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Popular Diffusion as an Instrument for Overcoming Barriers to Digital Health in Iran

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Popular Diffusion as an Instrument for Overcoming Barriers to Digital Health in Iran

Objective: The importance of champion leaders including tech-savvy leaders to digital government has been highlighted in the literature. Meanwhile, what was in our interest to explore was the role of business-savvy leaders or non-governmental digital champions as units of analysis; those who mobilized people's interest in digitalization and bypassed governmental barriers through this popular mobilization. They could be seen as policy entrepreneurs for understanding policy change in the digitalization of the health sector. This study sought to shed light on the barriers and drivers of digital health in Iran.

Design/methodology/approach: We conducted interviews with actors of digital health businesses in Iran, including the Health Information Technology Center affiliated with the Ministry of Health and Medical Education (MOHME) administrative body and authorities, private companies active in digital health, and health services providers. The purposive sampling method was applied, and 15 experts with relevant and valuable experiences as well as maximum variation to obtain representativeness and rich data were interviewed. Trustworthiness criteria were used to assure the quality of the results. The data were analyzed based on directed content analysis using the MAXQDA10 software.

Findings: We found out how popular diffusion was effective to overcome barriers to health digitalization. Access to the internet and diffusion of information technology helped the internet-enabled businesses to connect directly to people and provide services to them. Diffusion of these services forced the public sector to adjust itself and, thus, MOHME banned digital consultation services because of the so-called "insecure and unknown physicians", following the increased popularity of digital services diffusion, but was not able to resist popular diffusion of new technology. Hence, it allowed them to work. The main barriers to telemedicine spreading in Iran have been divided into five main categories including Government incapacity for digital health governance, Conflict of interest, Professional obligations for information transparency, Protection of patients' rights, and Data security and privacy.

Originality: Popular diffusion is a game changer in digital health governance in Iran and it will determine the future of digital health. To the best of our knowledge, this study is among the first ones to explore digital health governance in relation to the private digital health business in Iran with a public policy approach.

Key words: Digital health, popular diffusion, governance, Iran

Background

Digital health is a disruption technology transforming health care businesses. It changes the way human beings care about themselves with low cost and destabilize traditional health businesses. The digital revolution in health care creates new business opportunities and yields new business models to address issues in medical practice, value creation, and other related problems, among which the ageing society (Kraus et al., 2021). Digital health creates opportunities for utilizing and applying business models of the private sector (such as market-based diffusion of innovations) in governance so that we can see how processes used in private sector contribute to general environment governance. Moreover, in a "government as a platform" perspective, the concept of "shared plumbing" of the Internet has even contributed to reconfiguration of government reorganization (Brown et al., 2017).

Diffusion of e-health initiatives has been studied with a perspective of e-readiness of institutions. Having assessed e-health preparedness, Wickramasinghe et al. insisted on the role of healthcare providers as the key driving force in pushing e-health initiatives. They believed that medical staff were pivotal in building trust within an evolving framework in e-health (Wickramasinghe et al., 2005). Our perspective, which is different, is based on market as an institution for diffusion and not concentrating on technical readiness of governmental institutions. We see market as a complementary institution for e-governance, and market players as governance actors.

These institutions are essentially platform businesses that bring together producers and consumers in high-value exchanges recently recognized with the term "Platforms" that act as intermediaries developing and managing an aggregation platform for goods and services of the same type. They mainly operate on web sites or mobile applications. Their chief assets are information and interactions, which together are the source of the value they create as well as their competitive advantage (Ruggieri et al., 2018).

The importance of champion leaders including tech-savvy leaders to digital government has been highlighted in the literature. Meanwhile, what was in our interest was to explore the role of business-savvy leaders, startups, and non-governmental digital champions as units of analysis; those who mobilized people's interest in digitalization and bypassed governmental barriers through this popular mobilization. Public and private organizations would benefit from a better understanding of the current state of digital technology applications provided by startups and the challenges faced in digital health adoption (Hoe, 2022). They could be seen as policy entrepreneurs for understanding policy changes in digitalization of the health sector.

Among the structural barriers of digital transformation, organizational factors including lack of strategy, human resources, digital skills, and capacities of managers have been frequently mentioned in the literature. Orientation towards citizen perspectives is a tactic employed by digital champions in the U.S government to overcome barriers to digital transformation (Wilson and Mergel, 2022).

In a systematic review to study establishment and development of telemedicine technology in the health system in Iran, Mehrolhassani et al. discovered different barriers to telemedicine establishment. In their study, the most significant barriers were related to the building block of governance/leadership, which was an integral part of other building blocks of the health system in any country. The authors concluded that establishment and development of telemedicine technology in Iran, ensuring the existence of strategic policy frameworks coupled with some other factors such as effective supervision, coalition building, rules and regulations, inter- and intra-sectoral collaboration, and community engagement were necessary (Mehrolhassani et al., 2022).

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Nasiripoor et al. studied different methods of establishing e-health and concluded that the major obstacles to establishing e-health in Iran included the lack of strategy, vagueness (of policies) and complexity of information technology infrastructure, cultural obstacles, lack of enough IT training and technological skills, temporary managers due to frequent changes of managers especially in the Ministry of Welfare and the Ministry of Health, and inability to recruit specialized and skilled information technology personnel in the field of electronic health (Nasiripour et al., 2011).

Salehahmadi and Hajialiasghari found that cultural and language distinctions as well as the level of literacy were barriers to deploying tele-medicine. But 10 years later, along with the Corona pandemic, it seemed that these obstacles had been successfully overcome by ordinary citizens through the use of various health digital applications (Salehahmadi and Hajialiasghari, 2013).

The efforts and objectives of the individuals working in the public sector, including managers, institutional leaders, and chief information officers, have been a subject of digitalization research given their know-how to lead digital transformation and their capacity to coordinate and inspire other actors (Pittaway and Montazemi, 2020).

