to increase clinical experience, develop critical thinking skills, and ensure safety in patient care. With the simulation method, nurses have the opportunity to improve their practical skills and

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decision-making abilities while reducing the risk of making mistakes on real patients. This method helps newly graduated nurses to have a better clinical practice experience (Ackermann, Kenny and Walker, 2007).

There are many studies in the literature on the effectiveness and outcomes of simulation-based learning in undergraduate and graduate nursing education (Chen, Leng, Ge, et al., 2020; Li, Au, Tong, Ng and Wang, 2022), but there are very limited studies on the use of simulation in post-graduation clinical orientation programs. The aim of the research was to analyze the retrospective results of simulation-based learning of surgical practices in orientation programs to contribute to the literature and to present a national good practice example.

Study Design: This study was planned as a descriptive retrospective design.

Population and Sample: The post-graduate simulation based orientation program carried out in the "Nursing Education and Development Department" of a private health group in Turkey between 2017-2019. Totally 1615 nurses participated in the orientation program. The sample selection method was not used and it was tried to reach the whole population.

Orientation Program: The Health group has a total of 16 hospitals in Turkey. Simulation-based orientation program was applied to all nurses with different experience who are new to the health institution. In the program, a total of 64 hours of theoretical clinical orientation education (in-class education) and 27 hours of simulation based learning was carried out. Hospitals where the research was carried out mostly contain surgical patient populations. For this reason, this surgical nursing care specific program was applied to each nurse in the clinical orientation program.

Theoretical Education: The content of the education was patient safety, ethics in nursing, patient delivery, monitoring vital signs, safe drug administration, infection control, chronic disease management, physical assessment of patients, pressure injury management, preoperative care, postoperative care and pain management issues. Educations were carried out by expert trainers in the education development department of the health institution. The educations were carried out for 6 days in total, 9 hours a day. Participants who complete the theoretical section were taken to simulation based learning.

Simulation Based Learning: After theoretical section nurses participate in simulation scenario in groups of 6-12 people. The trainings last 27 hours (3 days) in total. Education content flow chart is indicated in Figure 1.

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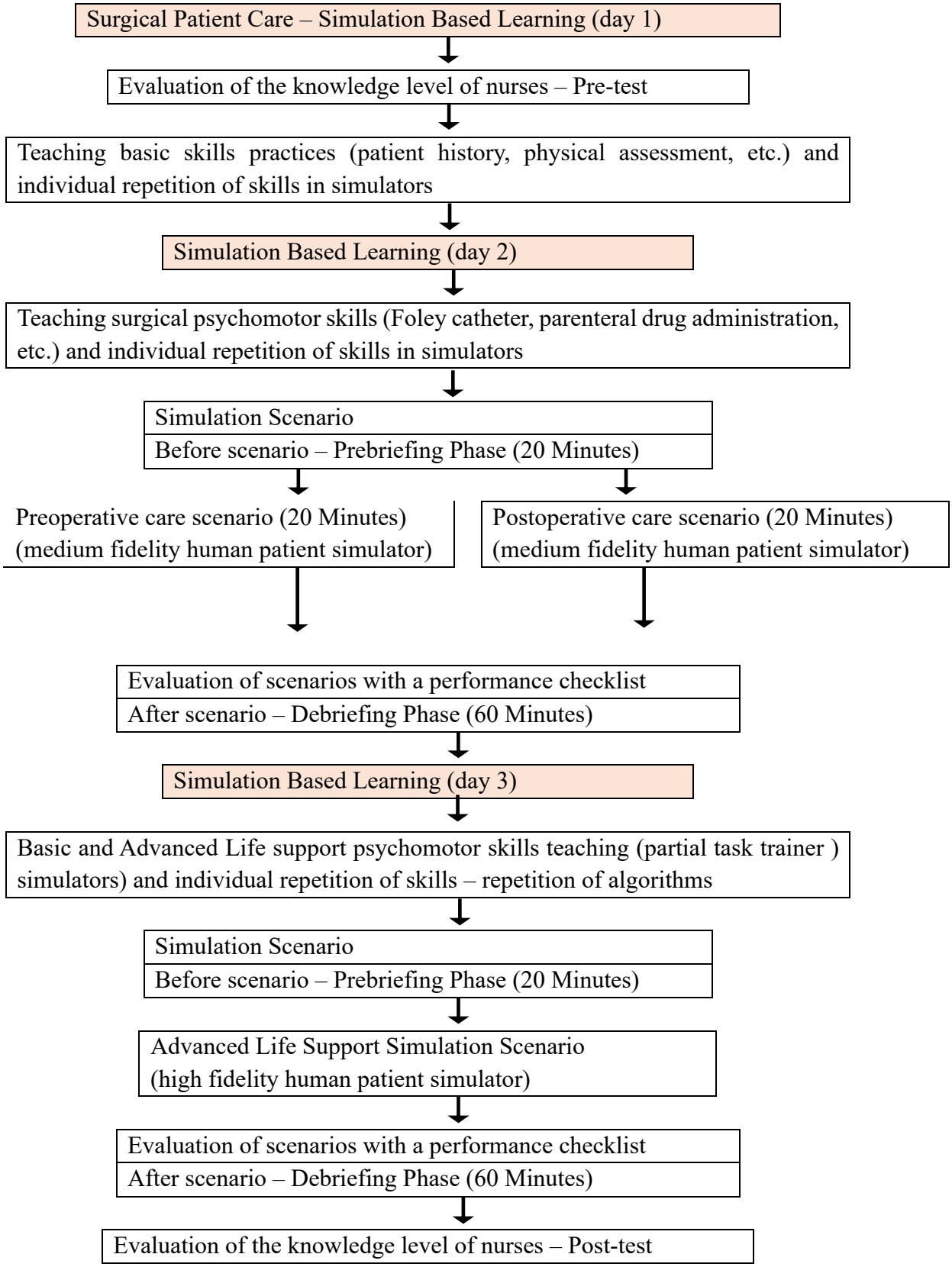
Figure 1
Simulation Based Learning Flow Chart



