



Identifying and Prioritizing Key Challenges in Launching Startups in the Health Sector in Iran

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Abstract

Background: The health sector (HS) has emerged as a pivotal arena for startups, propelled by technological innovation and the increasing demand for transformative healthcare solutions. Despite this, startups in this sector face unique challenges that hinder their growth and sustainability. A systematic understanding of these barriers is crucial to fostering a supportive ecosystem and enhancing their contribution to healthcare advancement.

Objectives: The present study aims to identify and rank the principal challenges encountered by founders when launching HS startups, providing actionable recommendations for entrepreneurs, policymakers, and stakeholders.

Methods: A sequential-exploratory mixed-methods design was employed. Qualitative data were gathered through semi-structured interviews with 14 founders of successful health startups in Kermanshah province, selected via purposive sampling. Thematic analysis was conducted following Graneheim and Lundman's (2004) framework. Quantitative validation involved a researcher-developed questionnaire administered to the same cohort, with data analyzed using the Friedman test to prioritize challenges by significance.

Results: The analysis identified 68 critical challenges, prioritized using the Friedman test, and categorized into 15 key factors: (1) Regulatory and licensing hurdles, (2) economic and financial constraints, (3) gaps in knowledge and technology infrastructure, (4) organizational and team dynamics, (5) market and marketing strategy deficiencies, (6) underdeveloped entrepreneurial ecosystems, (7) technological and communication barriers, (8) social and ethical concerns, (9) healthcare system complexities, (10) inadequate training and empowerment, (11) technical limitations, (12) international market entry challenges, (13) inefficiencies in research and innovation systems, (14) knowledge transfer obstacles, and (15) cultural barriers.

Conclusions: This study presents a prioritized framework to assist founders in proactively navigating challenges, devising risk mitigation strategies, and leveraging opportunities. For policymakers, the findings highlight the urgency of regulatory reforms, simplified licensing, and ecosystem development to foster innovation. Addressing these barriers can enhance the viability of health startups, driving sustainable advancements in healthcare delivery. The outcomes serve as a strategic guide for stakeholders to align efforts, optimize resource allocation, and strengthen the HS startup ecosystem, ultimately improving healthcare outcomes through scalable, technology-driven solutions.

Keywords: Startup, Health Startups, Challenges, Obstacles

1. Background

Startups are innovative enterprises that tackle prevalent problems with uncertain outcomes and high risks, often necessitating trial-and-error experimentation for success (1). They represent a modern form of business with significant potential for development and profit generation. However, the

decision-making process in startups is time-consuming and inherently risky (2). The health sector (HS), characterized by constant evolution due to technological advances, patient preferences, and regulatory changes, has become fertile ground for startups aiming to transform medical education, healthcare delivery, and patient outcomes (3). Despite challenges such as regulatory compliance, trust-

building, and financial sustainability, health startups have demonstrated resilience, particularly during crises like the coronavirus pandemic, attracting over 20\$ billion in investments globally since 2020 (4). This growth underscores the sector's potential, with significant increases in investment and market size observed worldwide, including regions like India, where health startups attracted 504\$ million in recent years (5, 6). However, data on health startups in Iran remain limited, highlighting the need for further exploration. Previous studies have examined challenges faced by startups in various industries, including regulatory hurdles, financial constraints, and market competition (7). However, there is a gap in understanding the unique challenges specific to health startups, which operate in a highly regulated and sensitive environment. While some studies have highlighted issues such as trust-building with healthcare professionals and proving clinical value (8, 9), few have comprehensively addressed the multidimensional obstacles faced by health entrepreneurs. Additionally, traditional educational methods often fail to equip future entrepreneurs with the skills needed to navigate these challenges, emphasizing the need for innovative approaches like experiential learning and e-learning (5, 6).

2. Objectives

Unlike previous studies, this research specifically focuses on identifying the key challenges of launching startups in the HS, offering a detailed analysis of obstacles related to regulatory compliance, financial sustainability, technological limitations, and trust-building. By addressing these gaps, this study aims to provide practical insights for founders, policymakers, and educators to foster a supportive ecosystem for health startups, ultimately helping entrepreneurs mitigate risks and capitalize on opportunities for success.

3. Methods

The present study adopted a mixed-methods (qualitative-quantitative) approach to comprehensively identify and prioritize the key challenges faced by founders when launching startups in the HS. From a design perspective, the study was non-experimental and descriptive (survey-based), while its objective was applied and developmental. The qualitative phase utilized content analysis to identify challenges, while

the quantitative phase employed a survey method with the Friedman test for prioritization.