Top-down health service innovations can be considered to be especially complex and problematic. Hence, the literature derived from "the field of marketing and economics" focused on the role of competition as a driver of diffusion, with successful innovations emerging as a consequence of the rational decisions of millions of individual actors (Huang et al., 2017). Ensuring that digital technologies in health care are efficient and effective for treatment is of importance for decision makers as well as expert bodies in this sector (Hallgren et al., 2017).

The necessary technology is no longer a key component to achieve digital transformation in health care. According to the OECD report, as to governance, "countries need to regulate technology to serve policy objectives. However, beyond regulation, they also need to overhaul the structures, policies, and institutions that govern health systems, and invest significantly in human and institutional capacities. A genuine digital transformation is a political choice .

Digital heath can increase the role of the patients and digital platforms in treatment processes in order to change "balance of power" between physicians (subsequently traditional professional heath institutions) and patients. While traditional organizations create values within the boundaries of their firms or supply chains, digital platforms leverage and orchestrate a platform-mediated ecosystem to create and co-create values with a much wider array of partners and actors (Hermes et al., 2020). Overcoming institutional barriers require the actions of multiple actors within and beyond the health sector, including judicial actors. Such cross-sectoral alliances are efficacious because they provide institutional workers with a broader range of strategies, framings, concepts, and forums with which to challenge institutionalized barriers (Mureyi, 2022). Literature shows the utilization of web-based social networks to make diagnostic consultations available on a national basis. This has been done by Iranian Society of Radiology (ISR) as a nongovernmental organization (Taheri et al., 2020). Therefore, the bottom-up approach for implementing digital health can be effective given the capacity of startups and small and medium knowledge-based companies. Having young and agile staff, these companies are able to achieve digital technologies. Organizational resistance, as an important barrier in governmental administration, does not exist in such companies.

In their review of literature, Lyamu et al. found inadequacy of the government to support the development and implementation of digital technologies in health, and the importance of technical leadership to facilitate the transformational change and integration of digital technologies in health as well. The lack of technical training, experience, and technical expertise is of importance for health practitioners and workforce for implementing digital technologies in health. The public

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health workforce has not been supported to develop these capacities at the same pace as the push for development of the technologies required in digital health. Health workers have also shown limited trust in digital technologies (Iyamu et al., 2022). The finding of the literature on governance in public policies by Mattjis and Mabillard showed that "there was no dynamics of co-creation and co-production, or there was at least less than expected when we focused on digitization in healthcare" (Mabillard and Mattijs, 2021).

Governance can be defined as "the interaction between governments, business stakeholders, and non-profit organizations by which policy decisions implementation are undertaken" (Ysa et al., 2014). In this article, we can see governance from this broad perspective in order to introduce a theory of popular diffusion of digital health applications by ICT startups. Meanwhile, the main objectives of good governance (transparent, accountable, and participatory institutions at all levels of government) (Holeman et al., 2016) can be realized by digital health applications as they provide new tools for participatory technological innovations.

The structure of digital health governance consists of the mechanisms, processes, and institutions through which all stakeholders articulate their interests, exercise their rights, meet their obligations, resolve their differences, and oversee the operation of the health information system (Carnicero et al., 2020). Good digital health governance is the foundation required to coordinate stakeholders and policies that enable effective ICT for a well-functioning health system (Marcelo et al., 2018). The lack of a transparent perspective and political direction, the absence of comprehensive and national strategies, and the lack of steady macro-planning are the most important problems in telemedicine governance in developing countries (Surya, 2018).

Baccianti et al. stated that the relationship between the quality of institutions and governance diffusion and digital technologies had not been addressed in the literature of policy-making (Baccianti et al., 2022). We provided evidence of health digitalization in Iran to show interplay of the diffusion process with the quality of institutions and governance. This study sought to explore the barriers and drivers of digital health based on the theory of digital health diffusion and governance in Iran.

Methods:

Study design

This is a generic qualitative study with an interpretive description approach conducted based on the Standards for Reporting Qualitative Research (SRQR) criteria (O'Brien et al., 2014) from August 2022 to October 2022. The qualitative descriptive approach is particularly suitable for obtaining straight answers to questions of special relevance to practitioners. This approach uses the participants' language, stays close to the data, and uses low interpretations (Sandelowski, 2000). A triangulation approach, including interviews with key informants and comparing with other informative sources such as the media to find out the complementary of findings, was applied to increase data confirmability.

Sampling and recruitment strategy

The purposive sampling approaches were used to select the participants. First, the research team prepared a list of potential samples and tried to communicate with them according to their previous acquaintance with the stakeholders of digital health in Iran. In the next step, in order to cover the maximum diversity, the participants were asked to introduce knowledgeable people who could provide information in this field. The sampling process continued until data saturation was reached and no new data was provided. After getting the initial consent of the people to conduct the

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interview, the consent form containing the general information about the research was sent to them via SMS or WhatsApp. On this form, the participants were assured that their information would remain completely confidential, and they were free to withdraw at any stage of the study.

Data collection

Individual face-to-face semi-structured interviews were conducted by M.E. (a female health policy Ph.D. graduate with a scientific and executive background in the field of health financing) in quiet rooms in the participants' workplaces. Before each interview, the interviewer explained the research objectives and how it would be done. If the interviewee agreed, the meeting would begin. In order to facilitate the interview process, an interview guide containing open questions was used. Based on the feedback received from the initial interviews, the questions were revised for more clarification. In addition to the audio recording of the interview sessions, reflective notes were also taken by the interviewer (M.E.) to be used later in the data analysis process. After the end of each interview, the recorded file was transcribed verbatim and saved anonymously in the word processing software.

