

Hepatitis B vaccination in Iran: Historical policies and programs

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Keywords

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Summary

Hepatitis B virus (HBV) infection is a main challenge of the health system worldwide. Health policymakers in most countries attempt to help HBV patients by implementing support programs in addition to controlling HBV in their community so that the economic burden caused by HBV do not deprive the patients of accessing health services and reducing their quality of life. There are several health interventions for the prevention and control of HBV. Providing the first dose of the HBV vaccine within 24 hours after the infant is born is the most cost-effective way to prevent and control HBV. The purpose of this study is to review the nature of HBV, its epidemiology in Iran and worldwide, and to review the various policies and programs in Iran regarding the prevention and control of HBV, especially the use of vaccination. One of the goals of Sustainable Development Goals (SDGs) is to consider hepatitis as a threat to human health. In this regard, one of the top priorities of WHO is the prevention and control of HBV. In connection with the prevention of HBV, it is claimed that vaccination is the most effective and best intervention. Thus, vaccination in the

safe's program of countries is highly recommended. According to the Ministry of Health and Medical Education (MOHME) reports, Iran has the lowest prevalence of HBV among the countries in Eastern Mediterranean Region Organization (EMRO). There is a hepatitis unit in MOHME whose responsibility is to coordinate and implement the hepatitis prevention and control programs. The HBV vaccine has been officially included in the vaccination program for children in Iran since 1993, and three doses of the vaccine are given to all infants. In 2007, during a large-scale program in Iran, 17-year-olds received the HBV vaccine, followed by adolescents born in 1990 and 1991. In recent years, the health system in Iran has made significant progress in preventing and controlling HBV. Over 95% coverage of the HBV vaccination is one of the achievements that have had a great impact on reducing the trend of HBV infection. In order to achieve the 2030 goals, the Iranian government, in addition to paying more attention to HBV elimination programs, should encourage other organizations to cooperate more effectively with MOHME.

Introduction

Hepatitis B virus (HBV) is a liver disease that can occur in both acute and chronic forms. Acute hepatitis refers to cases in which the virus takes less than 6 months from onset to recovery, during which time the infection is completely removed and the virus clears from the blood [1]. In this case, the structure and function of the liver remains normal, and usually the patient does not need any treatment except in special cases. On the other hand, in chronic hepatitis the virus stays in the body for more than 6 months, and the body's immune system is unable to kill the virus. Using contaminated syringes, unsafe sex, mother-to-child transmission, contacting with contaminated needles or equipment in hospital settings, and organ transplants are methods of disease transmission [2].

The World Health Organization (WHO) 2021 Report

states that approximately 296 (Uncertainly interval (UI) 95%: 228 to 423) million people worldwide have already been infected with HBV; however, this report underscores the very important point that health policymakers should pay special attention to this serious challenge [3]. According to the 2021 Report, the highest rate of HBV infection based on the WHO region is in the Western Pacific, African, and South-East Asia (Fig. 1) [3]. Compared with WHO 2017 Report [approximately 257 (UI 95%: 199 to 368) million people worldwide were infected with HBV], the number of people infected with HBV has increased. This increase is worrying, warning countries to adopt more coherent policies and programs in order to combat HBV. HBV and hepatitis C virus (HCV) can cause chronic diseases in infected people, and if these people do not receive appropriate health services, it can lead to liver cirrhosis, a malignant disease that is likely to cause death [4].

Fig. 1. Prevalence of HBV infection in general population by WHO region (Global progress report on HIV, viral hepatitis and sexually transmitted infections, 2021).



Mother-to-child transmission of hepatitis B continues to be a major mode of transmission [5]. Other reasons for the increase of HBV worldwide are: Increasing costs of care and medical services, lack of proper political interactions, lack of information and strategic surveys, lack of a meticulous action plan, and shortage and cost of diagnosis [6].

Meanwhile, HBV and HCV are among the most common causes of cancer and mortality worldwide [7]. Due to the nature of HBV and the highly likelihood of causing severe complications in infected patients, HBV can place a great economic burden on patients and their family. Alongside, health systems pay large sums for HBV annually [8].

