

АКТУАЛЬНІ ПИТАННЯ ОРГАНІЗАЦІЇ МЕДИЧНОЇ ДОПОМОГИ В УКРАЇНІ. ДОДИПЛОМНА ТА ПІСЛЯДИПЛОМНА МЕДИЧНА ОСВІТА.

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OVERVIEW OF HEALTHCARE INNOVATION AND ENTREPRENEURSHIP

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Summary.

The healthcare system is under constant pressure from a growing and aging population, escalating healthcare costs, limited resources and increasing demand. Achieving the triple aim of healthcare – improving care, improving health and reducing costs – requires innovation. According to the World Health Organization (WHO), health innovation is the development of new or improved health policies, systems, products and technologies, services and delivery methods that improve people's health, with a particular focus on the needs of vulnerable populations. Health innovations have both technological (innovative products, services or processes) and non-technological (organizational, policy, educational and social innovations) dimensions and play a critical role in improving the productivity, efficiency, reliability, sustainability, safety and cost-effectiveness of health care.

This article is the first in a series of publications on innovation and entrepreneurship in health care. The paper examines the main types and categories of innovation and entrepreneurship, analyzes current innovation trends and directions in healthcare, factors that influence the adoption of innovative technologies in medical practice, and the characteristics of a human-centered approach to design thinking in healthcare. The article also discusses the concept of value-based healthcare, which focuses on providing the best possible care to achieve the best possible outcomes for each patient, using available resources efficiently, and how innovation can improve the cost, quality, and access to healthcare.

Keywords: Innovation; Entrepreneurship; Healthcare.

Introduction

The history of medicine is one of innovation. Life science researchers, healthcare professionals and healthcare entrepreneurs continue the tradition of innovation through experimentation and invention. They are revolutionizing the way physicians treat patients, developing medical devices and procedures that would have seemed miraculous to their ancient counterparts, and transforming the way healthcare is delivered to patients and communities. Healthcare innovation is driven by a relentless focus on delivering outcomes that matter to patients and the implementation of Value-Based Health Care (VBHC).

The integration of entrepreneurship and healthcare is driving innovation, creating new opportunities and shaping the future of the industry. Entrepreneurs in this space are constantly seeking innovative solutions to address issues such as access to care, cost, and quality. Key trends in the field include telemedicine, artificial intelligence, wearable technology, and personalized medicine.

I. General Concepts in Healthcare Innovation and Entrepreneurship

The concept of innovation is not new. It has been borrowed from other industries and has similarities to terms used in business, technology, and marketing [1]. Innovation is the driving force behind progress. In healthcare, however, innovation is often confused with other terms such as invention and improvement [2].

Improvement refers to the process of enhancing an existing idea, which may include increasing speed, usability, reliability, or efficiency.

Invention is the creation of a new product, device, process, or concept that has never been made before. It involves translating new ideas or concepts into tangible products. A breakthrough invention is one that provides a completely new and unique function.

Some inventions are related to innovation; however, innovation is not the same as invention. Many ideas do not make it past the invention stage. The process of getting an invention accepted is difficult, and it may take many years before it can be called an innovation. It may never become an innovation, and many inventions fail to be commercialized [3].

Innovation is the act or process of introducing or implementing a new solution or way of doing something that differentiates it from existing offerings and creates measurable value. It involves the introduction of newer and better solutions that meet new requirements or existing market needs, making a significant contribution to something that has already been invented.

Innovation is a process and outcome that leads to change and improvement in practice through the stages of invention, commercialization, adoption, and diffusion, known as the «Schumpeterian trilogy» [3, 4]. In the invention stage, ideas are transformed into a viable product or service. In the commercialization stage, the

technological potential of an invention is transformed into economic value. Finally, the last stage is adoption and diffusion – the process by which innovations are adopted and spread throughout an environment.

Healthcare innovations are developments that lead to improvements in health outcomes and patient experience. Healthcare innovation is a type of social innovation that aims to solve societal problems by making system-level changes. The World Health Organization (WHO) states that ‘health innovations’ improve the efficiency, effectiveness, quality, sustainability, safety and/or affordability of health care. This definition includes «new or improved» health policies, practices, systems, products and technologies, services, and delivery methods that result in improved health care. They can be as simple as changing a form to check a patient out five minutes faster or as complex as an immunotherapy that targets specific types of cancer cells [5-8].