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The trainings are carried out in the accredited "Advanced Simulation and Endoscopic Surgery Training Application and Research Center" in Istanbul. Simulation scenarios were used for learning and evaluation purposes. In the "learning" dimension, basic skills are practiced and repeated on simulators. In the "evaluation" dimension, performance evaluations of nurses are made on an observational basis in line with skill forms structured by expert trainers. During the simulation, partial task trainers, medium, and high fidelity human patient simulators were used. Partial task trainers are non-computer-controlled models used to teach basic psychomotor skills (Maran and Glavin, 2003). Mannequin-based simulators are defined as human patient simulators. The reality level of the simulators is handled within the scope of engineering and psychological factors. Each simulator has a "fidelity" feature that is associated with the reality of experiences (Gaba, 2007). Mannequins with life size, realistic anatomical and dynamic physiological structures are called high-fidelity simulators. Other human patient simulators that can mimic physiological changes, partially or not fast enough, are considered medium fidelity (Maran and Glavin, 2003). Simulators were used in advanced life support with high fidelity (due to the response to drug administration) simulators, and medium fidelity simulators are used in scenarios related to the surgical care in the program.

In simulation scenarios, nurses work on scenarios that resemble real patient situations. These scenarios include various clinical skills such as patient safety in the surgical care process, patient assessment, material management, crisis management, basic skills practices, and communication. The goal was for nurses to gain experience in demonstrating their clinical skills, reducing the possibility of making mistakes, and ensuring patient safety while managing these scenarios.

The American Board of Nursing (NCSBN-National Council of State Boards of Nursing) recommends planning educational content using best practice standards in simulation (Sittner et al., 2015). These standards form a roadmap for trainers in the implementation of simulation (Sittner et al., 2015). The International Nursing Association for Clinical Simulation and Learning (INACSL) has developed simulation practice standards (Standards of Best Practice, 2016). This orientation program was also carried out in line with INACSL standards.

Performance Evaluation: During performance evaluations 20 multiple-choice questions (pre-post test) and performance checklists prepared in line with the practice guides are used by the educators who have received simulation "trainer training" and have nursing expertise. The test was conducted before and after the program. It took approximately 20 minutes to complete the questions. Performance checklists were filled in by observer educators, by watching from mirrored glass rooms during scenario in simulation centre.

Performance Checklists: Performance checklists developed in line with the literature and containing skill practice steps were used (Berragan, 2011; Cant & Cooper, 2010; Doolen et al., 2016). Evaluation of the skill through direct observation is defined as a competency-based assessment strategy (Sittner et al., 2015). While the nurses performed the skill, the clinical educators observed how the skill was performed and

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made markings on the structured and self-assessed checklists. For each skill step, the observer educator marked "Adequate (2 points)", "Partially Adequate (1 point)", and "Inadequate (0 points)". Performing the application correctly and sequentially was evaluated as "Adequate", performing the application correctly and sequentially but not being able to move from step to step easily was evaluated as "Partially Adequate", and performing the application incorrectly or skipping the application step was evaluated as "Inadequate".

"Basic and Advanced Life Support" application includes a total of 42 application steps (0-84 points), "Preoperative care" application was 33 (0-66 points), and the "Postoperative care" application includes a total of 33 steps (0-66 points). The scores were interpreted by calculating over 100 points in order to facilitate the evaluation. The interpretation system used in a similar study by Goharani et al. (2019) was used. The score was interpreted as 90% and above excellent, 80-89% good, 70-79% moderate, 60-69% poor, and <59% very poor (Goharani et al., 2019).

Ethical Consideration: Ethics committee approval was obtained for the the study (2022-04/23). In addition, prior to the education program, all applications carried out in the simulation center were recorded and consent is obtained from the participants for the use of the recorded data for scientific purposes, provided that personal data was protected.

