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Comparative Study of AEFI of Hepatitis B Vaccine between Iran Ministry of Health CDC and VAERS Data during 2015 to 2017

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ABSTRACT

Introduction: Hepatitis B Vaccine (HBV) is a safe and effective vaccine that is nowadays recommended for all infants at birth as well as adults who could be exposed to hepatitis B virus. HBV can provide lifetime protection against hepatitis B virus infection. Despite its highly effective disease prevention, HBV can also cause adverse effects for the vaccinated population. A vast majority of Iran's population are vaccinated with recombinant hepatitis B vaccine (rHBV) which is manufactured by the Production and Research Complex of Pasteur Institute of Iran. **Methods:** The reported adverse events of rHBV, obtained from Diseases Management Center of Iran's Ministry of Health were compared with those in The Vaccine Adverse Event Reporting System (VAERS, a United States program for vaccine safety, co-managed by the U.S. Centers for Disease Control and Prevention) during 2015 to 2017. **Results:** The most common adverse events after administration of rHBV, manufactured by Pasteur Institute of Iran was injection site reactions and no life threatening adverse event was observed. **Conclusion:** Despite reports by VAERS indicating that HBV can cause adverse events and even death in the United States, no such adverse effects were observed in rHBV manufactured in Iran.

Citation:

INTRODUCTION

Pharmacovigilance is a set of activities including diagnosis, assessment, prevention and announcements, related to adverse events and effects caused by using drugs or drug-related problems [1]. Pharmacovigilance helps to understand different aspects related to a drug, including its public safety monitoring and aftermarket adverse events, risk/benefit assessments and issues. It also helps to increase the awareness of the medical society regarding drugs adverse events to identify signals that could be used to alert the public, as soon as possible [2]. Pharmacovigilance signals are defined as data that are observed from a source which illustrates a potentially novel causal association or a new aspect of a known association, between an intervention and an event or a set of related events, either unpleasant or favorable, to which clinical or public awareness have been sensitized. These signals are judged to have enough probability to convince their validation or in some cases, to require remedial procedures [2-4]. For instance, Thalidomide was a drug marketed for nausea in pregnant women initially during 1950s in West Germany and while it seemed to be safe during pregnancy at first, it led to birth defects of embryos such as malformation in the limbs and problems with eyes and urinary tracts in those who survived. As society and clinical staff reported the adverse events of thalidomide, it was eventually recalled in 1961; although during its usage it had already caused a tragedy of thousands of neonate's death and malformations. This tragedy revealed that improvements in drug safety and regulations should be considered as a major global concern [5].

Since many vaccines are mandatory for global immunization, many Adverse Event Following Immunization (AEFI) may occur, after their administration. By definition, an AEFI is an unpleasant clinical incidence which is revealed after an immunization. The adverse event may be any unexpected sign, irregular laboratory result, symptom or disease. Although in some cases adverse events are shown quickly, in some cases delayed adverse events may develop related to a medicine or clinical procedure [6]. Hence, follow-ups in such cases should be patiently applied for a longer period of time and any irregular sign after administration of a new medicine should be reported.

Hepatitis B is one of the most important contagious viruses which leads to acute and chronic liver diseases both in the USA and worldwide [7]. It is estimated that 350 million individuals are living with chronic HBV infection worldwide with a major mortality rate related to chronic hepatitis, cirrhosis, and hepatocellular carcinoma. The prevalence of HBV infection varies significantly in different areas. Recently, Iran is considered as a low endemic area for HBV infection due

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to the main role of national vaccination program and public education about the related risk factors [8]. In order to prevent the life-threatening effects of hepatitis B infection, recombinant hepatitis B vaccines (rHBV) have been developed [7]. Hepatitis B vaccines have been approved since 1982 [9, 10] and the medical and scientific communities have generally accepted rHBV as a safe since it is a highly purified, single antigen vaccine, designed by high-tech genetic engineering [7]. Normal schedule of rHBV administration is based on injection in three separate doses (each containing 20 µg of HbsAg) at months 0, 1 and 6 after the first injection [11].Similar to other medicines and vaccines, wide varieties of adverse events have been reported worldwide after immunization with rHBV. These adverse events include irritation at the injection sites, as well as issues with gastrointestinal and neurological causes [12].