The source materials in the media analysis were newspaper or website articles and published interviews with the experts of digital health, as a secondary source. The interviews, as firsthand investigations, were considered primary sources (Hamilton, 2005). Analysis of the media content including the published interviews as well as the news and reports on digital health and telemedicine was carried out using the following keywords: digital health, telemedicine, complaint, resistance, opposition, Ministry of Health and Medical Education (MOHME), and Medical Council of the Islamic Republic of Iran. We also used the search engines and the websites of the MOHME and Iran Medical Council.

Data analysis

The data analysis process was done along with data collection and was based on directed content analysis. In this approach, the researchers began by identifying the key concepts or variables as initial coding categories (Hsieh and Shannon, 2005).

All interviews were recorded electronically and transcribed word by word. The data analysis process was done using the MAXQDA 11 software (VERBI GmbH, Berlin, Germany). Both researchers with different executive and scientific backgrounds worked on the data analysis process to make it more robust and better. When dealing with the media analysis findings, the main themes and subthemes were extracted by entering the published news and interviews into the MAXQDA software.

Rigor and trustworthiness

In qualitative studies, different approaches are considered in order to improve the credibility, confirmability, authenticity, transferability, and dependability of the findings (Kyngäs et al., 2020). In the present study, the first author was immersed in the study for a long time, and relevant experts were asked to check the data analysis process (credibility). In addition, the written texts and the data analysis results were provided to the participants to review and approve the findings (confirmability). To ensure authenticity, the research team strived to insert direct codes from almost all participants. Furthermore, as mentioned earlier, the highest diversity was adapted during sampling to enhance the transferability of the findings. In the end, the data analysis was conducted by the researchers with different backgrounds (dependability).

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Findings:

Through the data analysis of the qualitative interviews, the main drivers of startups diffusions and the main barriers were derived, and two main drivers as well as eight barriers were identified.

How Digital Health Startups Diffuse

1- Popular adoption of online application and passive attitude of government

Government adoption of digital health applications is a real phenomenon. The government had a passive attitude towards this business. These programs became especially popular during the Covid19 pandemic, as people preferred to stay home to avoid contacting the virus while going to clinics for their needs. Diffusion of online health services and "contaminating" people with this new technology caused the government to retreat.

> "The government couldn't regulate its own relationship with these businesses. While the business has been created and the data and the information flow in society, nobody can prevent it. Nowadays "Digikala" (Iranian site similar to Amazon) is dominating the Iranian market and working in every domain even in providing medications. In such a situation, no one can stop it anymore. Once this data flow is created, no one can stop it." P 1

> "At first, there's a demand; then, there's a solution or supply, which is technology. They find each other, so they bypass the rulers (administrators). Here, supply and demand reinforce and support each other due to many problems caused by the lack of a rational governance system. But it imposes itself on the ruler in order to introduce this business to the health system and expand it. When you don't have a mechanism for it, people will find their way themselves." P 15

> "Whether we agree or disagree, people like to get some services at their homes. Whatever we say, this is wrong; we definitely can't resist the people's demands and the growing need for IT. When these applications and startups are welcomed by people, government agencies can no longer resist, and therefore they're more or less forced to accompany them." P 6

> "During the Covid19 pandemic, this became very serious, the need for it increased abruptly, because the need for telemedicine services is a two-way need. One side is the doctor's need and the other side is the patient's. The patient likes not to go out because it's dangerous, or it's expensive. Considering their possibilities and lack of support from government, I think their growth is acceptable. The reason for their growth was people's demands. It means that both patients and doctors need this because of Covid19." P10

2- Lower cost

Due to the low cost (eliminating the cost of transportation) and high opportunity for doing other things as well as avoiding the risk of Covid19, people preferred online home care services. It was one of the main reasons for expanding these services.

> "The specialist charges $2 (USD), and the minimum price for two-way transportation is approximately $4; so, of course I use online visits when I'm sick. Comparing quality and costs, all the people who don't want to visit oncology specialists go to a physician to get simple services. Platforms facilitate the game between the actors. They put the doctor and the patient in contact. They facilitate communication between doctors, laboratories, and pharmacies. Besides, they

facilitate doctor's diagnosis process. This seems to have been following a routine path until now, as it was helpful somehow." P3

What Are the Barriers?

1- Government incapacity for digital health governance

Lack of knowledge

Insufficient knowledge of the governmental body of the health system regarding digital health, telemedicine, and the nature of online health consultation due to the heavy bureaucracy and large scope of the duties of the MOHME was one of the main reasons for opposition and resistance to the expansion of this business.

"Health governance actors themselves don't have much awareness and knowledge about online health. They don't have coherent knowledge; they have vague information about it. So they have hesitation and resistance against change. The most important reason for their resistance is their ignorance and unfamiliarity. As a result, they don't cooperate with startups working in this business. P6

"The entire Ministry of Health has no vision for the development of this digital subsector. It lacks a professional framework, partially because of ignorance. It's not able to respond to this pressure of demand for digitalization. It disclaims its responsibility, and leaves this to the other layers of government. Government doesn't accept responsibility because they have no understanding of it." P3

All the participants were unanimous in their opinion that, apart from a brief instruction that the Ministry of Health and Medical Education (MOHME) issued under the title of telemedicine instructions at the beginning of the Covid19 outbreak, there was no clear policy for implementation of telemedicine concerning licensing or monitoring mechanism for digital health companies. E-health companies confronted this uncertainty space. Thus, it was not surprising that when startups began their activities, health authorities opposed them and tried to ban such companies.

