

# Challenges of Implementation of Insurance Coverage Program for Infertility Services in Iran

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#### Abstract

**Background:** Population has long been known as the most important pillar of governments and societies. However, in recent years, the rate of infertility is increasing rapidly due to various reasons.

**Objectives:** This study aimed to identify the factors and challenges affecting the implementation of insurance coverage program for infertility services in Iran for the policymakers and implementers of the program. Accordingly, the correct implementation of this program provides the possibility for infertile couples to benefit from the services of this program.

**Methods:** This qualitative study was conducted in 2022. Purposive sampling was used for selecting a total of 20 Iranian scientific and executive experts of health system with work experience, especially in the field of infertility. The interviews were conducted in a semi-structured manner and analyzed using the content analysis method and MAXQDA 2020 software.

**Results:** The results showed that the challenges of this program include 6 main themes along with 39 sub-themes. The main themes are challenges of upstream laws and legal requirements; provision of health services; human resources; the service package and its pricing; financial issues, budgets, and methods of service cost reimbursement; and information technology challenges.

**Conclusion:** Although the service package is defined and announced, the implementation of this plan faces many challenges due to not taking into account the implementation conditions and requirements. By examining the problems of infertility insurance coverage, the present study provides a comprehensive and practical picture of these problems. Accordingly, the factors that can make the program successful in the future consist of inclusion of a part of the services related to infertility treatment in the package of insurance services, the awareness of managers and policy makers about the challenges of implementing this program, providing financial, electronic, and human resources needed by the program, and development and modification of standards of the program.

Keywords: Challenge, Health, Infertility, Insurance, Iran

## 1. Background

Population has long been known as the most important pillar of governments and the main pillar of societies, which has always been the focus of governments and policymakers (1) as it is an important and influential factor on various aspects of national authority and security (2). Today, the world is facing a challenge called population influx or negative population growth, which affects some parts of the world, including Iran. This negative growth and fertility below the replacement level, in other words, population decline, along with other factors, such as old age, will have wide political, economic, and social consequences(3).

In addition to the reduced desire to have children, in recent years, the rate of infertility is also increasing rapidly due to various reasons. This is one of the challenges of human societies, which has turned into a global epidemic and caused problems in many countries (4, 5) in a way that is estimated to affect one out of every four couples in developing countries. Although it is difficult to estimate it due to the inconsistent use of definitions and lack of standardization in population surveys, the prevalence of infertility has changed significantly in the last two decades (6). According to statistics, approximately 10-15% of couples are infertile (7).

In general, infertility is divided into two primary and secondary categories. Primary infertility refers to the inability to have children when a couple fails to have a child after one year of unprotected intercourse. However, in secondary infertility, a person has experienced fertility at least once, but currently cannot become pregnant again (8).

Due to different definitions of infertility, the rate of infertility has been reported differently in various national studies (9, 10). Based on the definition of total infertility, the prevalence of infertility in Iranian couples was reported at 20.3%

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with a confidence interval of 95% in the most recent report performed in Iran in 2018. Considering the population of married women between 15 and 49 years old is about 16 million people, it can be estimated that there are more than 3 million infertile couples in the country with primary and secondary infertility (11).

Increased age of marriage, especially in recent years, is one of the important factors of infertility in the country. This issue has led to an increase in the number of women seeking infertility treatment services over the age of 35.

In Iran, assisted reproductive methods have led to many advances in this field and opened new horizons for infertile couples (12). Infertility care delivery has improved dramatically in recent decades and has attracted increasing attention from healthcare providers. Several treatments, including expensive options, such as assisted reproductive techniques, are now widely available for clinical use. However, a significant number of couples are denied treatment or receive intermittent treatment due to economic problems. According to previous studies, about 30% of people have stated that financial problems prevent them from pursuing treatment. Therefore, to provide these services and finance them for all sections of the society is considered a major goal for all governments (13).

Based on the population policies of Iran and the budget law of the year 2021, the insurance coverage of infertility medical services was planned out by the board of ministers in order to provide financial support and increase the fertility rate and the satisfaction of people, facilitate and provide fair access to these services, and reduce out-of-pocket payment. However, the implementation of the instructions issued by the upper body and health system policymakers has faced different challenges.