The study population included experts in innovative businesses and health startups, mentors, advisors, entrepreneurs, founders of innovative companies in HS, specialists and researchers in healthcare, as well as representatives and managers of healthcare organizations. In the qualitative phase, conventional content analysis was conducted following the framework proposed by Graneheim and Lundman (10). This involved identifying meaning units (e.g., sentences or paragraphs) within textual data, assigning codes to condense their essence, grouping similar codes into homogenous categories, and abstracting these categories into overarching themes while retaining their broader meanings. Sampling in the qualitative phase continued until theoretical saturation was achieved, which is the point at which no new codes or themes emerge that contribute to further defining the characteristics of the identified categories. Semi-structured interviews were conducted with 14 purposefully selected participants aged 20 - 50 years, who were recruited through snowball sampling (Tables 1 and 2).

In the quantitative phase, a researcher-made questionnaire was designed based on the findings from the qualitative phase. The questionnaire utilized a Likert-scale format to evaluate the importance of the identified challenges. Content validity was confirmed by professors from the Department of Management and Entrepreneurship at Razi University. Given the specialized nature of the research topic, the statistical population for the quantitative phase was selected purposefully and conveniently, with details provided in Table 2. After collecting and completing the questionnaires, data were analyzed using SPSS version 25. Initially, the Kolmogorov-Smirnov test was used to assess the normality of the data distribution. Due to the non-normal distribution of the data, the non-parametric Friedman test was applied to rank and prioritize the identified challenges. The Friedman test is widely used by researchers to rank variables based on their significance (Tables 1 and 2).

To ensure the validity and reliability of the research indicators, a precise and structured process was followed, as outlined in Table 3. In the qualitative phase of the study, validity was assessed using methods such as pluralism (multiple perspectives), prolonged engagement with participants, selection of appropriate

Table 1. The Occupational Characteristics of Individuals in the Qualitative and Quantitative Sections of the Study^a

Attribute	Qualitative Section	Quantitative Section
Experts and researchers	3 (21)	10 (40)
Entrepreneurs or founders	5 (35)	2 (8)
Mentors or consultants	3 (21)	10 (40)
Managers in healthcare and medical organizations	1 (7)	3 (12)
Total	14	25

^a Values are expressed as No. (%).

Table 2. The Demographic Characteristics of Participants in the Qualitative and Quantitative Sections of the Study^a

Variables and Categories	Qualitative Section	Quantitative Section
Gender		
Male	11 (78)	18 (72)
Female	3 (22)	7 (28)
Education level		
Master's degree	5 (35)	6 (24)
PhD	9 (65)	19 (76)
Age (y)		
20 - 29	1 (7)	2 (8)
30 - 39	8 (57)	3 (12)
40 - 50	5 (36)	20 (80)
Experience in the field (y)		
1 - 4	0 (0)	1 (4)
5 - 10	9 (64)	13 (52)
More than 10	5 (36)	11 (44)

^a Values are expressed as No. (%).

samples, and member checking for participant confirmation. In the quantitative phase, face validity was evaluated by faculty members from the Management and Entrepreneurship Department at Razi University, and content validity was assessed through expert panel review. To measure reliability in the qualitative phase, member checking and re-coding were employed, achieving a 72% agreement rate, while in the quantitative phase, Cronbach's alpha ($\alpha = 0.83$) was used to assess internal consistency, indicating high reliability. Collectively, these measures ensured that the research instruments accurately measured the intended constructs, produced consistent results, and thereby significantly enhanced the scientific credibility of the study.

4. Results

In the qualitative phase of this study, data analysis was conducted using the framework proposed by

Graneheim and Lundman (10). The data were repeatedly reviewed, and key points highlighted by participants were systematically listed. Each point was assigned a label or code. The researchers then examined the codes extracted from the interviews and, through a deep analysis of the interview transcripts, grouped codes that reflected a shared concept into unified concepts. Subsequently, related concepts were abstracted into broader categories. Following this process, 68 distinct concepts were identified and organized into 15 overarching categories (Table 4).

To prioritize the identified challenges (concepts), the Friedman test – a non-parametric statistical method – was applied, as the data did not meet normality assumptions. The test yielded a significant result ($P < 0.001$) with 67 degrees of freedom, indicating that the ranks of the challenges were not identical, and meaningful distinctions could be drawn between them. Table 4 summarizes the integrated findings from both

Table 3. Validity and Reliability of Research Indicators

Validity of Indicators	Reliability of Indicators
Qualitative section	Recoding (72%)
Pluralism (multiple perspectives)	
Prolonged engagement with participants	
Selection of appropriate samples	
Participant confirmation (member checking)	
Quantitative section	Cronbach's alpha (83%)
Face validity (expert review)	
Content validity (expert panel review)	

qualitative and quantitative phases, juxtaposing the identified challenges (concepts and categories) with their statistical prioritization.

