

## Trends of Reported Cases of Hepatitis B Virus Infection, Kingdom of Saudi Arabia, 2009 – 2013

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### Abstract

**Purpose:** Hepatitis B virus (HBV) infection is widespread globally and a serious public health threat. Understanding the distribution of HBV is important to policymakers to evaluate public health surveillance and develop prevention and control policies. Therefore, we studied the trends of reported HBV infection in the Kingdom of Saudi Arabia (KSA) during the 5-year period from 2009 – 2013.

**Methods:** Laboratory-confirmed HBV cases reported to the KSA Ministry of Health (MoH) National Hepatitis Program (NHP) were analyzed by year, gender, nationality, region, and age group.

**Results:** There were 23,236 cases of HBV infection reported to the KSA MoH during the 5-year period 2009 – 2013. In 2009, the incidence rate (IR) of HBV infection was 19.3 (95% CI = 18.8, 19.9) per 100,000 population. The IR significantly decreased to 14.7 (95% CI = 14.2, 15.1) in 2013. The IR was consistently greater among males than females (in 2013, 16.7 versus 12.2). Over the study period, Saudi citizens had a 2- to 3-fold greater IR than non-Saudis (in 2013, 18.7 versus 5.9). There was a large variation among HBV infection IRs across regions, with Tabouk having the highest. The greatest

number of cases was found among those aged 15 to 44 years, followed by those > 45 years of age.

**Conclusion:** Despite the significant decrease in the IRs over the 5-year period from 2009 – 2013, HBV infection remains a major public health problem in KSA. Therefore, there is a need for continuous monitoring and evaluation of the disease's observation protocols and prevention strategies. Various strategies and preventive measures should be implemented to control HBV infection, and well-designed research programs should be carried out in different regions of KSA to improve planning and define the priorities in tackling this health issue.

**Keywords:** Hepatitis B infection, HBV, Trend, KSA

**Running title:** Trends of Reported Cases of Hepatitis B Virus Infection, Kingdom of Saudi Arabia, 2009 – 2013

{**Citation:** Homoud S Algarni, Ziad A Memish, Abdullah M Assiri, Raffat F Alhakeem, Khaled S Alghamdi, Hamed A Alshikh, Scott JN McNabb. Trends of reported cases of hepatitis B virus infection, Kingdom of Saudi Arabia, 2009 – 2013. American Journal of Research Communication, 2014,2(6): 33-44} [www.usa-journals.com](http://www.usa-journals.com), ISSN: 2325-4076.

## Introduction

Hepatitis B virus (HBV) infection is a major health problem leading to substantial morbidity and mortality (1). Currently, about 2 billion individuals have been exposed, 350 million persons are estimated to be carriers HBV, and over 240 million persons are chronically infected (2). HBV infection rates are generally greatest in developing countries, especially among people considered to be at high risk (3). Disease transmission occurs when a healthy person comes in contact with infected blood, vaginal fluids or semen, or sometimes the saliva, urine, or tears of chronic carriers (4). HBV is also transmitted from chronically infected mothers to their newborns, who consequently

develop chronic hepatitis B. The virus infects liver cells and can cause acute liver damage (5). Due to its widespread nature at a global level, HBV infection has had an overwhelming and dramatic impact on many nations, including the Kingdom of Saudi Arabia (KSA).

The prevalence of HBV infection has declined considerably in KSA since the introduction of the immunization program in 1989. Specifically, it fell from 7% before the program in 1989 to 0.3% by 1997 (6). However, different reports have shown that HBV infections continue to be a major burden on the KSA healthcare system due to its high morbidity and mortality (7). As reported in a 2008 KSA study, out of 74,662 persons who underwent premarital screening from January to May 2008, 1.31% of the subjects tested positive for HBV infection (8). In terms of HBV infection prevalence, another study done in the same year indicates that the HBV infection prevalence rates were reported to be between 1.5 and 2.6% among adults, specifically those who had blood transfusions during the study period (9). In 2007, cross-community data monitoring the effectiveness of HBV childhood immunizations showed a prevalence of 0.22% in children and 0.05% in adults (10). From another perspective, the mean incidence of HBV infection was around 0.15%, with massive variations ranging from 0.03% to 0.72% across regions (11).

The long-term HBV program in KSA exists to prevent virus transmission in all age groups with the ultimate goal of eliminating the virus. This has proven to be difficult due to the more than 300 million carriers worldwide and the HBV genotypes, which have distinct geographical distribution (2). The declining prevalence of infection in KSA's population can be attributed to an increase in preventive measures such as vaccination, screening of blood donations, maternal screening, pre-marital screening, and health education of the public through the media and social networks.

The increased number of cases of chronic infection has led to the need to understand how they are distributed and how they can be prevented. This requires a change in the healthcare system's approach to infections like HBV. The purpose of this study was to examine the distribution and trends of HBV in KSA during a five-year period from 2009 to 2013 and to analyze HBV IRs by gender, nationality, and region. In

addition, the study compared reported HBV cases among different age groups during this 5-year period. This study can serve program planners and policymakers by evaluating the HBV surveillance program and develop policies for preventing HBV infections in KSA.