"The government only resists in complete ambiguity because it has no clear policy. It doesn't know what its own expectation from these startups is. There's no framework for cooperation or supporting them. The MOHME has no R&D department to predict the future and to be able to have a solution. Thus, it just resists. They don't have enough knowledge about e-health and don't think about future and the unmet needs. They can't replace them for people. Lack of rules, instructions, and regulations led them to resist. They resist because they don't have any policy. They can't create a new solution; so they try to stop it. The MOHME is completely confused. It means that now, as a startup, if you want to go to the MOHME to get a business license, you don't know where to go, and then there will be resistance. (In this atmosphere) you're going to start your business yourself. Because they didn't define policies, they're going to sue you. And they don't let business to do its work". P1

Belief in the necessity of government intervention

The strong desire of the government to enter into various fields of providing services, including telemedicine, has caused opposition and resistance to the activities of the private sector in the online digital health care services.

"The government thinks it should interfere with everything. It has to mind its own affairs; I mean its regulatory position and policymaking. Let vendors and startups do their job." P1

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"If they're let, they would remove all the companies and startups, and they'll create their own governmental companies, which means they'll create a completely communist system." P2

2- Conflict of interest

According to the participants, the conflict of interests was recognized as one of the most important reasons for the opposition of the government and the health governance body to the expansion of startups in the field of e-health. The willingness to concentrate it in the government was considered the most important sings of this conflict of interests.

> "In our health system, conflict of interests is everywhere. I've seen a lot of barriers to new ideas. A new idea is shaped in private sector but it goes somewhere else in the public sector and becomes disfigured, transformed, and weakened by governmental agencies. Then, these agencies go on to create some startups artificially (governmental-made-startups). They think all the jobs should be done by these startups and with their own support. This conflict of interest doesn't allow you to create space. On the other hand, one who's resisting on e-health applications is also responsible for policy making (and) there he's a provider himself. In many cases, this conflict of interests has led to the formation of government resistance." P1

On the other hand, there were some levels of conflict of interests in some private companies influencing this field, including (but not limited to) access to information of prescriptions and physicians. It provides reasons to some policy makers to oppose the expansion of e-health in this field.

> "One of the biggest challenges we have in these companies is the conflict of interest. Some of these famous applications belong to big pharmaceutical companies. They monitor doctors' prescriptions as well as the medicines people take, and intervene in all of these. Doctors who prescribe their products are rewarded. This creates a very tough conflict of interest. This is one of the chains of corruption, which can't be eliminated. Who gave them the authority to check confidential information?" P5

The lack of clear regulations in e-consultation in health care created many challenges. However, it seemed that the problems were in the health system itself, such as conflict of interests, physician domination on the sector, collusion among actors, etc. Officials, for their part, believed that collusion of providers, fee-splitting, was a moral-legal complication of the country's health system, which was also prominent in the field of digital health. It was formed through the collusion of digital platforms with different providers in this platform and become a serious concern in terms of possible harms and financial difficulties for the patients.

> "Digitalization of healthcare often create induced demand. One of these platforms had sent a message to the patients of a doctor saying that if he got his medicine from a certain pharmacy, he would get 10% discount. The same message was sent to the doctor. In such a situation, induce demand will increase because of the interests of pharmacies, physicians, clinics, laboratories, and so on. It incentivizes the doctor to prescribe more para-clinics test. And finally, instead of providing health to people, you turn them into tools for business" P4

"No one accept responsibility in the field of digital health. This is a subsystem of the health sector with so many issues. Who is thinking on that? Who is theorizing it here? Who is doing the research? Nobody. Who accepts responsibility? The government?" P2

3- Professional obligations for information transparency

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Although lawlessness had no proper meaning in the absence of governing regulations in telemedicine, it was necessary for the private sector to comply with the minimum requirements of any businesses. In this situation, given the need of people because of the Covid19 pandemic, startups began their business prudently by providing appointment services with doctors and subsequently by phone consultations. The government was obliged to approve it and announced the online visit tariff in the Supreme Council of Health Insurance, but it was not possible for the businesses to obey it properly because of the technical and administrative costs. On the other hand, compliance with the minimum conditions of the workforce verification and systematic archiving of audios, videos, and corresponding evidence and documents were not observed properly.

> "If a startup finds that there's no supervision and no regulation, it risks to do its work illegally and it may deviate from the rules. Sometimes it may not even have a registered expert in its team to do tests. Startups may not consider that the agent who's going to do tests should be registered or has to be approved by the MOHME. So, it will be at risk to be sued by MOHME." P1

> "The price of online consultation is 1.5 K. but (some startups) charge about 3 to 5 K. You will hardly find a company that complies with these tariffs" P 4

> "Where do they record the financial transparency of these transactions? Where can they document their visits? There are IT platforms; they must have an electronic record. At least they have to record the description of the conversations and keep them for years. Do they have an archive? Do they have standards for this work? No, (they don't). Our objection is for these cases." P 4

4- **Protection of patients' rights**

Despite the development of electronic prescriptions in the country, digital identity of providers, which was supposed (based on the budget law) to be guaranteed through digital signatures by the Medical Council of Iran, had remained a mystery. In these circumstances and despite the registration of all doctors in the platforms, there was no mechanism to guarantee the correctness of the provider's identity to the patient when making a contact (in-person or video). MOHME banned digital consultation services because of the so-called "insecure and unknown physicians".

> Many times, it's not clear on the other side of the line whether this is a doctor or a nurse or what's the specialty of this doctor. You don't have any information about that doctor except a name and a phone number. This may cause abuse and harm to people. This is happening now. You call and say on one of these platforms: "I want an ENT specialist." Someone will talk to you by the name of an ENT doctor. You also look and see that yes, there is Dr. X, but is the person on the phone really the same doctor? Or is it someone else? In the electronic signature form, this can be controlled to a large extent, but it's not always possible, especially regarding psychiatric and psychological services and services that may not require a medical and paraclinical prescription. P4

5- Data security and privacy

Some participants pointed out the risk of disclosure of patient information by these platforms, especially in sensitive areas such as mental health. Nevertheless, some other providers believed

that privacy had always been used as an instrument to avoid the development of digital services in the Iranian health system.