5. Discussion

The present study aimed to identify the key challenges of launching startups in the HS. A total of 68 concepts and 15 categories were recognized, including licenses and laws (8 concepts), economic and financial issues (5 concepts), knowledge and technology environment (6 concepts), organizational and team structure (6 concepts), market and marketing (4 concepts), entrepreneurial ecosystem (7 concepts), level of technology and communication (3 concepts), social and ethical issues (3 concepts), health and treatment system (3 concepts), training and empowerment of individuals and teams (3 concepts), technical and technological limitations (4 concepts), international environment and foreign market (4 concepts), research and innovation system (5 concepts), knowledge and technology transfer (3 concepts), and cultural environment (4 concepts).

5.1. Challenges and Obstacles Related to Licenses and Regulations

The role of the government in fostering entrepreneurship is to create an environment that supports entrepreneurship and facilitates success in the risky process of creating and developing entrepreneurial businesses. Unfortunately, many entrepreneurs in Iran face obstacles such as strict, restrictive, and cumbersome laws (5.08), lack of awareness of relevant institutions (4.48), complexity and timing of licenses (4.40), and weak health technology policies (4.06), among the high-priority challenges. Bahrami et al. identified the existence of

strict and restrictive laws as one of the most important key challenges for big data startups (11, 12).

5.2. Challenges and Obstacles Related to Economic and Financial Issues

Every health system requires proper supply and allocation of resources to perform its tasks effectively. The issue of financing for startups is not specific to developing countries; various studies in developed countries have also cited financing as a significant obstacle. According to a report by the United Nations Conference on Trade and Development (UNCTAD) in collaboration with the Vice Presidency for Science and Technology of Iran, one of the significant challenges for startups in Iran is financing by private institutions, especially venture capitalists and angel investors. Suitable access to financial resources is a primary prerequisite for empowering startups for investment, growth, and job creation, such that this issue has been continuously elevated to a policy-making level in recent years (13). In the field of HS startups, participants in the current study also mentioned financial and economic obstacles such as lack of investment and private and government financial support, instability of the economic situation, high investment risk, instability of the market and currency, and problems of access to money and financial facilities. The instability of the economic situation (3.37) was cited as one of the most important factors leading to the fear of starting and launching startups.

5.3. Challenges and Obstacles Related to Knowledge and Technology

This domain of the health system, which includes six subdomains, highlights weaknesses in access to knowledge and technology, lack of efficient technology cores, weakness in the exchange of knowledge and

technology, exclusivity of knowledge, lack of health science and technology parks, and lack of awareness of specialized technical and engineering knowledge. According to the participants, weak knowledge of specialized technical and engineering knowledge was a more important challenge, with an average of 3.84. Chakraborty et al. also mentioned this challenge in their research (5).

5.4. Challenges and Obstacles Related to Organizational and Team Structure

In the HS, organizational and team structure can significantly impact innovation and the performance of innovative businesses. However, innovative businesses often face limitations such as traditional structures and one-dimensional perceptions of healthcare workers, which can discourage them from starting new ventures. Alm and Lindblad, Batman, and Boni and Weingart have highlighted the problem of team building and structure formation in health startups (14-16).

5.5. Challenges and Obstacles Related to Market and Marketing

For startups in HS to be visible and survive in the competitive market, they must overcome weaknesses in sales and marketing of their products and services, which is one of the biggest challenges they face. Despite its attractions, the health industry is relatively competitive in Iran, and health startups require extensive advertising and marketing campaigns to gain visibility, which are often costly and unaffordable. Bahrami et al. and Spigel emphasized this challenge as one of the most significant for startups (11, 17).

5.6. Challenges and Obstacles Related to the Entrepreneurial Ecosystem

In the healthcare entrepreneurship ecosystem, high startup costs and weak infrastructure are two main challenges. These issues can hinder access to appropriate financial and technical resources and reduce the competitiveness of entrepreneurs.

5.7. Challenges and Obstacles Related to the Level of Technology and Communication

In the category of technology and communication level, the main challenge in health is innovation and the application of advanced technologies. This includes the use of medical information systems, the establishment of communication systems between doctors and

patients, and the remote transmission of medical data. Issues related to privacy and information security in these systems are also considered.

5.8. Challenges and Obstacles Related to Social and Moral Issues

In the area of conflict of interest and ethical issues, healthcare providers in innovative healthcare businesses may face conflicts between financial and ethical interests when dealing with patients, potentially leading to poor decision-making.