There are several health interventions for the prevention and control of HBV. Vaccination is one of the most important interventions that can provide the 98–100% protection. Implementing blood safety strategies is another valuable intervention, which means that all donated blood and blood components used to transfuse blood to patients need to be carefully screened [9]. Another important intervention in the prevention and control of HBV is to educate and raise the level of awareness of all people in the community about the transmission and prevention of HBV. In this regard, syringes and condoms should also be readily available to anyone in the community, especially those with high-risk behaviors. Screening mothers before pregnancy, and creating a safe environment for tattoos and piercings are other health interventions in preventing and controlling HBV [10].

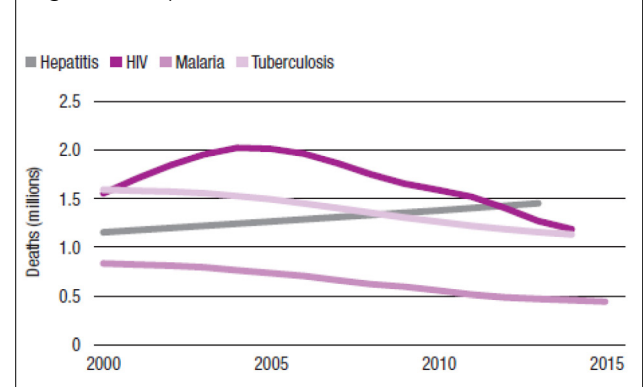
Hepatitis B virus (HBV) infection is one of the main challenges of the health system worldwide, where a large number of people die every year due to the complications of this disease [11]. Health policymakers in most countries attempt to help HBV patients by implementing support programs in addition to controlling HBV in their community so that the economic burden caused by HBV

do not deprive the patients of accessing health services and reducing their quality of life [12]. Reducing prices and making services available to patients, increasing insurance support, and reducing out-of-pocket (OOP) payments are some of the main patient support policies [13]. The purpose of this study is to review the nature of HBV, its epidemiology in Iran and worldwide, and to review the various policies and programs in Iran regarding the prevention and control of HBV, especially the use of vaccination.

Hepatitis and Sustainable Development Goals

The Millennium Development Goals (MDGs) were to focus on HIV, malaria, and tuberculosis; and with the efforts of many countries, the incidence and mortality of these diseases were reduced [14]. However, the mortality of HBV has been on the rise since 2000 [15]. Figure 2 compares the mortality rates of HBV, HIV, malaria, and tuberculosis [16].

Fig. 2. Mortality rate between 2000 and 2015.



In September 2015, world leaders agreed to set on a path toward Sustainable Development Goals (SDGs) by approving the 2030 Agenda [17]. The agenda, which contains 17 goals and 169 targets, envisages quantitative operational goals in the social, economic, and environmental domains of sustainable development that must be achieved by 2030 [18]. One of the goals of SDGs is to consider hepatitis as a threat to human health. In this regard, the following two targets should be achieved by 2030 [10]:

- *90% reduction in new cases of chronic HBV and HCV infections by 2030;*
- *65% reduction in HBV and HCV deaths by 2030;*
- Therefore, in order to achieve the 2030 goals, the coverage of some HBV- and HCV-related services should also be change, some of which are as below:
- *90% coverage of HBV vaccination by 2030;*
- *90% coverage of prevention of mother-to-child transmission of HBV by 2030;*
- *100% of blood donations screened in a quality-assured manner by 2030;*
- *90% of injections administered with safety-engineered devices in and out of the health system by 2030;*
- *300 sterile needles and syringes provided annually per person who injects drugs by 2030;*
- *90% of chronic viral hepatitis B and C infections diagnosed by 2030.*

The purpose of determining HBV controlling programs is to plan for reducing the incidence, mortality rate, complications, and transmission of HBV and HCV [19]. The implementation of these policies requires high political commitment, resource mobilization, and the advocacy of policymakers [20].