This study aims to evaluate adverse events that are reported after immunization with HBV in Iran and compare it with similar data related to the United States during 2015 till 2017 as documented by The Vaccine Adverse Event Reporting System (VAERS) database and with a few other nations. VAERS is a post marketing surveillance program that is co-managed by the US Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) .The raw data of vaccine adverse events are reported through VAERS website for global access [13]. VAERS accepts reports from vaccine providers, vaccine recipients, clinical staff and other related sources. After being reported, the signs and symptoms of adverse events, as well as physicians diagnosesare coded using the Medical Dictionary for Regulatory Activities [14]. VAERS generally cannot assess causality of an adverse event after vaccination; however, it may be useful to discover signals of potential vaccine safety concerns. Serious adverse events such as intussusceptions are more common to be reported [15-18]. Iran is among the countries that produce rHBV. Pasteur Institute of Iran is a high-tech research, production and education center that has been responsible for production of rHBV since 2007. Similar to other countries, Iran monitors adverse events following the immunization of rHBV which are reported by physicians , pharmacists and nurses of the health centers and hospitals to the Center for Disease Control of Iranian Ministry of Health and Medical Education (the Iranian CDC), and these reports are assessed and propagated continuously [19].

MATERIALS AND METHODS

AEFI Reports of Iranian rHBV

Reports of adverse events and occurred medical errors are sent through a system of yellow cards to the Iranian CDC via post or fax. Minimum inquiries to report are the patients' details, reporter's ID, name of the observed adverse events and suspected medicines that are supposed to cause the adverse events. Medical committees then will discuss the report and might need further information of the reported errors and the adverse events [20]. It should be mentioned that the yellow card reports to the Iranian CDC regarding serious cases of suspected medicinal products or their application in the hospitals and the health centers is considered mandatory and should be sent within 48 h of their occurrence countrywide. Such serious cases are mentioned for all cases leading to death, life threats, specific and permanent disabilities, hospitalizations and congenital anomalies. In addition, the approval of the authorized manager of the hospital is required to send the above-mentioned cards. It should also be noted that in order to send a report, it is not necessary to ensure the connection between a drug used and the occurrence of a complication and even having doubts about the occurrence of a drug complication can be reported.

The center is obliged to form a committee to handle serious cases within 24 h of receiving a report of serious adverse events, in order to review the submitted cases and the relevant report to the country's medical authorities and their provincial subdivisions including the forensic medicine organizations. The province should report the cases of adverse events and medication errors received to the center along with the results of the investigations within 10 days, and inform the serious cases within 24 h of the occurrence by fax or telephone. Most of the reporters of adverse events are nurses, pharmacists, general practitioners and other caregivers and unfortunately none of the patients are reporting any of such adverse events to the Iranian CDC [21].

All the data provided in the conclusion section have been provided by the Iranian CDC (The Ministry of Health) to the manager of the Production & Research Complex of Pasteur Institute of Iran and the deputy of this unit. It should be noted that due to confidentiality, details and identity of the reporters and the recipients of this information is not revealed.

AEFI Reports of HBV in the United States

VAERS is an online documentary website to receive reports of adverse events with public access to them. This website is a joint subset of the FDA and CDC in the United States and is one of the most up-to-date and complete sources of access to the required vaccine adverse events. The required information about the adverse events of vaccines in the form of an Excel file is available for the public on this website [13]. In the United States, three different HBVs have been used, namely Engerix-B, Recombivax HB and Heplisav B. Engerix-B and Recombivax HB contain aluminum hydroxide as an adjuvant while cytidine phospho-guanosine (CpG) oligonucleotide or 1018 (a Toll-like Receptor 9 agonist), is the adjuvant of Heplisav B.

All USA reports of adverse events after Hepatitis B vaccination in VAERS are evaluated from the date of FDA approval on March 23, 2015 through March 22, 2018. For all adverse events which are reported in Iran, we obtained information from the CDC of Iran, along with copies of vaccination records. In this analysis, adverse events are considered confirmed if they reach the Level 1 criteria of the Brighton Collaboration Case definition [23]. Onset date of adverse events was defined as the day of adverse events diagnosis.

RESULTS

Adverse Events after Immunization with rHBV in Iran during 2015-2017

The observed adverse events of rHBV are summarized in Table 1. All the data are prepared by the ADR (Adverse Drug Reaction) Center of the Ministry of Health and Medical Education.