Data Analysis: Analyzes were performed in IBM SPSS 26 program. Conformity of continuous variables to normal distribution was tested with the Shapiro Wilk test. Descriptive statistics were used to describe continuous variables. (average, standard deviation, minimum, median, maximum). The Kruskal Wallis test was used to compare more than two independent variables that did not conform to the normal distribution. The Wilcoxon test was used to compare two dependent variables that did not conform to the normal distribution. Statistical significance level was determined <0,05.

RESULTS

Within the scope of the research, the data of 1615 nurses who participated in the simulation-based orientation program were evaluated. The distribution of the units where the nurses work was given in Table 1.

Table 1
Clinical Working Areas of nurses (N=1615)

Clinical Area	N	%	Pre-Test Mean ± SD	Post-Test Mean ± SD	p
Surgical inpatient service	360	22.3	63.53±13.91	81.44±11.84	<0.001
Intensive care units	257	15.9	65.39±13.99	83.67±11.23	<0.001
Newborn and child intensive care units	202	12.5	63.73±13.44	80.66±12.04	<0.001
Mixed inpatient service (medical-surgical patient)	167	10.3	64.67±12.02	81.44±11.05	<0.001
Obstetrics and pediatrics service, delivery room	158	9.8	61.48±13.29	79.6±11.96	<0.001

ISBN: 978-618-5630-22-5

Emergency room	120	7.4	63.88±15.28	82.47±10.67	<0.001
Day surgery patients units	114	7.1	63.77±13.58	81.34±10.21	<0.001
Oncology service and chemotherapy unit	106	6.6	64.8±14.51	81.29±13.11	<0.001
Internal medicine inpatient service	70	4.3	60.71±14.13	82.77±11.71	<0.001
Bone marrow transplantation	45	2.8	62.6±12.03	82.41±11.72	<0.001
Special branch nurse	16	1.0	69.66±13.08	88.3±13.2	<0.001
			p= 0.113	p= 0.006	
Total score average	1615	100	63.8 ±13.7	81.7 ±11.6	p<0.001

*Wilcoxon test (intradepartmental pre vs. post), *Kruskal Wallis test (interdepartmental), SD: Standard deviation*

It was determined that nurses mostly worked in the Surgical inpatient service (22.3%; n=360) and intensive care units (15.9%; n=257). When the knowledge level of the nurses before the orientation program (pre-test) was evaluated, the scores ranged from 60.71 to 69.66 and the total score average was 63.8 ± 13.7 , the knowledge level scores after the program (post-test) ranged between 79.6 and 88.3 and the total score ranged from 79.6 to 88.3. It was determined that the mean score was 81.7 ±11.6. A statistically significant difference was found between pre-test and post-test scores (p<0.001). The post-test mean was found to be significantly higher. When evaluated in terms of post-test distribution among departments, it was determined that the post-test average of branch nurses was higher (p<0.05).

When the average skill scores of the nurses from simulation were evaluated, it was determined that the highest skill level in basic and advanced life support scenario was in the "material management" sub-dimension (95.75%), and the lowest skill level was in the "safety" sub-dimension (74.77%). In the preoperative care scenario, the highest skill level was found in the "communication" (88.63%) sub-dimension, and the lowest skill level was in the "medical records" (75.05%) sub-dimension. In the postoperative care scenario, the highest skill level was found in the "communication" (90.29%) sub-dimension, and the lowest skill level was in the " skill application" (79.27%) sub-dimension (Table 2).

Table 2
Distribution of Nurses' Simulation Scenarios Practices Skill Level Scores

Sub-Dimensions	Number of Skill Items	Total Score Mean ± SD	Percentage Value
Basic and Advanced Life Support	Total= 42		
Safety	3	4.49±1.17	74.77±19.47
Patient Evaluation	9	15.15±2.82	84.15±15.63
Material Management	3	5.74±0.94	95.75±15.66
Crisis management	5	9.11±1.64	91.1±16.37

ISBN: 978-618-5630-22-5

Skill Practice (SP)	22	38.98±5.23	88.6±11.9
SP- CPR application	5	9.33±1.38	93.34±13.75
SP- Ventilation Application	6	10.14±2.18	84.5±18.2
SP- Defibrillation	6	10.74±2.15	89.51±17.89
SP- Drug administration	4	7.13±1.9	89.09±23.81
SP- Medical Records	1	1.63±0.55	81.72±27.47
Preoperative Care	Total = 33		
Patient Safety	7	11.38±2	81.27±14.31
Communication	6	10.63±1.77	88.63±14.72
Crisis management	3	5.01±1.18	83.42±19.72
Medical Records	5	7.51±2.15	75.05±21.47
Skill Practice	12	19.16±3.22	79.84±13.4
Postoperative Care	Total = 33		
Patient Safety	5	8.28±1.71	82.85±17.05
Communication	6	10.83±1.81	90.29±15.08
Crisis management	3	5.14±1.2	85.66±20.07
Medical Records	4	6.53±1.87	81.65±23.4
Skill Practice	15	23.78±4.31	79.27±14.36

SD: Standard deviation

DISCUSSION

The simulation-based learning allows healthcare professionals to safely practice their skills. The importance of simulation in health education has become more apparent with the recognition that it is unethical to teach complex skills to patients at the "do it once" or "show how" level (Berragan, 2011). Due to the use of simulation methods in some universities in the development of clinical nursing skills today (Terzioğlu et al., 2012; Cant & Cooper, 2010), not every graduate nurse may have experienced the simulation method. For this reason, participants should be guided in advance about the simulation and what is expected from them during participation. Participants should be provided with a comprehensive overview of what simulation is and how to use this method to develop their competencies (Maran & Glavin, 2003).