5.9. Challenges and Obstacles Related to the Healthcare System

Paying sufficient attention to the healthcare system itself as the primary goal and driver of health startups is crucial (12). Unfortunately, recurring problems in health startups include conflicts of interest among physicians and the presence of a "mafia" in the health field. Additionally, there is a lack of government support for innovation aimed at improving public health.

5.10. Challenges and Obstacles Related to Training and Empowerment of Individuals and Teams

Human capital management is one of the biggest challenges for startups, but success in this area leads to overall business success. Entrepreneurial competencies and methods of skill development for members of digital health teams were among the most important challenges addressed by Kasperavičius (18). In health startups, founders face significant challenges in attracting and retaining skilled, creative, and capable personnel due to financial constraints. Attracting and retaining skilled and committed human resources is a major challenge, especially in health. If the team is not well-formed, or if proper and fair contracts are not made with team members before starting work, or if the entrepreneur cannot align team members with a common goal, these factors can easily lead to business failure (19).

5.11. Technical and Technological Limitations

The first important principle in the development of startup entrepreneurship is creating and developing suitable technical infrastructure and technological platforms for offering services and products in various sectors, which leads to differentiation, competitive ability, accelerated service delivery, increased productivity and efficiency, and the provision of

innovative services (17). Founders of health startups have identified four major obstacles related to infrastructure and technical platform delivery challenges: Lack of technical and technological infrastructure in health, internet filtering, weakness in communication networks and high-speed internet, and lack of modern medical equipment and diagnostic devices.

5.12. Challenges and Obstacles Related to Social and Ethical Issues and the International Environment and Foreign Market

Environmental and social factors are important indicators in establishing entrepreneurship in businesses, and numerous obstacles in this area, especially at the beginning, can prevent proper business formation and growth. Founders of health startups have identified various challenges, including unpredictable political/social conditions, threats of implementing protection plans, filtering, sanctions, exchange rate fluctuations, barriers in the connection between formal education and startups, and lack of access to ecosystems and accelerators in the early stages (19).

5.13. Challenges and Obstacles Related to Culture

Entrepreneurial ecosystems are a mix of social, political, economic, and cultural elements that support the development and growth of innovative startups and encourage novice entrepreneurs and other actors to accept the risks of launching, financing, and high-risk investments (17). However, cultural obstacles can be a serious impediment, especially for startups in HS. Participants in the research identified three cultural problems: Lack of public awareness of the importance of innovation and new technologies in health, cultural and social problems, lack of development of innovation skills among health workers, and resistance to change. Aghajani et al. identified this factor as one of the most important challenges in starting and launching startups (20).

5.14. Conclusions

In summary, our findings offer a comprehensive and actionable guide for founders of health startups to anticipate the challenges they may face when launching and sustaining their businesses. By understanding these challenges, founders can strategically prepare to address potential difficulties, mitigate risks, and

transform threats into opportunities through effective planning and execution. Additionally, the results provide critical insights for policymakers and legislators in Iran, offering a roadmap to design better-informed decisions and policies. These include reforming cumbersome laws and regulations, streamlining the process of obtaining activity licenses and fulfilling legal obligations, and creating a more supportive ecosystem for health startups. By addressing these barriers, stakeholders can foster innovation, enhance sustainability, and ultimately contribute to improved healthcare outcomes.

5.15. Limitations

While this study provides valuable insights into the key challenges of launching startups in the HS in Iran, it is not without limitations. First, due to the relatively low number of participants in both the qualitative and quantitative phases, caution should be exercised in generalizing the results to broader populations. Although theoretical saturation was achieved in the qualitative phase and the quantitative phase provided meaningful rankings, the sample size may not fully capture the diversity of experiences and perspectives across all health startup founders in Iran. Second, the study relied heavily on self-reported data from founders, which could introduce biases such as social desirability or recall bias, potentially influencing the accuracy of the findings. Third, the prioritization of challenges in the quantitative phase was based on the Friedman test, which, while effective for ranking, does not account for the intensity or magnitude of differences between ranked items. Finally, the dynamic nature of the health startup ecosystem, influenced by rapid technological advancements and evolving regulations, means that some of the identified challenges may change over time, requiring further longitudinal studies to track these shifts. Future research could address these limitations by increasing sample size, incorporating additional data sources such as policy documents or expert panels, and conducting longitudinal analyses to ensure the relevance and applicability of findings over time.

Footnotes

Authors' Contribution: B. R. and S. A.: Study conceptualization and design; S. A. and N. N.: Data analysis and interpretation; B. R.: Drafting of the manuscript; B. R. and N. N.: Critical review of the

manuscript for significant intellectual content; S. A.: Statistical analysis.