This comparison showed that the adverse events of the vaccine were 22% in 2015, 43% in 2016 and 35% in 2017, respectively (Fig. 1). According to this table, the highest rate of adverse events is related to the injection site reaction. Severe injection site reaction, high fever and purulent abscess were the most frequent adverse events reported, in this order.

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Table 1. Adverse events of immunizations by rHBV, produced by Pasteur Institute of Iran during 2015-2017.

Adverse events	2015	2016	2017
Sterile abscess	4	5	5
Purulent abscess	7	13	3
Inflammation and pain in the joints	4	4	9
Fever	4	7	4
High fever	9	14	9
Injection site reaction	24	58	59
Severe injection site reaction	12	17	12
Faint	0	3	3
Decreased level of consciousness	1	0	1
Allergic reaction	4	9	9
Other symptoms	5	12	2
Total adverse events	74	142	116

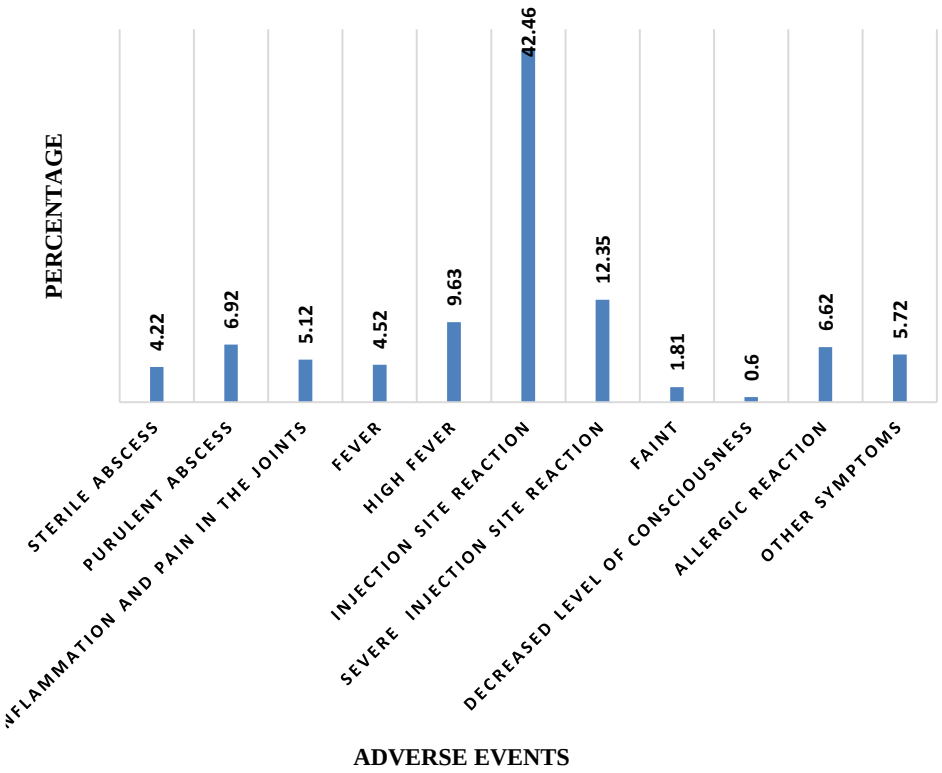


Fig. 1. Comparison of the percentage of adverse events observed after hepatitis B vaccine injection in Iran by type of adverse event during 2015-2017.

Fig. 2 compares the adverse events observed in different years with respect to the number of people with each of the symptoms (as listed in Fig. 1).

Adverse Events after Immunization with HBV in the United States during 2015-2017

The obtained adverse events of HBV by VAERS during the years 2015 to 2017 are tabulated in Table 2.

The comparison of the adverse events in the United States showed that the adverse events following immunization by HBV were 20% in 2015, 13% in 2016 and 67% in 2017. As shown in Fig. 3, the highest total number of organ related complications observed from the vaccine during the years of 2015, 2016 and 2017, are related to the local reactions.