## 2. Objectives

In this regard, the present study aimed to identify the challenges of implementing this service package in different areas and inform the policymakers to solve the problems. Accordingly, by solving the challenges, the problems of infertile couples to receive services will be solved.

## 3. Methods

This conventional content-analysis that is a qualitative study was conducted in 2022 with 20 Iranian scientific and executive experts, including policymakers and managers of the Ministry of Health and Medical Education, the secretariat of the Supreme Council of Health Insurance of the country, insurance organizations, universities of medical sciences, and service providers. Interviews were conducted to estimate the challenges. Purposive sampling was used to select participants in the study. The inclusion criteria were work experience in insurance organizations, the Ministry of Health, or affiliated hospitals in the fields of policymaking and financing management, payment systems and insurance packages as well as health services, especially in the field of infertility. Data were collected through semi-structured interviews. Before conduction of the interviews, the objectives of the study and the characteristics of the research team were explained to the study population and informed consent was obtained from them.

To conduct the interview, an interview guide was prepared using the supervision of experts and the research team based on the purpose of the study. Each interview was conducted by one interviewer in person using phone calls or via Skype, and no other person was present during the interview. Statements of the participants were recorded using a Sony icd-px33 voice recorder. During the interview, note-taking was also used to record data. Immediately after the end of each interview, the texts of the interviews were listened to several times, written down verbatim, and then typed until data saturation was reached.

Data analysis was performed in MAXQDA 2020 software using conventional content-analysis approach. Content analysis is a suitable method for obtaining valid and reliable results from textual data. For data analysis, the texts of the interviews were first read, and after obtaining a general impression of the interviews, the texts of the interviews were read word by word again to extract the codes from the interviews. After identification of the codes, the final analysis was carried out and the relationships between the codes and categories were determined.

According to Lincoln and Guba, the four criteria of credibility, conformability, transferability, and dependability were used to determine the trustworthiness of the data. The member check method was used for credibility. Moreover, conformability was made possible using the maximum variation sampling method and obtaining opinions of participants. In addition, transferability was made possible by describing all the research steps and assuring quality of data collection. Furthermore, reliability was provided through peer review. The agreement about the codes and revision of the texts of interviews were performed by the research team (peer check). Moreover, the method of reviewing the findings with the interviewees (member check) was also used. Finally, a list of problems and challenges of covering infertility services in Iran was prepared.

## 4. Results

In this study, a total of 20 experts were interviewed in three groups of health system

**Table 1.** Demographic characteristics of the study population

Demographic variables		Number
Gender	Male	12
	Female	8
Education	Ph.D., M.D.	14
	Master of Science degree	5
	Bachelor of Science degree	1
Place of work	Ministry of Health and Supreme Council of Health Insurance	7
	Insurance organization	9
	Service provider and University of Medical Sciences	4
Occupation	General manager and above	5
	Deputy general manager and head of department	12
	Service-providing doctor and expert	3
Work experience (years)	<10	1
	10-20	13
	>20	6
Total		20

policymakers, service providers and insurances, and service buyers. Most of the participants were women and had a doctorate degree. Demographic characteristics of the study participants are presented in Table 1. In order to analyze the data, first, the transcribed texts of the interviews were read word-by-word and the codes were extracted from the interviews. After identifying the codes, the final analysis was performed and the relationships between the codes were determined. In total, 512 codes were extracted from the interviews and the main challenges of implementing the program included 6 main themes and 39 sub-themes, which are summarized in Table 2.

# 4.1. Challenges of upstream laws and legal requirements

Based on the findings presented in Table 2, the most important challenges related to upstream laws and legal requirements included four sub-themes. In the field of the challenge of upstream laws, the participants believed that despite the usefulness of this plan, legislators and policymakers do not have a proper understanding of its implementation requirements, and the laws sometimes become an obstacle to the implementation of the plan.