According to the Deloitte Center for Health Solutions [9], innovation is any combination of activities or technologies that breaks existing performance trade-offs in achieving an outcome in a way that expands the realm of the possible. In healthcare, it is defined as providing «**more for less**» – more value, better outcomes, greater convenience, access and simplicity: all at less cost, complexity and time for the patient and provider, in a way that expands what is currently possible.

The main types of innovation

An innovation can be either a new product, service, process, or business model that uses an entirely new or existing technology in a new or existing market. Most innovations fall into more than one category.

The innovation matrix uses parameters that allow companies to categorize innovations according to the market in which they operate and the technology they use [10-13].

Incremental innovation involves the gradual and continuous small improvements of existing concepts, products or services in the existing market, using existing technologies for their implementation. Although incremental innovation does not create new markets and often does not use radically new technologies, it can attract higher paying customers because it meets customer needs identified through their behavior or feedback [13].

Sustaining innovation is a type of innovation that gradually improves a product with each iteration without creating new markets or value networks. Its purpose is to maintain a market by expanding an existing one.

Disruptive innovation involves the introduction of a concept, product, or service that uses new technology and creates a new value network by entering an existing market or by creating an entirely new market [13].

Both sustaining and disruptive innovation can be either incremental or radical. Incremental innovation is the kind that builds gradually, step by step, while radical innovation moves forward in much larger leaps.

In healthcare, disruption is happening everywhere – from AI to mHealth to 3D printing and robotics. Here are some recent examples of disruptive technologies in healthcare [14]:

- Consumer devices, wearables and apps – smartwatches and mobile fitness trackers are enabling consumers to gather health data and play a new role in their health journey.

- AI and machine learning – AI applications are transforming how healthcare systems operate and how care is delivered.

- Telehealth – COVID-19 accelerated its expansion, and most patients say they are interested in virtual care in the future.

- Blockchain – database technology that is transforming many aspects of healthcare, including patient records, supply and distribution, and research.

Architectural innovation refers to the use of existing technology to reach a new market. This often involves adapting an existing product to meet the needs of a different group of consumers. Architectural innovation can be both sustaining and disruptive.

The introduction of robotic surgical systems, such as the da Vinci Surgical System, is an incredible example of architectural innovation in healthcare and surgery. These systems enable greater precision, minimally invasive techniques and remote surgical capabilities – operations can be performed remotely, providing greater access to care for patients in remote or underserved areas [15].

Radical innovation also aims to expand the company’s customer base by entering a new market, and its implementation requires the use of new or revolutionary technology. For example, 3D printing has revolutionised healthcare by enabling the production of patient-specific implants, dental prostheses and even human tissues and organs.

Radical innovation is rare and has similar characteristics to disruptive innovation, but it differs in that it primarily uses revolutionary technology that can transform industries, create new markets, and change the way we live and work. Recent radical innovations include artificial intelligence, blockchain technology and genome sequencing.

Entrepreneurship is the act of taking ideas, innovations, and inventions, and turning them into new businesses and new business concepts and executing that.

Entrepreneurship is pursuing opportunities – often but not always based on innovation – without regard to the resources directly and currently controlled by them (*Prof. Howard Stevenson, Harvard Business School*). Opportunity implies an offering that is novel in one or more of four ways. The opportunity may entail: 1) pioneering a truly innovative product; 2) devising a new business model; 3) creating a better or cheaper version of an existing product; or 4) targeting an existing product to new sets of customers [16].

Healthcare entrepreneurship involves creating a product, process, or service that fulfils a need or introduces a new development in medicine or healthcare delivery. Healthcare innovators may have a clinical, scientific, and/or business background, or a combination of experience and education. Doctors and nurses may be inclined towards innovation and entrepreneurship due to their firsthand experience of identifying the need for new processes or medical devices.

The categories for healthcare innovations and entrepreneurship are as follows:

- Medical treatments, techniques, devices, and drugs (stents and valves, biologics, antibiotic envelopes, rescue inhalers, anti-tremor devices, heart monitoring devices, surgery tracers)
- Wearable health technology and consumer devices (smartwatches, fitness trackers, blood pressure/glucose monitors, biosensors, smart apparel)
- Administrative products and services (patient health records, scheduling, accounting, and invoicing)
- Technology, data, and AI (blockchain, big data, telemedicine, electronic medical records/EMR and electronic health records/EHR)

The healthcare sector has been significantly influenced by technological advances in recent years. This is evidenced by the numerous innovations in the diagnosis, prevention and treatment of diseases [17-20]. The expansion of artificial intelligence and the digitization of healthcare processes have played a key role in this transformation. This is partly due to the growing global challenges and the resulting increased demand for accessible, high-quality medical services.