In this program, the prebriefing phase, which is one of the INACSL standards, was carried out, and the nurses were informed about the physical environment and educational goals and objectives (Sittner et al., 2015). In the literature, it is stated that learning behavior can be improved with successive and repetitive scenarios (Doolen et al., 2016). Before moving on to complex scenarios, it is recommended to start with simpler skills and gradually move to scenarios that develop participant independence (Kim, Park, & Shin, 2016). In this program, skills were developed using partial task trainers, and then scenarios involving more complex skills were performed with human patient simulators. After the simulation, a debriefing phase was held in accordance with INACSL standards (Standards of Best Practice: SimulationSM, 2016).

ISBN: 978-618-5630-22-5

In the study, it was determined that the clinical orientation program based on simulation improved the knowledge level of nurses. Studies have also shown that the simulation method increases the knowledge capacity of students (Li et al., 2022) and improves the level of knowledge (Chen et al., 2020). In this study, the clinical orientation program was carried out in simulation laboratories with a high level of reality and fidelity. It is stated that high- and medium-fidelity simulators are effective in improving psychomotor skills and increasing clinical performance (Vincent, Sheriff, & Mellott, 2015). In a meta-analysis, it was emphasized that the simulation method had strong educational effects on the development of psychomotor skills (Kim, Park, & Shin, 2016).

Simulation is an effective method for improving cognitive and psychomotor skills as well as teamwork, critical thinking, leadership, and communication (Spies & Botma, 2020). In this study, non-technical skills such as crisis management and communication were evaluated in addition to technical skills during performance evaluations in scenarios. While it was determined that the nurses' communication, equipment, and crisis management skills were at a very high level (90% and above performance) in scenarios, it was determined that the skills of medical records, pre-postoperative psychomotor skills, and maintaining safety in basic/advanced life support were at a moderate level (70–79% performance).

The performance scores of the students increased in basic life support skills practices and prepared the students for the real clinical environment (Glory, Rajeswari, & Vasanthi, 2017). It has been stated that postgraduate neonatal nursing students develop team communication skills in neonatal resuscitation practice, that it is an effective method for gaining the competencies recommended by the guidelines, and that simulation can fill the gap between theory and practice (Rød, Kynø, & Solevåg, 2021). It has also been stated that high-reality simulation education improves readiness, especially in solving communication problems that arise in the intensive care environment, and contributes to the development of critical care skills in postgraduate education (Lindberg & Fridh, 2021).

In this study, it is thought that nurses have high performance in basic/advanced life support skills practices (cardiac massage, ventilation, defibrillation, drug administration, and recording) and that they can manage difficult processes more easily when they encounter a similar situation in the clinic.

Strengths and limitations of the study: This study was an example of good clinical practice as it was an exemplary and pioneering study on the use of simulation based learning in postgraduate orientation program in our country. The trainings were carried out in an internationally accredited simulation centre. The structuring of educational practices in line with INACSL best practice standards and the competence of educators in this regard are another strength.

There are some limitations of the research. During the scenario, performance evaluations were made by expert educators, but inter-observer agreement was not evaluated. During the evaluation of the effectiveness of the training, measurement tools developed by the educators, the measurement tools do not have validity and reliability.

ISBN: 978-618-5630-22-5

It is not a homogeneous group as there may be differences between the professional knowledge and experience of the nurses participating in the scenario. The results of the research can only be limited to the nurses in the health group institution and cannot be generalized for all nurses.

CONCLUSION

In this study, which can be a guide as a good practice example in our country, the main results of simulation based clinical orientation program were shared. It can be said that the clinical orientation program based on simulation increases the knowledge level of nurses and can be an effective method in gaining competence. It is recommended that institutions can use simulation methods suitable for their own conditions in their clinical orientation program, integrate different simulation techniques into the program, and use them in the development of affective skills apart from knowledge and psychomotor skills. In the future studies, it is suggested to conduct research on the effects of simulation based orientation program on patients (complication rate, patient satisfaction, etc.) and employees (professional satisfaction, medical error rate, etc.).