> "As a company, I could record communications in the process of consultation, and diffuse them. There is no mechanism (regulation) for this. It increases the sensitivity, even if I don't do it. Besides, it's quite possible that my infrastructure isn't adequate for avoiding the risk of hacking. The private information could be disclosed." P2

> "In this country, "security" and "privacy" in the field of health have always been the means to prevent the development of the filed. It is an excuse". P3

Media analysis

In media analysis, three main themes were identified including the reasons for opposition to the growth of digital health startups, drivers for their development and expansion, and the governance solution. There were also 13 sub-themes. The themes, sub-themes, and examples of the media quotes are listed in Table 1. The themes and sub-themes resulting from the media analysis consisted the results of the qualitative interview in the present study. A total of 12 interviews and news reports were selected for analysis. Among the 9 reasons why official authorities opposed the growth of the start-ups in the field of digital health care, the most emphasis was on the challenge of recognizing the identity of the provider and the activities of unqualified people .

Table 1- Media analysis of the causes of diffusion of online health services

Themes and subthemes (Repetition)		Sample quotes
Reason for opposition of government to digital health services	**Legal challenges (3)**	The biggest challenge of health startups is related to legal aspects. Nowhere in the world, online prescription is illegal, but in Iran we have difficulties. We have been recently told that it is not allowed to use the "online visit" term, and if you use it, you will undergo filtration.
	Activities of unqualified people(8)	The biggest problem we are facing is that unqualified persons are providing services. How can it be known whether the person providing health services is the same person who is qualified by the authorities? How the startup can verify this? The person who provides the service may have a Medical System Number; but S/he can be a medical student. We have had reports that a student or a resident provided services while they could not.
	Quality of medical diagnosis and treatment(4)	How a physician can understand a patient's condition without examination? There are standards for conducting a visit, and these standards cannot be met in an online visit, especially when you have no prior information about the patient. Relying on a simple conversation is not enough to prescribe medicine.
	Providers' Fear of transparency (4)	Digital health care creates transparency about what type of services have been prescribed. It could create problems for those who violate the rules. Undoubtedly, transparency put limitations on the lobbying of some doctors, laboratories, or special medical centers. Because of these resistances, health services could not reach complete success.
	Replacing medical consultation with visits (6)	These platforms use the term "consultation" for their services, which sometimes turn into a "visit" and even prescribe medicine. (In Iran, the term "visit" is used for a legal appointment between a doctor and a patient. The term "consultation" in not used in this case. That is why startups use the term "consultation" to bypass the law.) There is even confirmed news that tests are prescribed in these platforms. Even though according to protocols and

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		standards, medical consultation and visit are two separate categories and each has conditions, without these conditions, the act could be considered as a violation of law.
	Lack of an activity license (3)	Many of these health care platforms actually do not have official permission from relevant organizations to operate. If a platform claims to provide such services, it must have all the licenses from related organizations such as the MOHME, the Iran Medical Council, the Psychology Organization, and the Welfare Organization.
	Possibility of committing a crime(1)	In the cyberspace, crimes could be easily committed. As the doctor and patient do not meet face to face, the treatment process does not go well and many violations may occur. Therefore, this type of medicine creates ethical concerns, which not only makes it difficult for doctors to be responsive but also makes supervision difficult.
	Induced demand (1)	Internet advertising of platforms will create induced demand among people.
	Conflict of interest (1)	In the medical ecosystem, the executor, arbiter, and supervisor are all from the same guild . In fact, where a fair arbitration is required in a conflict-of-interest context, the fair result is not obtained because the arbitrator is from the same guild. When a law is established in a field, the executor and the referee should be separated. They should be outside the particular trade in order to apply the law fairly.
Drivers of startups' growth	**Ensuring the doctor's identity(7)**	For authentications of doctors, people can get information from the website of Iran Medical Council (IMC) to know whether such a doctor exists or not. Basically, the IMC has a list of the doctors, their specialties, and the places they work. Vice-chancellors for health affairs in universities also have this list. People can check for psychology services through the public relations of the psychology organization.
	Corona disease and the will of the people(7)	The impact of COVID-19 on transportation limitations regarding of the risks of visiting hospitals and clinics led to the expansion of providing remote medical services. If authorities cannot fulfill this need, the provision of services will be done through illegal processes.
Solutions	**Regulation(3)**	The proper way to use health digital platforms is to organize and legalize them. It seems that in the first stage, these platforms should be recognized by elaborating laws and regulations. Then, we should try to monitor them by scientific standardization.
	Monitoring(2)	Supervision is even more important than primary legislation because although these platforms do not operate illegally in general, violations such as overselling and sometimes monopoly of certain medicines could happen due to the lack of supervising the process of visits and the prescription of medicines.

Discussion:

The main idea of this article was that popular diffusion of health digital services provided by startups could fulfil the governmental failure in health digital policy. Our findings showed that conflict of interest, lack of expertise in administration, and complex administrative procedures were the causes of governance failure in digital health. The findings could also contribute to the theory of diffusion as well as governance theory both providing insight in digital health development. The top-down approach for diffusion of innovation in digital health was problematic due to the complexities of official institutions. This complexity led us to think of a bottom-up approach basically hold by startups in Iran. The main barriers to digital health diffusion in Iran

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based on the finding of this study were as follows: conflict of interest, ineffective regulation, administrators' lack of knowledge, interventionist government, and desire of governmental administrators to intervene in operational levels of governance despite the lack of expertise.

In digital transformation era, the role of startups becomes increasingly important in diffusion of innovation in digital health and e-governance. We are witnessing a digital health market that emerge from digital revolution. Gig economy, freedom of choice in work, crowdfunding for social activity and democratic practices, etc., change the nature of governance in e-health as startups contribute to policy delivery in health care. The struggle for freedom is intertwined with "making money" out of the confines of the traditional market and the state. The civil society, nowadays through startups, increasingly plays its own role in policy delivery and therefore influences public policies. They impose their own directions to the government and public management. In seeking to exploit digital technologies, civil society organizations must be cognizant of inclusion and exclusion, from both social and digital perspectives (Lynn et al., 2022).