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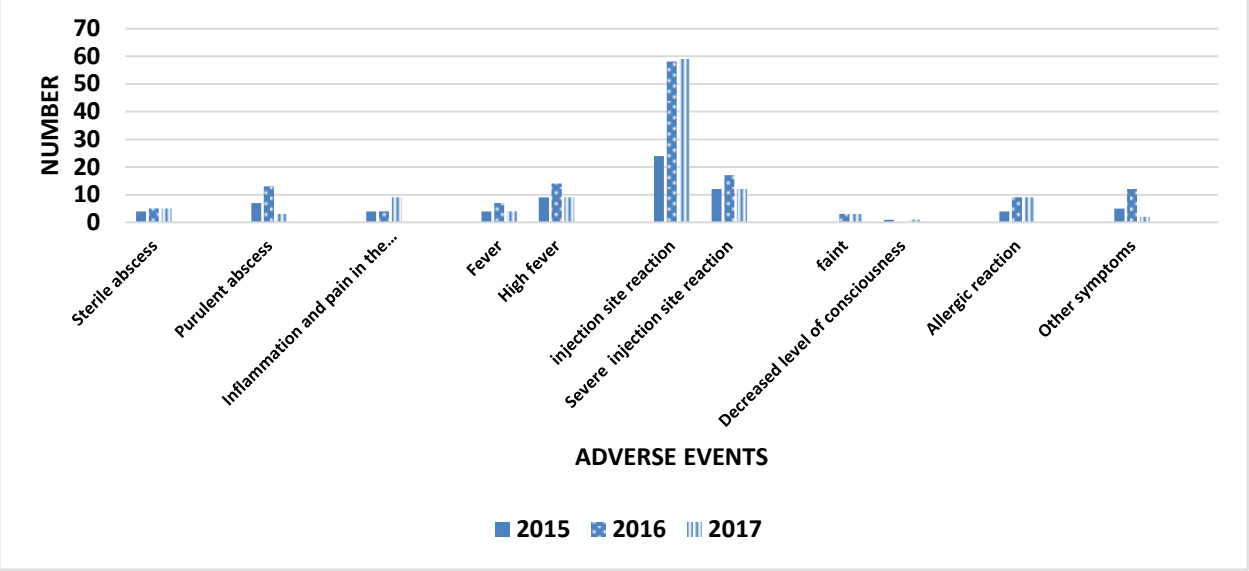


Fig. 2. Comparison of adverse events observed from Iranian rHBV in 2015-2017.

Table 2. Adverse events following immunization of hepatitis B vaccine in 2015-2017 in the United States.

General classification of adverse events	Type of adverse events	2015	Total adverse events of 2015	2016	Total adverse events of 2016	2017	Total adverse events of 2017
Cardiovascular adverse events	Cardiac arrest	3	60	2	36	1	141
	Chest discomfort	20		6		37	
	Syncope	23		15		67	
	Arrhythmia and palpitation	14		13		36	
Dermal adverse events	General rash	150	471	93	333	347	2334
	Injection site reaction	248		217		1688	
	erythema	73		23		299	
Gastrointestinal adverse events	Nausea	60	107	42	83	111	235
	Vomiting	47		41		124	
Nervous system adverse events	seizure	28	135	17	86	74	274
	Loss of consciousness	107		69		200	
Ocular adverse events	Eye pruritus	17	65	13	31	41	92
	Blindness and vision disturbance	28		10		26	
	Eye movement disorder	20		8		25	
Respiratory adverse events	cough	14	112	6	50	21	188
	dyspnea	23		20		50	
	Respiratory tract obstruction	26		13		28	
	Inflammation & infection of the Respiratory tract	46		8		81	
	Respiratory arrest	3		3		8	
General adverse events	Fever and chills	203	547	122	301	537	1591
	Anaphylaxis shock	2		0		1	
	death	10		6		24	
	fatigue	113		66		253	
	pain	152		78		620	
	Osteoarthritis and joint inflammation	67		29		156	
Total adverse events			**1497**		**920**		**4855**