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QUALITY ASSURANCE IN HEALTH UNITS

DIGITAL THERAPEUTICS AS AN EFFECTIVE MEANS TO ADDRESS PSYCHOEDUCATION AND HEALTH SERVICES

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ABSTRACT

Digital Therapeutics, referred to as "Digital Therapeutics" (or "DTx" in the abbreviation), can be characterized as technological innovations that "deliver therapeutic interventions facilitated by high-quality software applications, grounded in scientific evidence derived from methodologically rigorous and confirmatory clinical trials, aimed at the prevention, management, or treatment of a wide array of physical, mental, and behavioral health conditions."(Hu et al.,2024; Chung,2019; Kraft et al.,2008) Digital Therapies are not merely health-related applications, nor are they telemonitoring interventions, nor systems provided by pharmaceutical enterprises designed to assist patients in the management of their medical conditions, particularly from the perspective of adherence to pharmacological treatment (termed Patient Support Program) (Bochicchio et al.,2021). Occasionally, they may also be mistakenly equated with what are identified as "digital medicines" ("Digital Medicines"), which refers to pharmaceuticals embedded with an integrated sensor that activates in the gastrointestinal tract upon ingestion (Nomura,2023).Digital Therapies can operate in two different ways, either independently of a drug (therefore without the parallel use of a "classic" drug) or in combination with it. The present research seeks to validate the current advancements by analyzing the literature about digital therapies utilizing PubMeddatabase a resource internationally recognized by the U.S. and European agencies (Landers et al.,2023). Commencing with an advanced search employing the

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term "*Digital Therapies*", the authors addressed a series of keywords that served as the foundation for the currentstudy. The search encompassed clinical trials associated with the keyword array "*digital therapeutics*" , "*digital therapeutics*" , "*digital therapies*" or "*digital therapy*" that were documented on the website.Selected articles featured any element of information and communication technology, which includes mobile phones, cell phones, and smartphones; computer-assisted interventions and apparatus; the Internet, online platforms, and mobile applications; blogs and social media components; and email, text messages, and texts. We further refined our search parameters by also querying these terms within the "i*ntervention*" and "*title*" fields. Analyses were executed using SPSS version 29 and encompassed frequency distributions (for categorical variables) and means (for continuous variables). An additional analytical component involved examining the distribution of technologies employed by digital therapies across each disease category considered, to identify potential clusters of tools associated with specific diseases (Nwosu et al.,2023). The study was based on the analysis of 135 randomized clinical trials within the domain of digital health and therapies. The medical conditions wherein these digital tools are predominantly utilized are those in which cognitive behavioral therapies (CBT) and lifestyle modifications have already been integrated into conventional treatment paradigms, notably within the fields of mental health, chronic diseases, and addictions (Biskupiak et al.,2024; Orsolini et al.,2023). These digital interventions, by fostering a more proactive role for the patient in engaging with the therapy, enhance its implementation and adherence (Fürstenau et al.,2023). Moreover, it has been observed that certain digital tools are more effective for specific pathologies, exemplified by the usage of video games predominantly within mental health. In conclusion, we advocate for increased dissemination and comprehension of these matters among physicians, researchers, and developers, and, importantly, a heightened utilization of randomized clinical trials, which stand as the most robust methodology available for the scientific validation of these therapies.

Keywords: Digital therapies, digital intervention, non-pharmacological treatment, cognitive-behavioral therapies, mental health.

INTRODUCTION

Digital Therapeutics, commonly referred to as "DTx," are technologies that deliver therapeutic interventions through high-quality software programs grounded in scientific evidence derived from methodologically rigorous and confirmatory clinical trials(Biskupiak et al.,2024; Kim et al.,2024). These interventions aim to prevent, manage, or treat various physical, mental, and behavioral health conditions. It is important to distinguish Digital Therapeutics from basic health-related applications, telemonitoring systems, or pharmaceutical company offerings designed to assist patients in managing their conditions, such as Patient Support Programs focusing on medication adherence (Sawyer-Morris et al.,2024; Marsch et al.,2020). Additionally, Digital Therapeutics should not be conflated with "digital medicines," which are

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pharmaceuticals equipped with integrated sensors that activate upon ingestion, signaling to a smartphone app to confirm medication intake. While these digital medicines facilitate adherence monitoring, they do not constitute therapeutic interventions themselves. In contrast, Digital Therapeutics represents genuine therapeutic solutions that can enhance clinical outcomes similarly to pharmacological treatments (Noumora,2023). They are developed through randomized controlled trials and are supported by robust clinical evidence of their efficacy. Digital Therapeutics can manifest as applications, video games, websites, or wearable devices. Notably, these therapies can function either independently of traditional medications or in conjunction with them. When operating independently, Digital Therapeutics often provides Cognitive Behavioral Therapy (CBT), a psychotherapy approach grounded in cognitive principles (Brezing et al.,2022. This paper aims to explore the evolution of digital therapy and its effects on the psychological programs of interventions.