In relation to this challenge, one of the participants stated: "The law to protect the youth of the population was actually drafted in general terms and was not based on evidence. For example, in the clause of the written law "support for infertile couples, including diagnosis, follow-up, examination, visit, and para-clinical services without limits" the word "without limits" has no meaning even in the most essential medical services and anywhere in the world. When we define limits for infertility services according to the clinical standards, the clause of the law will be violated." (p. 2)

Moreover, the participants believed that not enough time was spent on policymaking and legislation, the job was not performed by a group of experts, and the plan was not communicated comprehensively. For example, one of the participants in the study stated: "In the law to protect the youth of the population, it is stated that the Ministry of Health should form a committee, but no action was taken until October. From October, when the law to protect the youth of the population was promulgated, they quickly held meetings and instructions were written overnight. There were also challenges regarding the issues related to egg donation and surrogacy options according to the Sharia laws." (p. 5)

One of the participants in the study stated that: "Scholars and religious authorities were against the egg donation and surrogacy." (p.1)

Finally, the main challenge in this field was the many ambiguities that existed in the definition and implementation of the insurance coverage of infertility services. In this regard, one of the participants in the study said: "The tier that was communicated to us for infertility services did not specify what type of infertility services this tier should be spent on, whether infertility treatment insurance or full coverage of infertility services." (p.6).

#### 4.2. Challenges of health services provision

Based on the findings presented in Table 2, the most important challenges related to the provision of infertility services include the insufficient number of infertility treatment centers in the country, inappropriate distribution of infertility treatment centers, provision of licenses for the activity of infertility departments in hospitals, and provision of licenses to specialists who deliver infertility services. One of the most important challenges in the provision of infertility services is the insufficient number of infertility treatment centers in Iran, which was expressed in the words of one of the participants: "In general, the number of infertility treatment centers in the country is limited and this causes waiting lists, especially in the government and academic sectors." (p.19)

In addition to the insufficient number of infertility centers in Iran, these centers have an unbalanced distribution in the country. According to one of the participants in the study: "Infertility treatment centers are not well distributed in the country and should be adjusted according to the population or the average distance of the centers from the users." (p.20)

In order to legally provide infertility services, it is necessary for centers and specialists to obtain an activity license from the Ministry of Health. This challenge was expressed by some participants in the study: "Some general hospitals do not include the infertility section in their operation license, so it is practically impossible to sign a contract with insurance organizations." (p.5)

"Unfortunately, insurance companies do not allow all gynecologists to visit and diagnose infertile patients and only allow infertility consultants or experienced gynecologists to do this, which causes conflicts and problems for service providers." (p.1)

#### 4.3. Challenges of human resources

Based on the findings presented in Table 2, the

most important challenges related to human resources include the challenge of providing the necessary workforce in hospitals, specialized training of infertility services to clinical staff and lack of sufficient information about infertility services, increased workload of the insurance reimbursement unit in medical centers that do not have a contract with insurance organizations (miscellaneous claims units), and lack of knowledge of human resources of insurance organizations to handle service cost documents.

Moreover, in the field of human resources, infertility service centers face the challenge of providing the necessary human resources. One of the participants said: "To meet additional demand, more clinical and non-clinical personnel are needed. It is difficult to provide clinical workforce in short term, particularly specialists in the field of infertility, and

Table 2. Main themes and sub-themes of the challenges of implementing the infertility coverage program in the country