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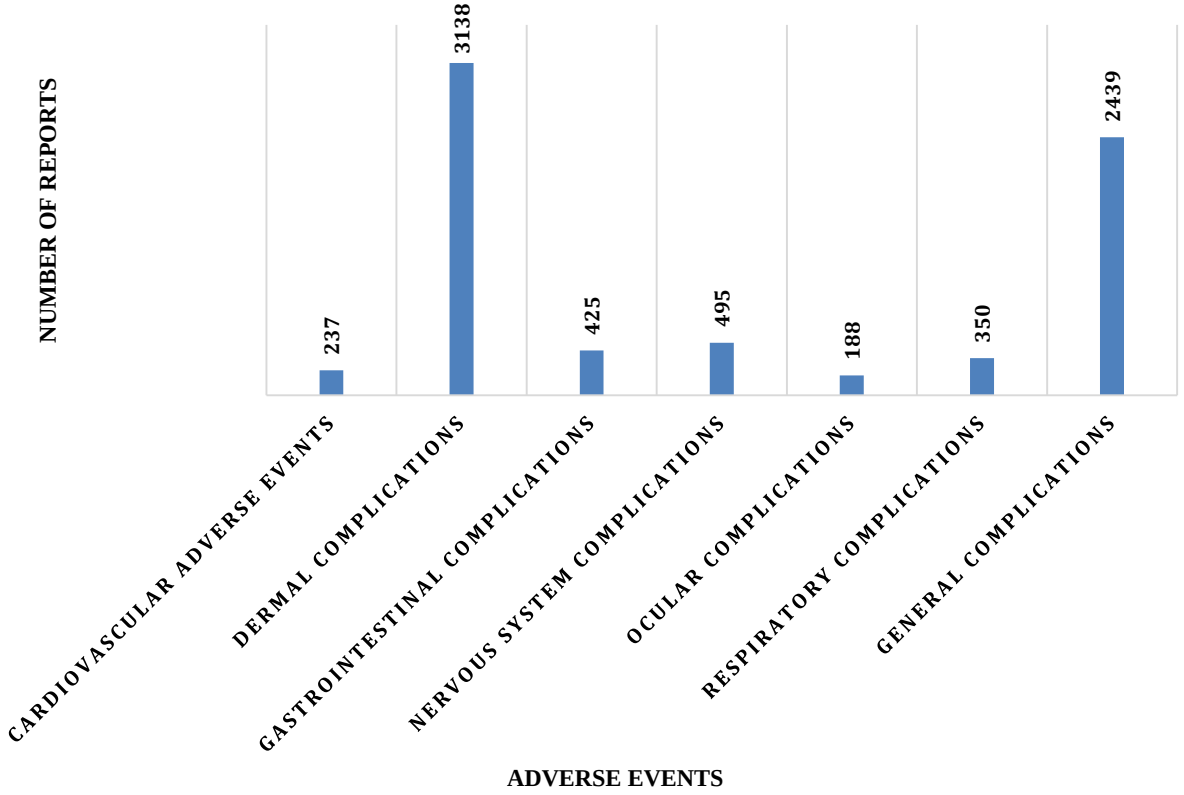


Fig. 3. Comparison of organ related adverse events reported during 2015-2017.

Fig. 4 shows the total number of adverse events observed from the vaccine during the years 2015 to 2017, by type of adverse events observed. According to this table, the highest rates of adverse events in 2017 were related to skin adverse reaction and in the other two years were clinical errors.