The Iranian Medical Council (IMC) is a traditional non-governmental regulatory body for Iranian healthcare professionals that represent physician interest in Iran. IMC is one of the most important organizations to lead campaign against digital consultation technologies developed by Iranian startups. The reason for this opposition is not clear-cut. IMC was anxious at the practice of health care by non-experts (threatening interests of doctors), although startups insisted on the fact that there was an identification procedure for permitting online consultation.

COVID-19 threatened the health care services all around the world. But it pushed forward the adoption of online consultations that "obviate the need for physical visits between patients and health providers" (Webster, 2020). During the pandemic, Iran was witnessing the emergent of a vast number of startups that provided different online services from online appointment scheduling to voice and video consultations. E-businesses, including digital health care services, provided opportunities for young people working in startups who suffered from high unemployment due to the US sanctions against Iran.

Although COVID-19 likely increased the exposure to online health services, the long-term willingness to use tele medical solutions largely depended on addressing some of the barriers that the health system faced (Nittas and Von Wyl, 2020). Telemedicine before the pandemic was facing legal barriers, insurance rules, regulations, and other barriers that previously prevented the widespread availability and in turn usefulness of telehealth services. The industry overcame many of the barriers that were preventing telemedicine's widespread use during the pandemic (Anderson et al., 2022).

Our findings are in line with the literature in prior studies that stated that in healthcare setting, the diffusion and implementation of a technology was influenced heavily by multiple factors such as the nature of the intervention, the healthcare system and local context, and the views and characteristics of the adopters (Warty et al., 2021). Popular diffusion was recognized as the main driver to scale up telemedicine in the Iranian health system. The social impacts was the most important factor affecting the adoption of health information technology in accordance with other studies (Garavand et al., 2016).

Telemedicine technology created many challenges related to informational and communicational infrastructures, health standards, laws and regulations, training, and security (Mafi-Moradi et al., 2019, Furlepa et al., 2022). It was the same for the Iranian case in challenging the government, traditional non-governmental regulatory bodies such as the IMC, traditional health market, the Iranian regulatory system, and traditional bureaucratic institutions.

One classification of barriers addressed policy, organizational, technology, and individual levels against the use of technology in health-care delivery. (WHO, 2021) At the policy level, the identified barriers in the SEA region included licensing requirements for providers as well as modalities, the lack of strong regulatory frameworks, and the lack of well-defined payment and reimbursement guidelines, as was identified to have a significant role in our findings. The result of a systematic review indicated that the barriers to legal liability, privacy and confidentiality concerns, and security of data totally accounted for 11% of the barriers in the world (Scott Kruse et al., 2018). Most of the Middle East countries did not have well-defined standards and guidelines for telemedicine. It was the same in Iran regarding the lack of adequate regulatory standards and weak professional expertise in administration that led to the lack or ineffectiveness of government policies in terms of the adoption of telemedicine standards (Al-Samarraie et al., 2020). Although high costs and cultural resistance in developing countries were considered as the main barriers to their approach to apply telemedicine (Hassibian and Hassibian, 2016), in Iran the governmental barriers were more visible.

Privacy and data security issues related to health care information technology were the key barriers to the adoption of telemedicine in this study. Nevertheless, it was not a social or cultural phenomena; it could be basically interpreted as a lack of regulations that threatened patients, doctors and even administrators to let startups to work in a secure environment. As large quantities of personal health data were generated with the growing use of telemedicine, there was a strong need to invest in technologies that could best protect patient privacy and allow for secure patient data transfer and storage (Lopez et al., 2021). On the other hand, when medical malpractice and liability issues continued to be areas where the law was unclear in terms of telemedicine practices, hospitals and doctors would be left open to unknown legal obligations and responsibilities (LeRouge and Garfield, 2013). Unclear legal provisions regarding liability when using telemedicine practices created a huge barrier for medical professionals (Almathami et al., 2020); the case that was a neglected necessity in Iran.

Governments need to support the health technology industry in developing and testing novel telehealth solutions that are simultaneously safe and agile (Blandford et al., 2020). Leadership is an essential trigger for digital innovation and adoption (Schlieter et al., 2022) and Involvement and support of governments is crucial for the successful implementation of telemedicine.

Conclusions:

Along with popularity of health care applications, we are witnessing net-enabled citizens influencing public policies including digital health policies. It is a new form of citizenship engaging actively in e-business that can be called: “etizens”. They complement the government's role in providing e-services and correct government's failures, as the government has corrected the market failure.

Inefficient administrations are among the most important barriers for e-governments. In this situation, startups can function as a shortcut for delivery policy. Thus, the point is that net-enabled citizens and diffusion of digital services in health care are two important factors challenging inefficient administration. Organizational resistance can be overcome in popular diffusion of digital health applications. The lack of sufficient expertise in public institutions paves the way for civil experts to diffuse digital technologies in the health sector.

To our best of knowledge, this study is one of the first ones to explore digital health governance in relation to the private digital health business in Iran with the public policy approach. Like other

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qualitative studies, this study was subject to some limitations. First, there were some opposite viewpoints mentioned by the participants about the barriers to digital health governance in the Iranian health system. It is not clear which participant provided a more accurate interpretation of the reality about the barriers. Second, although collecting information from a diverse group of policymakers and analyzing data by peer debriefing enhanced the trustworthiness of the study findings, the interpretations might still persist subjectively.