Themes of challenges	Sub-themes of challenges
	<ul> <li>Legislation regardless of executive requirements</li> </ul>
Upstream laws and	<ul> <li>Ambiguity in the definition of infertility insurance coverage</li> </ul>
legal requirements	<ul> <li>Ambiguity in the definition of budget credits</li> </ul>
	•Challenge of egg donation and surrogacy
	•Insufficient number of infertility treatment centers in the country
Health services	•Challenge of improper distribution of infertility treatment centers
delivery	•Challenge of the operation license of the infertility departments in hospitals
	•Challenge of provision of licenses for experts delivering infertility services
	•Challenge of provision of the necessary human resources in hospitals
	•Challenge of specialized training of infertility services to clinical staff
Human resources	•Increase in the workload of the reimbursement unit for the insured in medical centers that do not have a
	contract with insurance organizations (miscellaneous claims units).
	•Challenge of the lack of knowledge of the human resources of the insurance organizations regarding the cost
	documents of the provided services
	•Old standards and service delivery guidelines compiled by the Ministry of Health
	•Being uninsured and starring infertility services in the book of relative values •Lack of definition of a number of infertility services and service codes in the book of relative values
	•Lack of definition of a number of infertility services and service codes in the book of relative values •Challenge of missing some infertility services in the service package
Service package and	•Non-pricing of services in accordance with the conditions of the health services market
its pricing	•Length of the service delivery process and its lack of predictability according to the global definition
its pricing	•Challenge of missing some infertility service codes
	•Pricing challenge for consumables and medical equipment
	•Challenge of the low prices of medical services, compared to the cost of the provided services
	•Challenges of the pricing of medical services in private infertility centers
	Inadequacy of the announced budget for the number of infertile couples
	•Long-term reimbursement of the cost of infertility centers and the weak foundation of infertility centers in
Financial and	continuing to provide services under insurance coverage.
budgetary issues and	•Payment method of the cost documents of the insured people of all insurance organizations by Iranian
service	Health Insurance Organization
reimbursement	<ul> <li>The challenge of applying deductions by insurance organizations</li> </ul>
methods	<ul> <li>Lack of a clear policy in defining the appropriate payment system</li> </ul>
	•Challenge of developing a service package in most of the global payment methods
	<ul> <li>Change of the payment method from the global payment system to payment per service</li> </ul>
	•Failure to pay attention to the electronic technology requirements of the plan
	<ul> <li>Lack of proper infrastructure in the SEPAS system of the Ministry of Health</li> </ul>
	•Lack of coordination and connection between the systems of insurance organizations and the systems of the
	Ministry of Health
	•Absence of some electronic infrastructures for exchange and processing of cost documents for services
	provided to the insured
Information	•Challenge of definition of the coding of medical supplies and equipment
technology	•Impossibility of electronic monitoring of the patient in case of change of insurance organization
	•Challenge of lack of health information management system (HIS) with a valid certificate from the Ministry of
	Health in infertility centers
	<ul> <li>Challenge of lack of SIAM code in some infertility centers to exchange documents and cost information electronically</li> </ul>
	electronically •Lack of transparency in accepting documents electronically
	•Challenge of how to mark people as infertile patients

on the other hand, there is uncertainty regarding the continuation of this project, which increases the risk of recruitment. Also, before this, service fees were received from patients in cash, but after signing contracts with insurance organizations, medical centers need trained personnel regarding the preparation of insurance, legal and financial documents, and laws." (p.18)

Furthermore, there is the challenge of specialized training of infertility services to clinical staff. This challenge was mentioned by one of the participants: "Due to the fact that they do not have expert staff in this field, specialized training is needed for personnel, which is time-consuming and expensive. It costs a lot." (p.13)

In addition to service providers, insurance organizations are also facing the challenge of human resources. In order to implement this plan, it is needed to overcome the challenge of insufficient knowledge of human resources of insurance organizations to deal with financial documents of infertility services. This challenge was expressed by one of the participants in the study: "Considering that these infertility services are mostly specialized services that have not been covered by insurance organizations, we had little information about them." (p.17)

Moreover, the implementation of this plan caused an increase in the workload of the miscellaneous claims unit of insurance organizations, which is responsible for reimbursing the costs of insured people in medical centers that do not have a contract with insurance organizations. According to one of the participants: "At the beginning of the plan, the insurance organizations failed to sign contracts with many medical centers, so the patients themselves brought the cost documents to the insurance organizations, and therefore, the workload of reimbursement units increased. Also, despite the fact that the plan was announced in the middle of the year, the insured people who had received services at the beginning of the year were asked to bring their documents, and suddenly many documents were brought to the miscellaneous claims units of the insurance organizations." (p. 16)

## 4.4. Challenges of the service package and its pricing

Table 2 presents the most important challengesrelated to the service package and its pricing.