The Center for Disease Analysis (CDA) and the Center for Disease Analysis Foundation (CDAF) evaluate countries' performance on hepatitis B and C in their programs. According to these organizations, Australia, Austria, Egypt, and Georgia were successful in achieving the 2030 goals [21].

Despite ubiquitous efforts to achieve the 2030 goals, it seems that some countries are not yet on the track toward achieving these goals [22]. In order to achieve the 2030 goals regarding viral hepatitis, awareness of these infections should first be increased. In terms of the political commitment to achieving the 2030 goals, governments need to use all their resources, especially for diagnostic, screening, and treatment services, which require extensive financial resources to be provided to the health system. Having an action plan based on demographic, cultural, social, political, and economic characteristics that are based on valid data will be also effective [17].

The Iraninan healthcare system

The Ministry of Health and Medical Education (MOHME), as the main custodian of health in Iran, has the responsibility for taking care of public health [23]. At

the macro level, the ministry prioritizes some services by adopting policies and programs based on the country's health problems. Also, the centers for disease control (CDC) in Iran is responsible for planning and controlling diseases [20]. In all provinces of the country, medical universities also play the main role in implementing health policies and programs at the regional level [23].

Epidemiology of HBV infection in Iran

According to MOHME reports, Iran has the lowest prevalence of HBV among the countries in Eastern Mediterranean Region Organization (EMRO). The MOHME estimates the prevalence of HBV in Iran at less than 1%. Also, it is estimated that about 1.4 million people are infected with HBV in Iran, many of whom are not aware of their infection with this disease [24]. In this regard, Rezaei et al. (2020) conducted a small-scale meta-analysis study in order to assess the HBV prevalence in Iran between 2000 and 2016. The findings of their study showed that the prevalence of HBV decreased from 3.02% in 2000 to 1.09% in 2016 [25]. To the best of our knowledge, however, no large-scale study in the general population of Iran has ever been conducted in order to assess the status of HBV in the country.

HBV surveillance system in Iran

There is a hepatitis unit in MOHME whose responsibility is to coordinate and implement the hepatitis prevention and control programs. Screening is provided to diagnose patients in public and private health-care centers. Also, all insurance companies in Iran cover these services; thus, OOP payments have declined in recent years [12]. Due to the limited financial resources of the MOHME, free and universal diagnostic tests are not available to everyone in the community [20]. Meanwhile, the National Committee for Hepatitis in the MOHME is responsible for all hepatitis programs, their annual evaluation, preparation of guidelines, and coordination with other health-related departments in the fight against hepatitis [26].

Also, there is a monitoring and reporting system throughout the country. All public and private laboratories are required to report the latest patient cases to CDCs in the cities, which is eventually is reported to MOHME [26]. One of the most important and valuable parts of the health system in Iran is the primary health-care (PHC) network that exists even in small villages [27]. This network has played a significant role in improving health indicators in recent decades; some of its achievements are: reducing infant and maternal mortality, increasing access to health services, and increasing life expectancy [27]. In connection with hepatitis programs, the network runs training programs annually in order to raise awareness about HBV; in parallel, the network is undoubtedly the most important player in the field of immunization through the HBV vaccination [28].

HBV vaccination

One of the top priorities of WHO is the prevention and control of HBV; in this regard, various programs and policies are introduced by this organization to be on the agenda of policymakers worldwide [29]. Along the same line, various hepatitis B training programs have been set up around the world in order to raise public awareness [30].

There is no treatment for acute hepatitis B. Thus, a safe and effective vaccine can play a very important role in preventing HBV, which is also a cost-effective prevention policy. Meanwhile, the implementation of this policy might motivate policymakers to continue to support HBV vaccination [22].

Providing the first dose of HBV vaccine within the 24 hours after the infant is born is the most cost-effective way to prevent and control HBV. By adopting this policy, protection is thus created for other groups in the general population that also reduces the incidence of chronic HBV [31].