As to areas of future research, it is important for public policy researchers to study the role of new actors in policy making in low-income countries for the improvement of e-government. Due to the lack of expertise in resource-poor countries, the role of a new class of expert citizens needs to be assessed in digital policy. The government needs to adapt to the emerging governance structure and process to facilitate digital health development through using startup capacities with clear and transparent policies to regulate this ecosystem.

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Editorial Board Member
International Journal of Health Governance

Dear Editor,

Resubmission of Manuscript: **Popular Diffusion as an Instrument for Overcoming Barriers to Digital Health in Iran**

Thank you for providing us with the opportunity to revise and resubmit our manuscript to *International Journal of Health Governance.*

We have revised the manuscript according to the two Reviewers' suggestions. Our detailed responses to the reviewers' comments are itemized by the referee and comment. We thank two reviewers and the Editor for their helpful comments, which substantially improved the manuscript. Please let us know if there are any additional comments or suggestions; we will be glad to address them.

Thank you again for the opportunity to revise and resubmit our paper to *International Journal of Health Governance*.

Sincerely,
Authors

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Reviewer: 1

Comments: Thank you for your efforts to share your research. Your paper has so many interesting ideas and findings, but it requires a lot of editing and reorganization to be suitable for publication. I hope you will consider doing that because your topic is so important, not only in Iran but in other countries.	Thanks for your helpful comments on our manuscripts. We have done numerous corrections to the paper.
Additional Questions: 1. Originality: Does the paper contain new and significant information adequate to justify publication? This is a challenging paper to evaluate. The organization and content certainly require a lot of reorganization and editing. However, the findings are presented with a freshness and urgency that make the reading effort worthwhile. The content is significant because I believe it reflects problems that may be present in many resource-poor countries with immature governance systems. The information is not so much new as a reflection of a rapidly developing and evolving situation. The driving technology is advancing faster than social capacity to manage it. This paper illustrates the risks and barriers as a foundation to governance problem-solving.	We have revised the content and did our best to address the theoretical disorganizations.
2. Relationship to Literature: Does the paper demonstrate an adequate understanding of the relevant literature in the field and cite an appropriate range of literature sources? Is any significant work ignored? I don't know about significant omissions, appropriate range and adequate understanding because I rarely read in this field. One major problem is that the "Background" and "Discussion" sections are both really Literature Review, Both sections need to be combined and extensively revised to present a clear flow of ideas.	We corrected both sections and followed a clear flow of ideas in the background which include: a brief introduction of digital health and its necessity for contemporary modern world, the diffusion of digital health, role of startups and private companies in the digital health, challenges of digital health and telemedicine in Iranian health system and finally the digital health governance. In the discussion (and conclusion) we kept our distance from the merely literature review and inserted our understanding and perception as the implication for policy makers and health system research.

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3. Methodology: Is the paper's argument built on an appropriate base of theory, concepts or other ideas? Has the research or equivalent intellectual work on which the paper is based been well designed? Are the methods employed appropriate? 1. Theory or conceptual base appears absent. This appears to be a descriptive effort: "This study sought to shed light on the barriers and drivers of digital health in Iran." 2. The biggest problem is that there is no explicit linkage to governance structures and processes in the background section and it appears the main interest is in the "diffusion" issue. The research base is - as noted in previous response - a muddle. 3. Methodology is OK for the key informant interviews. However, the media analysis is not well described, e.g. what were the source materials?	It was a theory-based manuscript and the main hypothesis was that startups help to digital health governance. The release of applications will bypass government policy and reduce their resistance to digital transformation. We correct the sentence to: *"This study sought to explore the barriers and drivers of digital health based on the theory of digital health diffusion and governance in Iran."* Moreover, we organized the content based on the governance structure (government and/or startups) and governance process (diffusion). The source materials in the media analysis were newspaper or websites articles and published interviews with the experts of digital health, which is a secondary source.
4. Results: Are results presented clearly and analyzed appropriately? Do the conclusions adequately tie together the other elements of the paper? The results are what kept me interested. The quotations are very well selected and amply demonstrate the themes and sub-themes. 1. There are too many Barriers and these should be combined (e.g. 2 + 4; 1,6,7; 3+5) under broader themes - such as government capacity, freedom of information (transparency) and protection of ; privacy (data security); professional obligations and conflict of interest. 2. The media analysis almost reads like it should be a separate paper with just a reference to validation in the Results section.	Thank you so much for this piece of advice. We combined the barriers which are used to be eight and reach to five main barriers including: Government incapacity for digital health governance, Conflict of interest, Professional obligations for information transparency, Protection of patients' rights, Data security and privacy. That was exactly what we aimed to use media analysis as a triangulation approach to validate our result.
5. Implications for research, practice and/or society: Does the paper identify clearly any implications for research, practice and/or society? Does the paper bridge the gap between theory and practice? How can the research be used in practice (economic and commercial impact), in teaching, to influence public policy, in research (contributing to the body of knowledge)? What is the impact upon society (influencing public attitudes, affecting quality of life)? Are these implications consistent with the findings and conclusions of the paper? This is a big request for such a situation. The authors have done a reasonable job of identifying a complex problem in a very basic fashion.	We inserted governance perspective in the discussion section. Actually, we used the diffusion as an instrument for governance process, so our manuscript dealt with the digital health governance through the popular diffusion of digital technologies. We inserted contents on the implication of our study for policy makers and health system research.

1. As in the methodology section, the governance lens is not very focused in the Discussion section. The authors seem to go back and forth between diffusion and governance. 2. The implications probably deserve a separate paper. Maybe for this paper, the authors could suggest some priority governance actions based on their key informants' views.	
6. Quality of Communication: Does the paper clearly express its case, measured against the technical language of the fields and the expected knowledge of the journal's readership? Has attention been paid to the clarity of expression and readability, such as sentence structure, jargon use, acronyms, etc. Fairly hard to read with numerous problems in language usage, paragraph organization, flow of ideas. Next version needs a major edit by someone with greater proficiency in English.	We utilized a native English editor to correct the whole manuscript.