Between traditional pharmacology and digital therapies in psychology

When considering digital therapy in comparison to traditional pharmacological treatments, the literature argues that the terminology employed for the latter is surprisingly applicable to this innovative therapeutic approach (Chung,2019) . In describing digital therapy, the focus should be moved to the references to active ingredients and excipients. In pharmacology, the active ingredient typically refers to a chemical or biological compound, whereas in the realm of digital therapies, the active ingredient is represented by an algorithm or software that encompasses the therapeutic component capable of yielding both beneficial clinical outcomes and adverse effects. The active ingredient may either be specifically designed for the digital platform or derived from established scientific literature, such as existing Cognitive Behavioral Therapy (CBT). In the former case, digital therapy serves as an alternative delivery mechanism for pre-existing methodologies, while in the latter, it may involve the creation of a novel approach that integrates elements from CBT, Motivational Interviewing, and Psychoeducation, all informed by feedback from patients, caregivers, healthcare professionals, and the algorithm development team (Moryia et al.,2023).In traditional pharmaceuticals, excipients accompany the active ingredient and serve various functions depending on the formulation; they not only act as carriers for the drug but also affect its pharmaceutical properties, user satisfaction, and preparation (Biskupiak et al.,2024). Similarly, excipients play a crucial role in digital therapies, enhancing the digital bioavailability of the active ingredient and facilitating its accessibility. One of the most compelling features of digital therapy is the dynamic involvement of the patient, characterized by ongoing interaction and engagement (Orsolini,2024. The therapeutic experience is designed to resemble a game, offering patients opportunities to earn rewards, share their therapeutic journeys on social media, receive reminders for their digital therapy, and, when necessary, integrate complementary treatments (Green,2023).

ISBN: 978-618-5630-22-5

Guidelines for using DTx in the Albanian clinical setting

The following are the guidelines established by the Code of Deontology in the Order of Psychologist in Albania for internet services as updated in 2023.

Ethics

1. The ethical principles and regulations outlined in the Code of Ethics apply to services delivered through remote communication technologies (refer to Article 1 of the Code of Ethics). These principles and regulations must be clearly articulated through documentation available on the website or platform of the professional offering the service.

*Adequ*acy

2. It is the responsibility of each psychologist to assess the suitability of digital interventions before their implementation, considering the nature of the intervention and the characteristics of the individuals involved.

Competence

3. Psychologists are required to deliver online services strictly within the boundaries of their professional competence, which is informed by their education, training, internship experiences, or other relevant professional activities. They must also be aware of the limitations and appropriate applications of various technologies.

4. The advancement of remote communication technologies facilitates e-health interventions of a psychological nature. Given the complexity and specificity of these contexts, it is essential for professionals to have access to suitable technologies and to possess the requisite skills for their effective use.

5. Psychologists are encouraged to make their professional credentials clear to clients by disclosing their identity, such as their geographical location, and by providing verifiable evidence of their qualifications, relevant experience—including experience in delivering online services—and membership in recognized professional organizations. They should also guide clients on how to verify this information. Furthermore, psychologists' websites should present this information in a professional manner that is grammatically correct and free of jargon.

6. Psychologists must engage in ongoing self-assessment of their competencies in this domain.

7. Psychologists who provide services online must communicate with the web address where these services are offered, along with details regarding the software tools and media utilized.

Legal Aspects

8. Psychologists are required to be knowledgeable about and adhere to all applicable laws and regulations, particularly when offering online services that may cross jurisdictional or international boundaries. This includes understanding whether online psychological interventions are permissible in specific jurisdictions and identifying any applicable restrictions.

9. Current legal standards regarding the handling of data and information must be strictly followed.

ISBN: 978-618-5630-22-5

10. Psychologists should inform users that their qualifications enable them to provide online services.

Confidentiality

11. Psychologists must consistently update their knowledge and implement all necessary precautions, such as computer security measures, to safeguard the confidentiality of client data and information. They are also required to inform clients about the measures taken to protect confidentiality, as well as the potential risks associated with different technologies used (e.g., email versus videoconferencing) and the limitations of each method in maintaining confidentiality.

12. Psychologists utilizing electronic technologies for remote communication must employ hardware and software systems that ensure robust data protection measures.

Consent

13. It is imperative for psychologists to secure and meticulously document informed consent, fully adhering to all relevant laws and regulations.

14. Consent for e-mental health services should encompass critical aspects related to the technology and the intervention process, including privacy and confidentiality, the structure and duration of the services offered, potential risks, limitations associated with the communication methods employed, fees, adopted security measures, reliability of the online connection, necessary technological equipment and competencies, constraints on communication and the potential for misunderstandings, record-keeping practices (including how and where personal information will be stored and who will have access), risk management strategies, availability for contact, rules regarding participation and termination, cancellation policies, and alternatives to online psychological interventions.

Crisis Management

15. Before initiating online interventions, psychologists should provide referrals to clinical facilities located within the client's geographic area in the event of an emergency.

THE CURRENT STUDY

Research question

The research question that the current study aims to answer is: RQ1= What is the state of the art of Digital Therapies? This inquiry has been central to our investigation from the outset. Digital Therapies hold the potential to significantly transform the management of chronic conditions that often utilize conventional treatment methods, such as diabetes and hypertension. Moreover, they may play a crucial role in addressing mental health disorders, including anxiety and depression, as well as in areas such as rehabilitation, sleep improvement, autism, and addiction treatment (including smoking and substance use). However, these therapeutic approaches remain relatively unfamiliar, particularly in a nation like Albania.