II. Healthcare Innovation Adoption and Implementation

With significant increases in life expectancy and the diseases of affluence, the need for innovation in healthcare has never been more critical. In healthcare, innovation can come from a variety of approaches, including new technologies, medical devices, drug development, innovative management approaches, or new clinical pathways [2, 3, 7, 9, 19, 20].

Regina Herzlinger, in her Harvard Business Review article «Why Innovation in Health Care Is So Hard» [21], identifies six factors that facilitate or hinder the implementation of innovation in health care. These are actors, financing, policy, technology, customers, and accountability.

Three types of innovation can make health care better and cheaper. One changes the way consumers buy and use health care (*process innovation*). Another uses technology to develop new products and treatments or otherwise improve care (*product innovation*). The third creates new business models, particularly those that involve the horizontal or vertical integration of separate health care organisations or activities (*business model innovation*).

The process is the combination of technical infrastructure, technologies, skills and procedures that are used together to solve a problem. An innovative process therefore has a novelty component that has been successfully applied for the clear benefit of its stakeholders (patients, healthcare professionals, payers and regulators). Process innovations are perceived to be less risky than other types of innovation, making them theoretically more acceptable to the inherently risk-averse healthcare industry, which operates under the Hippocratic Oath of «first do no harm» [22].

Ensuring end-user access to innovation is a critical milestone on the path to success for all types of innovation. Identifying the key stakeholders involved in the pathway between innovation and end-users, and understanding

their specificities, is crucial for the adoption and uptake of innovations.

Adoption of the new solution requires that stakeholders see and value a relative advantage. An innovation is more likely to be adopted if stakeholders have the ability to adopt the new solution and if it is in line with their interests. It also helps if the innovation is not too difficult to put into practice and can be tested on a small scale before implementation. Finally, minimizing risks increases the chances that the innovation will be accepted [22].

Design Thinking in Healthcare

Design thinking is a problem-solving methodology that aims to create innovative solutions that meet user needs. It involves understanding and empathizing with users to identify their needs and develop effective solutions. The human-centered approach to the design process consists of several stages, including empathizing with the user, defining the problem, brainstorming potential solutions, prototyping, and testing.

Human-centered design in healthcare is an approach that places people – primarily patients and healthcare professionals – at the center of the design process. This approach has the potential to improve efficiency and effectiveness by focusing on their needs and developing optimal solutions. To achieve this, it is essential to involve all stakeholders in the healthcare system, including organizations, clinicians, administrators, and healthcare innovators.

Previous research indicates that integrating co-creation into the design of healthcare solutions can facilitate greater acceptance and adaptation, ultimately leading to more efficient healthcare services and improved usability of implemented solutions. Analysis of the adaptation and acceptance of new technologies reveals the problem of misunderstanding and the need for greater trust in modern tools implemented in the healthcare system. The use of co-creation can be an effective solution in the process of developing modern medical products and services [23].

EIT Health was established in 2015 as a «Knowledge and Innovation Community» (KIC) of the European Institute of Innovation and Technology (EIT). EIT Health offers programs [24] and supports co-design and co-creation-driven projects that bring together key stakeholders in the healthcare sector:

- *EIT Jumpstarter*: Pre-accelerator run by seven communities of the European Institute of Innovation and Technology (EIT)
- *EIT Health Bootcamps*: Intensive incubation programmes for start-ups
- *i-Days*: Student competition to tackle health challenges
- *Patient Innovation Bootcamp*: Supporting patients and caregivers to develop and launch their innovations
- *Open Innovation*: Solving healthcare challenges

EIT Health gives you the opportunity to learn new skills, connect with a vast network of experts, access new markets and funding, and support the development and adoption of innovative solutions for healthcare.

III. Value-Based Health Care (VBHC)

Healthcare should be driven by a constant focus on delivering outcomes that truly matter to patients. The

concept of Value-Based Health Care (VBHC) is based on providing the best possible care to achieve better outcomes for each patient, using available resources in an efficient manner [25-27].

The definition of value in health care, as introduced by Michael Porter and Elizabeth Teisberg in their book *Redefining Health Care* [28], is the relationship between the outcomes that matter to patients and the effort (costs and resources) required to achieve those outcomes. This definition was instrumental in the development of VBHC.