Reviewer: 2

Additional Questions:

1. Originality: Does the paper contain new and significant information adequate to justify publication? I believe the data collected and the findings of this study to be of value and interest to the global health community. Many countries around the world face similar challenges to those identified here. One aspect that this article does bring to light was how the COVID pandemic impacted attitudes and utilization of telemedicine in a country like Iran that had not yet developed the telemedicine legal/regulatory infrastructure and frameworks. Overall, I think the article provides a good snapshot of the current state of telemedicine development in Iran, and I found it to be educational and interesting.	Thanks for your helpful comments on our manuscripts.

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2. Relationship to Literature: Does the paper demonstrate an adequate understanding of the relevant literature in the field and cite an appropriate range of literature sources? Is any significant work ignored? I felt the paper should reference and discuss more of the previous research that has been done about telemedicine in Iran. While the authors reference the Al-Samarraie et al 2020 article on telemedicine in the Middle East, there are other examples that I found doing a simple search on Google Scholar that may be worth referencing, including a discussion of how this research adds to the work and findings that have already been made. 1- Salehahmadi, Z., & Hajialiasghari, F. (2013). Telemedicine in Iran: chances and challenges. World journal of plastic surgery, 2(1), 18. 2- Ahmadi, M., Meraji, M., & Mashoof, E. (2018). Evidence on telemedicine in Iran-systematic review. Journal of Paramedical Sciences & Rehabilitation, 7(1), 112-124. 3- Alizadeh, A., Mohammadi, A., Khademloo, M., & Hosaini, H. (2013). Survey of views of medical students on telemedicine methods developed in the Mazandaran university of medical sciences iran. Strides in Development of Medical Education, 10(2), 247-259. 4- Safi, S., Ahmadieh, H., Katibeh, M., Yaseri, M., Nikkhah, H., Karimi, S., ... & Kheiri, B. (2019). Modeling a telemedicine screening program for diabetic retinopathy in Iran and implementing a pilot project in Tehran suburb. Journal of Ophthalmology, 2019. 5- Taheri, M. S., Falahati, F., Radpour, A., Karimi, V., Sedaghat, A., & Karimi, M. A. (2020). Role of social media and telemedicine in diagnosis & management of COVID-19; An experience of the Iranian Society of Radiology. Archives of Iranian medicine, 23(4), 285. 6- Nobakht, S., Bagheri, S., ESMAEIL, M., & Shamsabadi, A. R. (2018). The feasibility of telemedicine technology implementation in the selected hospitals of Iran.	Thank you for sharing the valuable literature with us. We cited some studies, among ones you suggested, to the background section.

3. Methodology: Is the paper's argument built on an appropriate base of theory, concepts or other ideas? Has the research or equivalent intellectual work on which the paper is based been well designed? Are the methods employed appropriate? Based on my limited expertise, I felt that the qualitative methodological approach made sense and was appropriate for what the authors set out to do.	Thanks for your comments on our manuscripts.
4.Results: Are results presented clearly and analyzed appropriately? Do the conclusions adequately tie together the other elements of the paper? For the most part, yes...the results are presented clearly and organized and analyzed in a methodical way. 1. In some places, I think the English-language terminology used seems a little vague and unclear and could be improved, however. For example, the 4th barrier (listed on page 7) "Concern on possible complications of telemedicine" isn't very specific; it doesn't really tell the reader what this barrier is referencing. 2. Also, if space allows and if the content exists, I would have liked to have seen 1 or 2 more quotes/examples for barriers 4-8 (pp. 7-10).	We utilized a native English editor to correct the whole manuscript which we hope it helps to resolve the ambiguity. In the case of the 4th barrier, we eliminated it and merge it with the "conflict of interest" barrier. In addition, we combined the barriers which are used to be eight and reach to five main barriers including: Government incapacity for digital health governance, Conflict of interest, Professional obligations for information transparency, Protection of patients' rights, Data security and privacy. I have added three more quotes for the mentioned barriers.
5. Implications for research, practice and/or society: Does the paper identify clearly any implications for research, practice and/or society? Does the paper bridge the gap between theory and practice? How can the research be used in practice (economic and commercial impact), in teaching, to influence public policy, in research (contributing to the body of knowledge)? What is the impact upon society (influencing public attitudes, affecting quality of life)? Are these implications consistent with the findings and conclusions of the paper? The authors are pretty clear in highlighting areas where the government could make improvements and/or where government action is needed. I think it would be useful to add a comment on the authors' perceived limitations of the study as well as areas of future research that could build on the work the authors have done.	We have inserted the study limitations and recommended areas for future research to the conclusion section.

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6. Quality of Communication: Does the paper clearly express its case, measured against the technical language of the fields and the expected knowledge of the journal's readership? Has attention been paid to the clarity of expression and readability, such as sentence structure, jargon use, acronyms, etc.: 1. I feel the Background section needs to be revised significantly. The quality of the English in the background often makes the points confusing, and is certainly inferior to the quality of the English in the rest of the paper. 2. I think the background could also use some more definitions; for example, what are the full list of components of a well-functioning digital health governance system required to support telemedicine. 3. There is also confusion in a couple of places where the authors refer to three main categories of barriers, but then only seem to list two--governance and technical (e.g., p. 1, 12). If it's feasible, getting a professional English-language editor would be advisable.	We utilized a native English editor to correct the whole manuscript which we hope it helps to resolve the ambiguity. We have inserted contents on the components of a well-functioning digital health governance system to the background section. We corrected the sentence as below: *The main barriers to telemedicine spreading in Iran have been divided into five main categories including Government incapacity for digital health governance, Conflict of interest, Professional obligations for information transparency, Protection of patients' rights, Data security and privacy.*