HBV vaccination in Iran

The HBV vaccine has been officially included in the vaccination program for children in Iran since 1993, and three doses of the vaccine are given to all infants. In 2007, during a large-scale program in Iran, 17-year-olds received the HBV vaccine, followed by adolescents born in 1990 and 1991 [28]. Since 1993, with the inclusion of the HBV vaccine into the immunization program in Iran, various groups have received the vaccine.

The data shows that various countries have made great strides in preventing HBV through vaccine immunization. Figure 3 compares the coverage of the third dose of HBV vaccine between the geographical region of WHO and Iran.

The trend in Figure 2 demonstrates that HBV vaccination coverage has been very high in Iran. According to

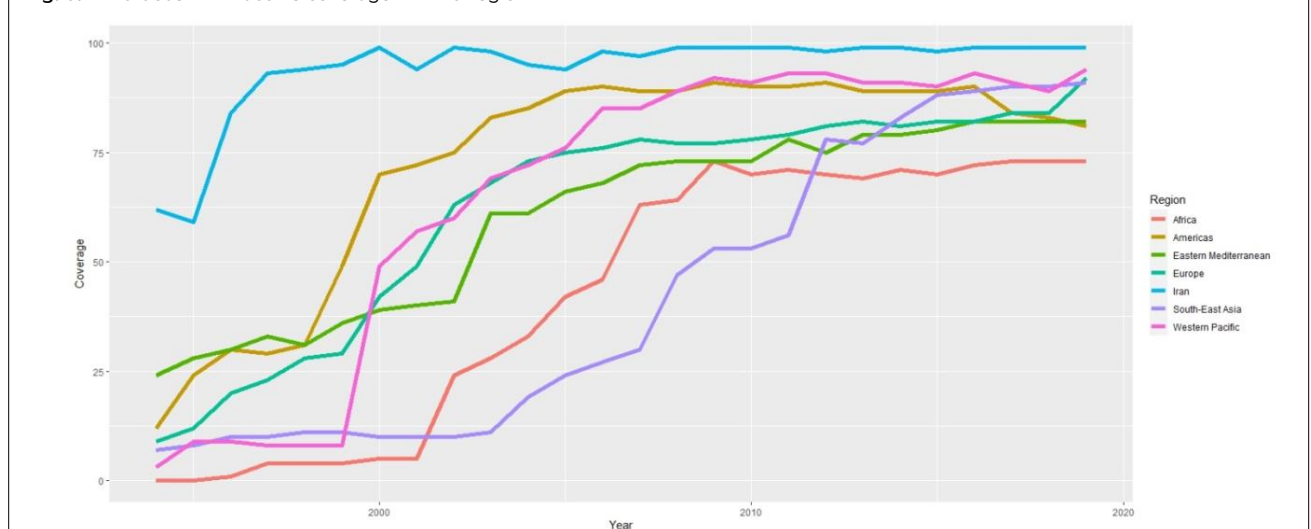
MOHME reports, with the implementation of various policies and, most importantly, the high percentage of vaccination coverage, a decrease is observed in the cases of HBV infection in Iran.

Challenges of HBV immunization program in Iran

Although health policymakers in Iran hope to make the HBV immunization program as effective as possible, there are still some issues that need to be addressed. After the COVID-19 pandemic, most health-related programs in Iran, like other countries, have been suspended. Alongside, care and screening programs in connection with the HBV prevention and control programs have been decreased. Also, some families were reluctant to visit health centers for HBV vaccination because they were afraid of being infected with COVID-19. Due to the pandemic and a higher number of patients visiting health centers, the routine activities that health professionals were to take care have unprecedentedly increased in these centers; therefore, the quality of services related to HBV programs has been reduced.

Meanwhile, Iran's being under crippling sanctions in recent years caused MOHME to face serious problems in importing laboratory equipment, drugs, and WHO-approved rapid hepatitis virus kits. Also, sanctions reduce Iran's economic revenues, affecting negatively the financial resources allocated to the health sector. Another issue influencing the HBV programs is the population dispersion in Iran; the health sector due to lack of sufficient health professionals could not provide services to all residents appropriately. In this regard, the refugee population in Iran, mainly from Afghanistan and Iraq, has also increased marginalization. Due to insufficient financial resources available from international organizations, the refugees face serious problems accessing all services, including the HBV vaccine.