The VBHC approach emphasizes performance rather than just fee-for-service (FFS) and volume of care, resulting in lower costs. It also eliminates wasteful care and leads to better outcomes by reducing complications and readmissions, benefiting patients and lowering costs to society.

In value-based care, healthcare providers engage in a collaborative process aimed at managing an individual's overall health, taking into account personal health goals. VBHC puts the individual at the center of care, with a focus on continuous measurement of outcomes and costs for each patient. While measuring and optimizing outcomes is critical, it is not the only factor in ensuring the long-term sustainability of interventions and health systems. To achieve this, it is essential to integrate a comprehensive assessment and validation of the costs and resources involved in adding value to the system. This approach will not only ensure long-term financial stability, but also equitable access for patients.

Value-based healthcare encourages providers to experiment with care management and patient engagement approaches that can improve health outcomes and reduce spending. Some stakeholders recognize the importance of engaging patients in their own care and are investing in capabilities to facilitate this.

The European Commission Expert Panel on effective ways of investing in Health (EXPH) therefore proposes to define «value-based healthcare (VBHC)» as a comprehensive concept built on four value-pillars: appropriate care to achieve patients' personal goals (*personal value*), achievement of best possible outcomes with available resources (*technical value*), equitable resource distribution across all patient groups (*allocative value*) and contribution of healthcare to social participation and connectedness (*societal value*) [29].

Jan-Philipp Beck, CEO of EIT Health, acknowledges the pivotal role of healthcare professionals, innovators and policy makers in the implementation of VBHC. The practitioners who drive change towards higher value care on a daily basis provide inspiration and additional insights, innovators aspire to deliver new solutions and offer greater understanding of needs and the value of innovation, and policy makers are interested in driving much-needed system change [30].

The role of innovation in implementing VBHC

Currently, many health systems are organized around the delivery of services without necessarily considering health outcomes. Innovation can help transform these systems into what experts call a learning health system that continuously improves care in three ways: through

digital transformation, evolving business models and health care ecosystems, and innovations in health care delivery [31, 32].

Over the past decade, technology has driven the healthcare industry through various innovations in disease prevention, detection, and treatment. Modern healthcare technology and the move to digital records have revolutionized the practice of medicine. Further innovations aim to increase the connectivity of these records, enabling healthcare systems to leverage big data and insights to improve patient care. As networks of people and technology become more connected, healthcare organizations will need better tools to solve health challenges at scale. Innovation is critical to achieving this goal.

New healthcare business models, such as value-based care, compensate care teams for patient outcomes rather than services. As a result, healthcare organizations must refine their processes and improve collaboration with other organizations in the broader healthcare ecosystem to deliver the best care. To adapt to value-based care, healthcare organizations must strive to improve the quality of care and reduce costs. This requires streamlining both clinical and business processes. For example, making financial approvals more efficient to minimize delays, or ensuring that clinicians have immediate access to a patient's most recent records to facilitate better decision-making.

According to the World Health Organization (WHO), health innovation refers to the development of new or improved health policies, systems, products and technologies, and services and delivery methods that improve people's health, with a particular focus on the needs of vulnerable populations.

Health innovation has both technological (product/service and process innovation) and non-technological (organizational, policy, educational and societal innovation) dimensions, and the outcomes of innovation should always include some degree of improvement. When technological improvements are coupled with non-technological innovations, this can lead to societal transformation and change [33].

EIT Health programmes [24] on innovation management and high-value care:

- *Healthcare Transformation Academy*
- *High Value Care Introduction Course*
- *High Value Care Ambassadors Course*
- *Creating ValEU*

IV. Top Healthcare Innovations and Entrepreneurs

The Deloitte Center for Health Solutions (<https://www2.deloitte.com>) surveyed healthcare leaders to identify the innovations they believe are most likely to transform healthcare. The following ten healthcare innovations have the potential to overcome the limitations of the fee-for-service (FFS) healthcare system and expand the frontier through new business models that can deliver care in ways not previously thought possible. Those who have already experimented with business model change as a result of recent transformative market shifts, such as value-based healthcare (VBHC), consumerism, and the proliferation of new data sources, are likely to be early adopters of these innovations. New data sources and tools are

revolutionizing clinical trial design, treatment decisions, and ongoing patient care [9].