One of the challenges related to the service package is the outdated standards and guidelines that have been compiled, which should be revised based on the requirements and scientific findings of the day. In this regard, one of the participants said: "Considering that the infertility standards were all old, it was necessary to update these standards at first." (p. 3)

Moreover, the infertility services that are announced in the service package are mostly noninsured and starred in the book of relative values of health services. In this regard, one of the participants stated: "Considering that these services were starred in the book of relative values of health services, we were facing a lot of challenges to summarize the services that can be provided." (p.1)

In addition, a number of infertility services and service codes are not mentioned in the book of relative values, and insurance organizations are facing challenges to reimburse them. In this regard, one of the participants in the study stated: "A series of services in the book did not have relative code values, or it was necessary to define a new service code for it to be included in the package and the global payment system was not suitable for the implementation of this plan. We had to divide the service package into more detailed services and change the payment system to payment per service. However, a number of services in the book of relative values did not have a service code." (p.1)

Some other specialized infertility services, which are necessary for some patients, are not mentioned in the service package. In this regard, one of the participants in the study pointed out: "The anounced service package includes common services for infertile patients, but some patients, in addition to these services, receive very specialized and advanced services that are delivered in some super-specialized centers, and these services are not included in the service package." (p.1)

In addition to the challenges of the services in the anounced service package, there are challenges in service pricing. For example, the services provided in the service package are not priced according to the conditions of the healthcare market, and this creates some challenges for service delivery centers. One of the participants in the study mentioned: "Unfortunately, an accurate estimate of the price of consumables in the health market has not been made. Considering that the preferred currency has been removed, we do not have an accurate estimate of the price of the equipment." (p.3)

Another issue was that the pricing of medical services was relatively low, compared to the cost of the provided services. One of the participants in the study stated: "These prices do not cover the costs of the provided services, and we do not want to sign a contract in the form of these service packages with insurance organizations." (p.11)

This challenge was even greater in private sector infertility centers, since according to one of the participants in the study: "Infertility service prices were predicted for government and non-government centers and payments are made based on that, while services provided by the private sector cost more, they are paid based on the non-governmental public pricing." (p.18)

Furthermore, the pricing of medical equipment provided by infertility centers for patients had a price difference. In this regard, one of the participants believed: "The average price of medical equipment available in the market was used for the pricing in the insurance obligation. While medical centers claimed that there is no medical equipment with the minimum price announced in the market, and if it is available, it is not of the required quality." (p.10)

# 4.5. Financial and budgetary challenges and service reimbursement methods

Table 2 summarizes the most important challenges related to financial and budgetary issues and the method of service fee reimbursement. According to the findings, the inadequacy of the considered budget in relation to the target population makes the services of the mentioned plan inaccessible to some people. According to one of the participants: "Based on the reports in Iran, 15% of couples are infertile and the announced budget does not provide enough services for them." (p.13)

There are also challenges in accepting and reimbursing the infertility documents of all insured people in the country by the Iranian Health Insurance Organization. In this regard, one of the participants in the study said: "Initially, it was decided that the Iranian Health Insurance Organization would be given credit for the services provided to all insured individuals of all insurance organizations, but the method of accepting infertility documents from other insurance organizations has not been specified. Also, the method of handling and payment to these organizations has not been determined." (p.12)

Furthermore, the long-term reimbursement of the cost of infertility centers is a challenge for the continuation of their activities since these centers recieve weak financial support to continue to provide services in the form of insurance. One of the participants stated: "The process of accepting documents and processing them is usually delayed; as a result, the payment of the insurance organization is also delayed. In addition, payments are made to the university in government centers, and the university itself pays the centers in the form of the treasury's circulation and it is delayed too. This delay in payment causes the provider centers to have challenges for the provision of medicine and medical equipment and they don't want to sign a contract as they used to receive the cost of services in cash and in advance from the patients." (p.13)

Infertility centers are also facing the challenge of applying deductions by insurance organizations regarding the requested cost for infertility services provided for the insured patinets.