Fig. 3. Third dose HBV vaccine coverage in WHO region.



Tab. 1. List of all the groups that received HBV vaccine in Iran.

No	Group
1	All infants
2	People who are exposed to have occupational exposure to blood
3	People who have been hospitalized and cared for a long time in certain institutions due to their disability and special medical problems
4	Patients with chronic liver disease and people infected with HCV
5	Hemodialysis patients
6	Frequent recipients of blood or blood products
7	Users of injecting drugs
8	People with high-risk sexual behaviors, especially those with a history of sexually transmitted diseases
9	Prisoners with a history of high-risk behaviors and a stay of more than 6 months in jail
10	Municipal sweepers, firefighters, emergency workers, prison guards, forensic experts, and crime scene experts
11	People who are candidates for organ transplants
12	Health-care workers
13	People with HIV infection
14	Families of patients with HBV
15	Residents of homeless shelters
16	Patients with hemophilia and thalassemia

Many of these refugees may be unaware of their infection with HBV. Due to the financial problems of the health system in Iran, the diagnostic, prevention, and control services are not provided for all patients, which can lead to a failure in achieving the 2030 goals. Accessing to health services for the vulnerable refugee population is important, and in line with the international community's call for the elimination of viral hepatitis, countries need political and health strategies in order to combat this infection.

Iran has implemented extensive programs to prevent and control HBV that seems to have made good progress, given its priority in widespread vaccination, especially at birth. The use of skilled professionals, the provision of vaccines, improving the safety of blood and blood products, as well as the establishment of harm reduction centers in all provinces are other successes that can be a good example for other countries. However, serious issues in the nuclear Iran deal have affected Iran's economic activities that have led to a devastating effect on plans to eliminate viral hepatitis by 2030 due to financial issues. Also, to produce the vaccine inside the country, companies need raw materials, and the Blood Transfusion Organization of Iran uses imported kits for hepatitis screening. In addition, due to Iran sanction and the refusal of foreign companies to have financial transactions, Iran has suffered from hepatitis B immunoglobulin. We believe that these restrictions can affect the goals of eliminating viral hepatitis in Iran, as well as international programs.

Meanwhile, the weak hepatitis registration and reporting systems have deprived MOHME away from receiving comprehensive information. Another issue is the fact that several small urban areas in Iran cannot afford to have a diagnostic laboratory; and thus, the residents of such areas can not have access to the HBV services. In addition, many organizations that are involved with high-risk groups in the community do not have proper

cooperation with MOHME in implementing the HBV prevention and control program; thus, MOHME alone is not able to cover all the services. Although MOHME has been working with insurance companies to reduce the cost of diagnosing HBV, its costs are still high for many, making them unable to use diagnostic services. The final issue we want to mention here is that achieving the goals of SDGs has been only acknowledged as a political commitment, and because of insufficient financial resources it has never been top on the agenda of policymakers in Iran.

Conclusion

In recent years, the health system in Iran has made significant progress in preventing and controlling HBV. Over 95% coverage of the HBV vaccination is one of such achievements that have had a great impact on reducing the trend of HBV infection. In parallel with efforts to provide a high coverage of vaccination in Iran, and paying attention to at-risk groups, lack of financial resources, lack of sufficient health professionals, international sanctions, and lack of sufficient attention from top policymakers are the major challenges in implementing HBV-related programs. In order to achieve the 2030 goals, the Iranian government, in addition to paying more attention to HBV elimination programs, should encourage other organizations to cooperate more effectively with MOHME.

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Ethics approval

The study was reviewed and approved by the Ethics Committee of the School of Health Management and Information Sciences, Iran University of Medical Sciences.

Conflict of interest statement

The authors declare no conflict of interest.

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