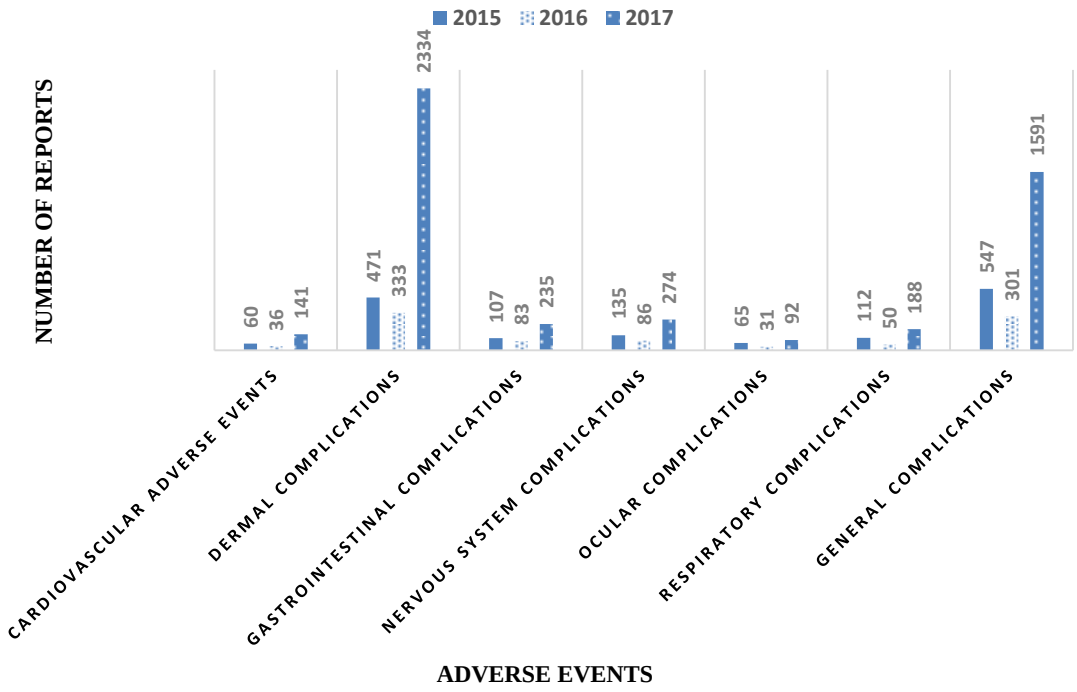


Fig. 4. Comparison of reported adverse events by relevant organ and reporting years in the United States.

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The details of the observed symptoms of each of the above categories have been reported as follows:

A) Cardiovascular adverse events:

In this case, the most frequent life-threatening adverse event is related to syncope, which is in the category of serious adverse events. In the next ranks there are arrhythmias and chest pain disorders. It is noteworthy that several cases of cardiac arrests were observed in each of these years (a total of 6 reports).

B) Skin adverse events:

Injection site reactions, especially in 2017, are the most common complication in this category. Rash on the body and inflammation and redness of the skin are in the next ranks.

C) Gastrointestinal adverse events:

Nausea and vomiting are the most reported, followed by abdominal pain and discomfort.

D) Nervous system adverse events:

Among the adverse events of this group, the decrease and disturbance in the level of consciousness had the highest rate in all three years. Seizures have been reported in a lower rate.

E) Ocular adverse events:

In 2017, the most reports were related to eye movement disorder. However in 2016, eye pruritus and in 2015, blindness and visual disturbances were the most reported among other complications. However, the number of reports of ocular adverse events in 2017 is higher than the other two years.

F) Respiratory tract adverse events:

In 2017 and 2015, the most common respiratory adverse events was related to infection and inflammation of the respiratory tract, while in 2016, the most common adverse event was shortness of breath. It should be noted that a total of 14 respiratory arrests have been reported in 3 years.

G) General adverse events:

There were a wide range of adverse events in this category. However, fever and changes in body temperature and fatigue among them were the most reported in each of the three years, respectively. Fatigue, headache and migraine were also notable in this category.

Comparison of Common Adverse Events of rHBV between Iran and the United States during 2015 to 2017

A comparison of common adverse events reported in Iran and the United States after immunization by HBV are summerized in Table 3.

Table 3. Comparison of common adverse events in Iran and USA during 2015-2017.

Common adverse events	Country of reporter	2015	2016	2017
Purulent abscess	USA	14	2	74
	Iran	7	13	3
Sterile abscess	USA	8	7	23
	Iran	4	5	5
Osteoarthitis and joint inflammation	USA	67	29	156
	Iran	4	4	9
faint	USA	18	6	5
	Iran	0	3	3
Decreased level of consciousness	USA	12	15	37
	Iran	1	0	1
Fever	USA	77	52	84
	Iran	4	7	4
High fever	USA	37	25	42
	Iran	9	14	9
injection site reaction	USA	176	101	484
	Iran	24	58	59
Severe injection site reaction	USA	11	7	60
	Iran	12	17	12
Allergic reactions	USA	210	231	1075
	Iran	4	9	9

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DISCUSSION

As mentioned earlier, the study of drug adverse events plays an important role in promoting the safety of pharmaceutical products. Vaccines, like drugs, can cause a variety of adverse events in patients. Recognizing and rooting out these symptoms can be a great help in limiting the unwanted adverse events after an immunization. To achieve this goal, the science of Pharmacovigilance has a significant role in promoting the safety of pharmaceutical products.

HBV is one of the recombinant vaccines used worldwide to create immunity against infection by hepatitis virus. Various pharmaceutical companies around the world have produced this vaccine, which in Iran, the Pasteur Institute of Iran is the responsible producer. This institution has succeeded in producing rHBV by a transferred technology and is responsible for the exclusive production of this product in Iran.