Lack of a clear policy regarding the definition of the appropriate reimbursement system for expenses is one of the other challenges. One of the participants in the study said: "At the beginning, it was suggested to globally define the services that were going to be provided for the patients. However, due to the diversity of the methods and services provided for patients with different characteristics and the price range of services, it was not possible to reach a single price. Therefore, the global payment method was not welcomed by service providers and insurance organizations." (p. 8)

Change of the payment method from the global payment system to payment per service also created a new challenge. This challenge was expressed by one of the participants in the study as follows: "The nonglobal payment method makes it more difficult to handle the payments and limits our monitoring. In addition, induced demand is another issue that will involve us in this payment method." (p. 2)

## 4.6. Information technology challenges

According to the findings presented in Table 2, one of the main challenges of information technology was not paying attention to the electronic technology requirements of the infertility services plan. This challenge was expressed by one of the participants in the study as follows: "Before the announcement of the plan, information technology requirements were not foreseen and currently there is no coordination between the systems of insurance organizations and the SEPAS system of the Ministry of Health. Also, there are no health information management system (HIS) software development companies." (p. 1)

Another challenge regarding information technology is the lack of proper infrastructure in SEPAS system as a reference for electronic health records. In this regard, one of the participants said: "There is no necessary infrastructure for the exchange of infertility documents, and this needs infrastructure appropriate changes; unfortunately, the development of SEPAS system is slow." (p. 4)

Another challenge is the lack of coordination and continuity between the systems of the insurance organizations and the systems of the Ministry of Health, which was mentioned by one of the participants in the study as follows: " Many changes are necessary to be made in the systems of the Health Insurance Organization and the Ministry of Health. It is also necessary that these systems are linked together in this regard, so that accurate information is recorded in the medical centers and sent to the insurance organizations to pay the costs." (p. 14)

In some infertility centers, there is no HIS with a valid certificate from the Ministry of Health. One of the participants said: "Major infertility centers, such as Royan and Academic Center for Education, Culture, and Research, were using a system that did not have the certificates approved by the Ministry of Health regarding the electronic health record. So, we will face a challenge for the electronic exchange of cost documents of the insured." (p. 17)

Besides, one of the participants stated: "Most of

the independent infertility service centers do not have the SIAM code from the Ministry of Health. It is necessary to have a valid SIAM code for the electronic exchange of documents. Centers with no active SIAM code do not have the possibility of exchanging documents electronically." (p. 18)

Another participants declared: "There is no electronic infrastructure in the social security and armed forces insurance organizations. Social security and the armed forces insurance organizations do not have a system for exchanging and processing medical documents, and practically paper files are exchanged between them." (p. 13)

Regarding the challenge of lack of transparency in accepting documents electronically, one of the participants said: "The infertility services may not be delivered in one center and be provided in different centers, such as doctor's office, pharmacy, independent para-clinical and infertility centers. The process of accepting documents has not yet been clearly defined in order to determine whether these documents are accepted through outpatient systems or through the inpatient systems of insurance organizations. Private centers do not have a SIAM code and cannot send documents through the electronic document exchange system. Therefore, they have to send their documents through the electronic system. Of course, the electronic version of the codes still does not exist in the form of global and separated codes." (p. 2)

Another challenge regarding information technology is how to mark an infertile patient in the system. In relation to this challenge, one of the participants in the study pointed out: "People who need infertility services should be marked in the relevant systems of insurance organizations. The social security and the armed forces organizations do not have an online system for marking the insured people, so they must go to their own organizations to be marked."(p. 15)

In addition to marking infertile patients, patients face problems in case of changing the insurance organization and changing the type of insurance. This challenge was stated by one of the participants in the study as follows: "It is impossible to monitor these patients due to the lack of a common system among all insurance organizations. If there is a change in the fund, it will not be possible to control the limit of approved medical services." (p. 14)

In addition to the above-mentioned points related to the information technology challenges, there is the issue of service coding, especially in the field of medical equipment. According to one of the participants in the study: "Now, we have identified about 30 or 40 items of medical equipment and made a commitment to upload their code in the medical equipment system so that we can control the price of the equipment. We should also be able to control the authenticity of medicine and supplies in this way." (p. 17)

## 5. Discussion

The findings showed that the implementation of the insurance coverage plan for infertility services has faced some challenges. The most important challenges in the field of upstream laws and legal requirements were the provision of health services, human resources, service packages and prices, financial and budget issues, service reimbursement methods, and information technology challenges.

One of the issues in the implementation of the insurance coverage plan for infertility services is the challenges of the upstream laws and legal requirements, which seem to be a challenge in all areas of the country and the health system, such as the disease care system (14), goals, stewardship, and the governance of the family physician program and the urban (15) and rural (16) referral system, health services pricing (17), and the issue of telemedicine (18).