Top 10 healthcare innovations (*The Deloitte Center for Health Solutions*)

1. **Next-generation sequencing:** Applications of genetic sequencing to identify at-risk populations or target therapies to patients who are likely to respond

2. **3D-printed devices:** Lower-cost and highly customized medical technology products that can be tailored to suit the physiological needs of individual patients

3. **Immunotherapy:** Treatments with the potential to significantly extend survival for cancer patients, without the negative side effects and related health care costs of traditional chemotherapy

4. **Artificial intelligence:** The ability of computers to think like and complete tasks currently performed by humans with greater speed, accuracy, and lower resource utilization

5. **Point-of-care diagnostics:** Allow for convenient, timely testing at the point of care (e.g., physician office, ambulance, home, or hospital), resulting in faster, more cohesive patient care

6. **Virtual reality:** Simulated environments that could accelerate behaviour change in patients in a way that is safer, more convenient, and more accessible

7. **Leveraging social media to improve patient experience:** Tapping data from social media and online communities to give health care organizations the ability to track consumer experience and population health trends in real-time

8. **Biosensors and trackers:** Technology-enabled activity trackers, monitors, and sensors incorporated into clothing, accessories, and devices that allow consumers and clinicians to easily monitor health

9. **Convenient care:** Retail clinics and urgent care centres that provide more convenient and lower-cost care to patients for a number of health issues

10. **Telehealth:** A more convenient way for consumers to access and increase self-care while potentially reducing office visits and travel time; may also prevent complications and emergency room visits

In healthcare entrepreneurship, innovation plays a key role in addressing challenges, improving patient outcomes and creating new business opportunities. Innovation gives rise to disruptive business models, such as direct-to-consumer healthcare, which allow entrepreneurs to bypass traditional channels of healthcare delivery. By embracing innovation, healthcare entrepreneurs have the potential to transform the industry and make a significant impact on patients' lives [34]. Healthcare entrepreneurs identify gaps in the market and create effective solutions, fostering the development of disruptive technologies such as AI-based diagnostics or telemedicine platforms to make healthcare more accessible and convenient. They are also using data analytics to improve decision-making and personalized medicine, tailoring treatments to individual patients [35].

It is clear that those engaged in the pursuit of healthcare innovation face a number of significant challenges. These include legal and regulatory concerns, the need for capital investment in research and manufacturing, a lack of medical or scientific expertise, and compensation structures. However, despite these obstacles, the field of healthcare innovation is thriving and entrepreneurs are achieving success.

By seizing opportunities and taking risks, healthcare entrepreneurs are reshaping the industry and improving patient outcomes. Their impact extends beyond individual startups, inspiring others to explore entrepreneurial ventures in healthcare and contributing to the overall advancement of the field.

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ОГЛЯД ІННОВАЦІЙ ТА ПІДПРИЄМНИЦТВА В ОХОРОНІ ЗДОРОВ'Я

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Резюме.

Система охорони здоров'я перебуває під постійним тиском через зростання і старіння населення, збільшення витрат на охорону здоров'я, обмеженість ресурсів на тлі зростання попиту. Для досягнення потрібної мети охорони здоров'я – покращення обслуговування, зміцнення здоров'я та зниження витрат – необхідні інновації. Згідно з визначенням Всесвітньої організації охорони здоров'я (ВООЗ), інновації в охороні здоров'я – це розробка та впровадження нових або вдосконалених політик, систем, продуктів, технологій, послуг і методів їх надання, які покращують здоров'я людей, з особливим акцентом на потреби вразливих груп населення. Інновації в охороні здоров'я мають як технологічний (інноваційні продукти, послуги чи процеси), так і нетехнологічний (організаційні, політичні, освітні та соціальні інновації) виміри та відіграють критичну роль у підвищенні продуктивності, ефективності, надійності, стійкості, безпеки та рентабельності охорони здоров'я.

Стаття є першою у серії публікацій, присвячених темі інновацій та підприємництва в охороні здоров'я. У роботі розглянуто основні типи та категорії інновацій та підприємництва; проаналізовано сучасні інноваційні тенденції та напрямки у сфері охорони здоров'я; фактори, які впливають на розвиток та впровадження інноваційних технологій; продуктів та процесів у практиці медицини, особливості підприємницької діяльності та застосування людино-центрованого підходу до дизайн-мислення в охороні здоров'я. У статті також розглянуто концепцію ціннісно-орієнтованої охорони здоров'я, яка фокусується на наданні медичної допомоги високого рівня для досягнення найкращих результатів для кожного пацієнта, ефективно використовуючи наявні ресурси, а також роль інновацій у покращенні якості, вартості та доступу до медичних послуг.

Ключові слова: інновації; підприємництво; охорона здоров'я.

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