In this study, adverse events following immunization of rHBV produced by Pasteur Institute of Iran were examined, reviewed and compared from different points of views. As indicated in Table 1, several complications such as purulent and sterile abscesses, inflammation and joint pain, types of fever based on severity, local adverse events, decreased level of consciousness, fainting, allergic reactions and some other symptoms have been observed following the injection of rHBV produced by Pasteur Institute of Iran during 2015-2017. The highest incidence rates of complications were related to local complications (141 out of 332 reports in Iran in 2016, 2017 and 2015). Severe injection site reaction, high fever, purulent abscess and allergic reactions were in the next levels, respectively. Among these, the decrease in the level of consciousness and fainting with 2 and 6 reported cases were the least reported of all reports (frequency of 0.6 and 1.8). A detailed review of the number of adverse events reported by the type of adverse event for each year shows some types of adverse events, including the injection site reaction as well as its severe type such as fever, abscesses (purulent and non-purulent) are more in one year than the other.

The HBV immunization data provided by VAERS in the USA (Table 2) indicated HBV adverse events, categorized by the affected organs and systems, including the cardiovascular system, nervous system, eyes, skin, gastrointestinal system, respiratory system, and general adverse events. Also, due to the high incidence of adverse events related to clinical errors, a separate section was assigned to this type. According to the results presented, most of the observed adverse events were related to general adverse events and in the next stage with a small difference were related to skin adverse events. Among these, ocular and cardiovascular complications had the lowest rate of reporting.

The common adverse events of rHBV between Iran and the United States during 2015 to 2017 were also evaluated which indicated that hypersensitivity in the United States in comparison to Iran has been reported more. Osteoarthritis and joint inflammation occur equally in both countries. It should be noticed that no serious adverse events have been seen in Iran, while adverse events such as apnea, syncope, ocular defects and death have been reported in the United States. Studies show that the vaccine produced and administered in Iran has not reported any serious adverse events leading to death, life-threatening, permanent disability, hospitalization and congenital anomalies, and this might be related to several factors such as poor reporting system or more awareness to the history of patients who had recently injected hepatitis B vaccine or watching and training patients to look after the signals of adverse events. On the other hand, Iran's population is much smaller than the United States (approximately a quarter of the USA population) and the reported cases were much less than the USA due to lack of a proper system for reporting the adverse events. It has also shown that the adverse events of the injection site are the most reported adverse event that can be related to the injection method and can be reduced in the future with proper training to healthcare personnel.

In addition to Iran and the United States, there are other countries active in the field of Pharmacovigilance that have published numerous articles in this field that show the association of some drug adverse events with immunization following vaccination [23].

It is also noteworthy that a study in United States illustrates some special adverse events of HBV, indicating that children who received HBV containing thiomersal were more likely to receive more educational services. However, the direct relationship between the injection of this vaccine and mental impairment has not been completely proven [24].

In India, immunization following HBV is performed by reputable committees, trained by WHO algorithms and assessments have been made to inform and reduce the adverse events of vaccines, including HBV. According to studies, 1 to 2 cases of anaphylaxis shock have been reported per million doses of rHBV vaccine in India [25]. In case of Hepatitis-B, vaccination out of 10 AEFI, most common AEFI was swelling at injection site with the rate of 80% of reports [24]> 26. In addition, based on the study that performed in 2017 on periodic safety of hepatitis B vaccine in this country, various types of adverse events had been reported. Among the total adverse events following immunization, the highest rate of AE was related to fever (58.8%) and injection site reaction (11.4%). Life threatening adverse events were also reported as death (n=1), respiratory arrest (n=1), coma (n=1) and cardiac arrest (n=1) [25])> 27. Moreover, in a study in Italy, adverse events following immunizations have been reported. In 2003, 211 people showed AEFI related to hepatitis B vaccine while most of them were related to skin manifestations (38 reports) and allergic disease (42 reports)[26]>28. In Oman, a series of reports have been published regarding the monitoring of adverse events of hepatitis B vaccine. According to the AEFI study of hepatitis B vaccine from 1996 to 2005, 1.5 adverse events were observed per 100,000 doses (total adverse events observed: 23 reports) while 4 of them were related to systemic reaction and 6 were local reaction and 10 were injection abscesses [27]> 29.

In the developing countries and the Middle East, the culture of reporting and monitoring adverse events from vaccines and drugs is weaker and nascent, thus available results are more limited in these regions. It is hoped that with development of Pharmacovigilance to inform and train the medical society to better recognize and report the adverse events of drugs and to educate the public to be aware of the drugs and vaccine symptoms and signals, more such adverse effects could be avoided. Also facilitating the means of reporting the AEFI to the responsible authorities in each country would be beneficial in this regard.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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