A study performed by Mehr Al-Hassani also showed that weakness in the comprehensiveness and implementation of guidelines was one of the challenges of implementing the family physician policy in Kerman province, Iran (19). Therefore, the challenges found in this study indicate that the formulation and design of a policy require a comprehensive review in various dimensions, such as the structure or context of the problem, the content of the policy, the policy implementation process, and the involved stakeholders. If the desired policy is formulated with various involved factors in mind, it will definitely be associated with successful results. Therefore, there are challenges related to upstream laws and legal requirements in the implementation of existing plans in the Iranian health system, including the infertility insurance coverage plan.

Crosignani et al. in 2015 emphasized that if infertility management becomes an integral part of the healthcare system with public or private funding, in order to achieve the goals, the policy makers should first, have a vision about how to deliver services and the quality of services as well as a deeper and evidence-based economic analysis in the field of infertility treatment (20). This is because laws and regulations, like strong levers, play an important role in regulating the structures and relationships that improve the quality of healthcae services (21). It is suggested that in the field of compliance with upstream laws and regulations and facilitating the implementation, the infertility insurance coverage plan in Iran be re-examined carefully to have a higher enforceability after removal of the weak points.

Another issue in the implementation of the insurance coverage plan for infertility services is the challenges related to the provision of infertility services. These challenges include the insufficient number of infertility treatment centers in the country, inappropriate distribution of infertility treatment centers, certifying licenses for the infertility department in hospitals, and certifying licenses to specialists who provide infertility services. In a study conducted by Shaerbafchizadeh, one of the challenges of the cross-border supply of health services in the Iranian health system was the lack of diagnosis and treatment centers with international accreditation (18). A study performed by Demari also showed that providing health services is one of the challenges of the family physician program and urban referral system (15).

Therefore, increasing the establishment of infertility centers in academic and tertiary centers and deprived areas and their proportional distribution in the country can increase their accessibility, reduce direct non-medical costs, and ultimately increase health justice. Supplying specialized human resources in infertility service centers and insurance organizations is also one of the challenges of implementing the insurance coverage program for infertility services in the country. The provision of infertility services, like other health system services, is highly dependent on human resources since human resources are the most important input of the health system. Moreover, the implementation of a policy or executive plan requires examining all resources, especially human resources, in the short, medium, and long term (22). A study carried out by Mir also showed that although the number of specialized human resources in the field of health has been increasing in recent years, the distribution of specialized human resources does not follow the scientific and efficient model in the field of health (23).

Various studies have highlighted the impact of lack of human resources on the implementation of hospital accreditation standards (24),the implementation of family physician program and the urban referral system (15), and establishment of clinical governance program (25). In addition, a study by Jafari Pouyan et al. showed that the lack of presence, the small number of insurance representatives and hospital revenue personnel, the lack of timely delivery, and incomplete delivery of hospital files are among the challenges of hospitals and insurances. Based on the findings of the aforementioned research, these challenges require provision of a large number of documents by the clinical staff that imposes a large financial burden on the hospitals in order to provide documentation (26). It is suggested that during the formulation of national policies and programs, the required manpower and how to provide it be clearly defined.

The old standards and guidelines for the provision of infertility services, lack of insurance coverage for the infertility services, lack of some infertility services in the service package, and lack of pricing of services according to the conditions of the health services market are among the most important challenges of the infertility service package and its pricing. Shirjang et al. in their study showed that covering some services regardless of stratification and lack of restrictions is one of the challenges of the rural family physician program (16). Demari et al. in their study also showed that one of the challenges of implementing the urban family program and the referral system in Fars and Mazandaran provinces in Iran was that the service packages were not designed according to the position of all medical and specialized groups. Moreover, they found that the lack of approved guidelines for management of common issues and diseases are among the problems of the program (15).