MATERIALS AND METHODS

Utilizing the "advanced search" feature in PubMed allows for the exploration of one or more terms, which can be combined using standard logical operators, across the primary fields of the database. Beginning with the advanced search and the term

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"Digital Therapeutics" (which is referred to as "Digital Therapeutics" or "DTx" in abbreviated form), we curated a set of keywords for our inquiry, which we entered the "condition and disease" field. Consequently, the search encompassed clinical studies associated with the keyword string "digital therapeutics" "digital therapeutic" or "digital therapies" or "digital therapy," which incorporates various elements of information and communication technology, including mobile phones, smartphones, computer-assisted devices and interventions, as well as online platforms such as websites, mobile applications, blogs, social media, and communication methods like emails, messages, and texts. Additionally, we refined our search by including these terms in the "intervention" and "title" fields. We combined the two sets of findings and removed any duplicates. Subsequently, we scrutinized the individual entries for each study identified through this search and excluded those that did not fulfill specific criteria. These criteria included: the absence of randomization in the studies (for a study to qualify as digital therapy, it must be evaluated through a randomized clinical trial), the lack of support from any technological tool (the term "digital" in English also refers to medical techniques performed manually), or failure to align with the definition of digital therapies. Initially, we excluded studies that were not randomized, followed by those that did not incorporate a technological tool, and finally, those that, while utilizing a technological tool as an intervention, could not be classified as digital therapy. After identifying the randomized trials of digital therapies, we extracted the necessary information from the database for the current analysis. This included the study's status (referring to enrollment status), the age and gender demographics of the populations involved in the digital therapy, the availability of results (for studies that had concluded), the study phase (clinical trials are typically categorized into phases I, II, III, and IV based on the objectives, statistical power, and sample size), the number of enrolled patients, the year the study commenced, and the type of institution sponsoring the study (whether industry or public entities).In addition, we systematically categorized each clinical trial based on the nature of the technological intervention employed and the specific pathology under investigation, utilizing the descriptive data available from the associated files. The analyses were performed using JPM Pro, focusing on frequency distributions for discrete variables and means for continuous variables. Furthermore, we analyzed the distribution of technologies utilized in digital therapies across the various pathologies examined, aiming to identify potential clusters of tools associated with conditions. For certain continuous variables, such as the number of patients enrolled, we compared the means across the different technological interventions assessed.

RESULTS

The keyword search yielded a total of 550 results. Out of these, 415 studies were excluded for a variety of reasons: 82 were observational studies, 123 were non-randomized studies featuring only a single intervention arm, and 181 did not incorporate any form of technological intervention. Additionally, 38 studies that did involve technology were not classified as digital therapy. Consequently, this analysis focused on 135 randomized trials. Among these studies, a significant proportion of the

ISBN: 978-618-5630-22-5

interventions utilized were applications, accounting for 41.91%. Web-based interventions, which are accessible, comprised 25.74% of the total. Furthermore, video games have begun to capture a notable segment of the market, representing 8.82%, particularly appealing to younger patient demographics. In the studies we examined, the predominant pathologies identified pertain to the domain of mental health, encompassing neurodevelopmental disorders, Alzheimer's disease, dementia, epilepsy, depression, and anxiety, which collectively account for 34.56%. This is followed by chronic conditions and those associated with chronic pain, including diabetes, asthma, chronic obstructive pulmonary disease (COPD), and orthopedic issues, representing 19.12%. Addictions, such as smoking, alcohol use, and the abuse of other addictive substances, constitute 12.50%. Sleep disorders, particularly insomnia and related sleep improvement issues, account for 8.8%, while concerns regarding nutrition and physical activity, including obesity and weight management, make up 8.09%. Cardiovascular diseases, such as heart disease, hypertension, and stroke, are represented by 7.35%. Additionally, 3.68% of the studies focused on patients with at least two concurrent pathologies, while 5.88% addressed other conditions not included in the primary categories. A cross-analysis of the types of interventions with the pathologies targeted by digital therapies reveals noteworthy insights. Applications are predominantly utilized in the domain of chronic conditions and pain management, with a usage rate of 54% in this specific area, in contrast to an overall rate of approximately 42% across a total of 135 studies. Similarly, in the realm of sleep disorders, the usage rate is around 67%, again surpassing the overall rate of about 42% from 135 studies. Video games are notably employed in mental health interventions, with a prevalence of 21.28% in this category, compared to a mere 8.82% in the aggregate of 136 studies. Text messaging is exclusively utilized in the contexts of nutrition and physical activity (18.18%) as well as addiction treatment (17.65%). In addition, web-based systems are primarily focused on mental health applications, accounting for 38% of their usage. No significant variations are observed in the application of other technological interventions across different categories of pathologies. In 2021, the proportion of activated studies stands at 16.91%, a figure that remains consistent in 2022. In contrast, the year 2020 saw a notable increase due to the COVID-19 pandemic, resulting in a percentage of initiated studies reaching 24.26%. The data indicates a rise in 2021, with the percentage of initiated studies already at 8.82% as of March. Our analysis reveals a trend where the utilization of more advanced technologies correlates with a decrease in patient enrollment. Specifically, video games have the lowest patient enrollment at 94, followed by virtual reality with approximately 108 patients, social media and applications with 120, and web-based interventions with 131. Enrollment figures begin to increase with more user-friendly technologies, reaching 270 patients for computer-based interventions, culminating in the highest overall enrollment with emails and text messages, which engage 480 patients. Among the 135 studies examined, the data regarding the enrollment status is summarized in Table 3. Of these, only 33.82% have been completed, while 25% are currently active and in the recruitment phase. Additionally, 19.12% are active but not recruiting participants currently. The enrollment