Conflict of Interests Statement: The authors declare no conflict of interest.

Data Availability: The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Ethical Approval: All measures and activities in this study were performed based on accepted scientific principles and ethical considerations in accordance with relevant guidelines and regulations (Declaration of Helsinki).

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Informed Consent: The personal information of all participants was protected. Before commencing the study and conducting interviews with the experts and individuals participating in the study, informed consent was obtained from all individuals and/or their legal guardians. In addition, in the qualitative phase, voices of participants were recorded with their permission, and instead of their names, specific codes were used in the interview texts.

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Table 4. The Integration of Qualitative Categories and Quantitative Prioritization of Challenges in Health Sector Startups in Iran

Categories and Concepts	Mean Rank
Licenses and rules	
Strict, restrictive and cumbersome rules	5.08
Weakness of health technology policies	4.06
The rules are not up to date	3.71
Problems with knowledge of licenses and related laws	4.35
Difficulty registering new standards	3.52
Multiple licenses and rules	4.19
Ignorance of relevant institutions	4.48
Complexity and timing of permits	4.40
Economic and financial issues	
Lack of private and public investment and financial support	2.44
The instability of the economic situation	3.37
High investment risk	2.94
Instability of the market and currency situation	3.29
Problems with access to money and financial facilities	2.97
Knowledge and technology environment	
Weak access to knowledge and technology	3.13
Lack of efficient technology cores	3.73
Weakness in knowledge and technology exchange	3.65
Exclusivity of knowledge	3.27
Lack of health science and technology parks	3.39
Weak knowledge of specialized technical and engineering knowledge	3.84
Organizational and team structure	
Lack of manpower and specialized staff	3.26
Weakness in forming a team and performing interdisciplinary activities	3.68
One-dimensionality of health workers and medical education	3.89
Lack of motivation of health workers towards new businesses	3.69
Weakness in leading and managing teams	3.19
Incompatibility of working styles in teams	3.29
Market and marketing	
Lack of accurate and correct statistics of the consumption market	2.56
Weakness in sales and marketing of produced products or services	2.71
Confidentiality of health statistics	2.10
High risk of accepting innovative and new businesses in the market	2.63
Entrepreneurial ecosystem	
Lack of mentorship and professional guidance	3.29
Not prioritizing innovation in the ecosystem	3.90
Weak cooperation and participation in the ecosystem	3.61
Weakness in infrastructure	4.68
High start-up costs	4.79
Weak ideation and lack of idea recognition	4.05
The weakness of geographical development in the market and the traditional structure of the market	3.68
The level of technology and communication	
Weakness in networking	1.89
Data supply problems and access to information sources	1.83
Weak support for innovation by health organizations	2.27
Social and moral issues	
Conflict of interest and ethical issues	1.94
Resistance to adoption of innovation by health workers	1.94
Lack of medical ethics education and empowerment	2.13

Categories and Concepts	Mean Rank
Health care system	
The existence of the mafia in the field of health	2.06
Conflict of interests of doctors and medical centers	2.10
Problems of government support for innovation in improving public health	1.84
Training and empowering individuals and teams	
Weak training and specialized support	1.94
Lack of business angels in HS	2.05
Weakness of empowering universities and cultural development	2.02
Technical and technological limitations	
Lack of technical and technological infrastructure in the field of health	2.00
Internet filtering	2.60
Weakness in communication networks and high-speed internet	2.87
Lack of medical equipment and modern diagnostic devices	2.53
International environment and foreign market	
Problems caused by sanctions and international trade restrictions	2.34
Weakness in international communication	2.53
Weakness in competition with international businesses in the field of health	2.39
High inflation rate compared to the global community	2.74
Research and innovation system	
Lack of basic and applied research in the fields of health innovation	2.87
Patentability of the concept of innovation in Iran	2.81
Failure to use scientific and technological advances in the health industry	3.27
Parallel research work in Iran	3.10
Lack of proper recognition of health problems and needs	2.95
Knowledge and technology transfer	
Problems of knowledge and technology exchange between universities and health industry	2.21
Lack of effective programs for technology transfer and sustainability of start-up businesses in the field of health	1.79
Lack of communication between the universities of the Ministry of Health and the Ministry of Science	2.00
Cultural environment	
Lack of public awareness of the importance of innovation and new technologies in the field of health	2.53
Cultural and social problems	2.35
Lack of development of innovation skills among health workers	2.31
Resistance to change	2.81
Abbreviation: HS, health sector.	