Furthermore, in most of the countries that support infertility treatment, there are limitations on the frequency of providing the services and the age of the clients. The findings of this study are in line with those of Morshed Behbahani in this regard (27). Results of a study performed by Jafari Pouyan et al. showed that lack of realistic pricing is one of the challenges of private hospitals and insurance companies. In addition, the number and cost limits in the bills are among the challenges of hospitals and insurance organizations (26). Therefore, redefining the service package in order to create a unified approach and unite the service package and obligations of the insurance organizations will solve many challenges of the insurance organizations and improve the quality and quantity of the health insurance system in Iran (28). It is suggested that repricing should be done after calculating the cost of infertility services and obtaining advice from experts in this field. Moreover, existing standards and guidelines should be modified and rewritten according to the actual situation.

The most important challenges related to financial budgetary issues and the method of and reimbursement of the cost of services include the inadequacy of the anounced budget for the number of infertile couples, system of reimbursement of documents for the patients insured by insurance organizations, and the weak financial support of infertility centers regarding provision of services under insurance coverage. Inadequacy of the considered budget in relation to the target population causes some people to not have access to the services of the mentioned plan. Studies have shown that limited public budget, provision of financial resources to provide the necessary infrastructure, weakness in per capita adequacy and its allocation, and payment system are among the challenges of implementation of clinical guidelines (29), establishment of a clinical governance program (25), and implementation of the family physician policy in the studied province (19).

In addition, a study conducted by Jafari Pouyan et al. showed that hospital deductions and failure to pay money on time by insurance organizations are among the main challenges between hospitals and insurance organizations (26). Therefore, the long period of collection of claims causes disturbances in the financial payment of the centers and as a result, has a negative effect on the method of providing services (30). It is suggested to calculate and allocate sustainable financial resources according to the number of infertile couples in the annual budget.

The most important challenges related to information technology include lack of anticipation and attention to the electronic technology requirements in the systems of the Ministry of Health, insurance organizations, and centers providing infertility services to record patient information and services provided and also exchange and process cost documents for those services electronically. In a study by Shaerbafchizadeh, it was also stated that according to experts, the speed of development of information and communication technology in the country is slower, compared to many other countries (18). Results of a study by Nasiripour et al. indicated that the electronic health strategy in Iran lack necessary requirements and the information technology authorities and policymakers of the country are not exactly known and different institutions in the country approve related documents separately (31).

Defects in the communication infrastructure of the country are among the disadvantages of electronic health development (32) and a study carried out by Mehrolhassani showed that the weakness of the health information management system is one of the challenges of implementing the family physician policy in Kerman province, Iran (19). Recording infertility data in Iran has never had a trustee and it has not been performed systematically. By announcing the support package for infertility treatment, insurance organizations have registered this information in the systems to manage the coverage of infertile couples and target the clinical data. This approach is in line with the study performed by Rosenfield regarding infertility data registry that is inevitable for a healthcare system (33). In this regard, it is suggested that a comprehensive and reliable system be added to the existing electronic systems in the health system for registering infertility data and services, and the health system trustees design the required information systems according to the local and indigenous conditions in Iran.

One of the limitations of the current study was the newness of the insurance coverage plan for infertility services in Iran. This limitation made it difficult to find related studies performed on these services. Therefore, other plans implemented in the country, such as the family physician program, were used for comparison. Moreover, considering that the study was conducted during the outbreak of COVID-19 in the country, face-to-face interviews were not possible for all participants; hence, so some interviews were conducted by phone or through Skype software.

## 6. Conclusion

Findings of this study revealed the most important challenges of implementing the insurance coverage program for infertility services in Iran. As shown by the findings of the present study, due to the high costs of infertility treatment, complexity of the treatment, risk of success, and importance of having children to reduce the effects of population-aging crisis, it is necessary to include some of the infertility treatment services in the basic health insurance services package. The awareness of managers and policymakers of the health system about the challenges of implementing this program can be the first step to improve the insurance coverage program for infertility services. Providing the financial, electronic and human resources needed by the program and developing and modifying standards of the program can make the program successful in the future.

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## Footnotes

**Conflicts of Interest:** The authors declare that they have no conflicts of interest.

**Author Contribution:** Concept and study design: M.K., M.A., and K.A.M.Data collection: F.H. and M.K.

Analysis: H.A. and M.K.Writing the article: H.S.P., M.A., and F.H.Critical revision of the article: K.A.M. and P.K.Statistical analysis: H.A., M.K., and P.K.Final approval of the article: F.H. and M.K.

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