ISBN: 978-618-5630-22-5

status remains unknown for 8.82% of the studies. Furthermore, 5.88% of the studies are active but not recruiting, and 4.41% are active studies that allow participation solely by invitation. Lastly, 2.94% of the studies have been terminated. Thus, it can be concluded that approximately 55% of the studies are ongoing, likely initiated in recent years, in contrast to 37% that have either been completed or terminated. In recent years, ClinicalTrials.gov has mandated the publication of all study results. When results are not available, it typically indicates that the studies are either still ongoing, recently completed, or were conducted before the implementation of this requirement. An analysis of the available studies reveals that only 6.62% present results, in stark contrast to the 93.38% that do not. Additionally, ClinicalTrials.gov provides insights into the gender demographics of the populations studied about digital therapies. A significant 91.91% of studies do not specify a gender, while 5.88% focus on female participants, particularly in studies related to gynecology and postpartum depression. Only 2.21% of studies are centered on male participants. The most represented demographic in the analyzed studies is adults and older adults, comprising 67.65%, followed by children and adults at 11.03%. Studies specifically targeting older adults are notably scarce, accounting for just 1.47%, which may reflect the challenges this demographic faces regarding the "digital divide." Other demographics include solely adults at 8.09%, only children at 6.62%, and a combination of children, adults, and older adults at 5.15%. Randomized clinical trials are typically organized into phases 0 through IV to assess the intervention's efficacy, safety, and associated adverse events across different timeframes and population sizes. However, trials that focus on medical devices or behavioral interventions may not adhere to this phased structure, resulting in the absence of phase-related information in the ClinicalTrials.gov database. Our study corroborates this observation: among 135 trials examined, 125 (91.91%) lacked reported data regarding the study's phase. This indicates that the most critical trials—those classified as phases 1, 2, and 3—are the least represented. Specifically, phase 1 trials account for only 1.47%, phase 2 trials for 2.94%, and phase 3 trials for 2.21%. Furthermore, the average enrollment across these studies was 282 patients; however, when considering the median, which provides a more accurate reflection in cases of data dispersion, this figure drops to 120. This highlights a significant disparity between the mean and median values. Notably, only one-quarter of the studies enrolled 300 patients, while another quarter exceeded this number, indicating that the mean is skewed by a small number of studies with high patient enrollment. The data indicates that a total of 282 patients were enrolled in the studies; however, the median figure of 120 reflects significant variability among the different studies. Notably, the seventy-fifth percentile aligns closely with the average, reaching a value of 300. A total of 11.76% of the studies are solely funded by industry, predominantly in the digital or technological sectors, while 14.71% are the result of collaborations between industry and other entities. This brings the total proportion of studies involving industry participation to slightly over 26%. In contrast, many studies (73.53%) are supported by organizations and institutions outside of industry, including academic institutions, scientific societies, public agencies, and independent non-profit research entities.

ISBN: 978-618-5630-22-5

Industries are beginning to recognize the critical role of clinical trials in validating the effectiveness of digital therapies; however, this understanding is not yet widespread. The industry is more focused on therapies classified as digital compared to the broader concept of digital health. There is a clear need for increased industry involvement, particularly considering the regulatory landscape surrounding digital therapies. This is especially pertinent given that while a limited number of studies may suffice for the commercialization of technologies like applications, the same cannot be said for digital therapies.

CONCLUSIONS

The world is currently in a crucial moment of profound transformation, caused by the incessant evolution of new technologies. Many jobs are on the way to disappearing, man is being replaced by the machine, with its perfect and punctual action; other professions, however, can now use technological innovations as a springboard to get beyond what until yesterday were insurmountable limits. This is one of the possible scenarios of psychological support. The surrounding context can also be integrated and exploited by a discipline that has always made use of physical proximity and the power of communication. The pitfalls can be innumerable, but in order not to put the future of psychology at risk in a way that is instead increasingly faster, an objective and open attitude on the part of psychologists and psychotherapists towards technologies is necessary. The identity of an individual, on the other hand, also develops thanks to the interaction with the surrounding context, which is today mostly digitalized. The new generations are already accustomed to establishing relationships using a device and an Internet connection as a medium, and it is therefore important that young psychologists at this precise moment in history learn to familiarize themselves with technologies, so as not to risk being overwhelmed by the new that never ceases to advance.

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