## Methods

### Data Sources

Surveillance teams in each KSA region send monthly reports of laboratory-confirmed HBV infections to the MoH's National Hepatitis Program (NHP). These case reports include clinical and epidemiologic data, including age, gender, and nationality. KSA population data were obtained from the Ministry of Economy and Planning, Central Department of Statistics and Information. This statistical information was drawn from registers, census and field surveys, and statistical studies. These population data include age, gender, and nationality, by region for the years 2009 to 2013 (12).

### Case Definition of Hepatitis B Virus Infection

The NHP defines HBV infection using the standard case definition for suspected and confirmed cases approved by the World Health Organization (WHO). Suspected cases have an acute illness featured by a discrete onset of symptoms, jaundice, or elevated serum aminotransferase levels ( $>2.5$  times the upper limit of normal); confirmed cases are laboratory confirmed by hepatitis B surface antigen (HBsAg) positive or anti-hepatitis B core immunoglobulin M (anti-HBc-IgM) positive results (13). Laboratory-confirmed HBV cases were studied in this report.

### Study Variables

The independent variables in this study included age group, gender, nationality, and administrative region. The age groups are divided into  $< 1$  year, 1 to 4 years, 5 to 14 years, 15 to 44, and  $> 45$  years of age. Nationality was defined as Saudi or non-Saudi. There are 13 administrative regions: Riyadh, Makkah, Madinah, Qasim, Eastern, Asir, Tabouk, Hail, Northern Border, Jizan, Najran, Al-Baha, and Al-Jouf (14).

### Statistical Analyses

Incidence rates (IRs) were calculated per 100,000 people by gender, nationality, and region. IRs were analyzed over a 5-year period (2009 – 2013) using Poisson regression and classified as increasing, decreasing, or stable; this was determined by positive, negative, or non-significant coefficients. Significance was determined at the 5% level using two-sided P values. Rates were compared using rate ratios and 95% confidence intervals (CIs).

### Ethics

This research involved secondary data analyses without personal identifiers. Thus, it did not meet the definition of human subjects research and was classified as exempt by the Emory University Institutional Review Board.

### Results

The total number of reported HBV infection was 23,236 cases. Over a 5-year period of monitoring for HBV infection from 2009 to 2013, there is significant decrease in the IRs from 19.3 per 100,000 in 2009 (95% CI = 18.8, 19.9) to 14.7 in 2013 (95% CI = 14.2, 15.1) (Table 1). The rates were 18 in 2010, 16.1 in 2011, 15.9 in 2012, and 14.7 in 2013.

**Table 1. Reported cases of hepatitis B virus infection and incidence rates, Kingdom of Saudi Arabia, 2009 – 2013**

Year	# Cases (IR <sup>o</sup> )	95% CI*
2009	5020 (19.3)	18.8 – 19.9
2010	4854 (18)	17.5 – 18.5
2011	4494 (16.1)	15.6 – 16.5
2012	4609 (15.9)	15.4 – 16.4
2013	4259 (14.7)	14.2 – 15.1
Total	23,236	

<sup>o</sup>IR = incidence rate per 100,000 population

\*CI = confidence interval

When we studied the IRs of hepatitis B according to gender, we found that the rate among males and females was somewhat comparable in 2009, 2010, and 2011. However, in 2012 and 2013, the IR was significantly higher among males than females: in 2012, the incidence rate was 17.2 (95% CI= 16.6, 17.9) per 100,000 men compared to 15.43 (95% CI= 14.7, 16.1) per 100,000 women. In 2013, the difference in the incidence rate was more marked. It was 16.7 (95% CI= 16.1, 17.3) among men compared to 12.2 (95% CI= 11.6, 12.8) among women (Table 2).

**Table 2. Incidence rates of reported cases of hepatitis B virus infection, by year and gender, Kingdom of Saudi Arabia, 2009 – 2013**

Year	Male		Female	
	# Cases (IR <sup>o</sup> )	95%CI*	# Cases (IR <sup>o</sup> )	95%CI*
2009	2905 (19.4)	18.7 – 20.1	2115 (19.2)	18.4 – 20.1
2010	2816 (18.8)	18.1 – 9.5	2038 (18.5)	17.7 – 19.4
2011	2614 (16.3)	15.7 – 17	1880 (15.7)	15 – 16.4
2012	2758 (17.2)	16.6 – 17.9	1851 (15.4)	14.7 – 16.1
2013	2677 (16.7)	16.1 – 17.4	1582 (12.2)	11.6 – 12.8
Total	13,770		9,466	

<sup>o</sup>IR = incidence rate per 100,000 population

\*CI = confidence interval

By nationality, we found that Saudi citizens had a two- to threefold greater HBV incidence than non-Saudis over the five-year surveillance period. The greatest difference in incidence rates between Saudis and non-Saudis occurred in 2013: the rate among Saudis was 18.7 (95% CI= 18.1, 19.3) per 100,000 compared to 5.9 (95% CI= 5.4–6.4) among non-Saudis. The smallest difference in the incidence rates occurred in 2011: the rate among Saudis was 19.8 (95% CI= 19.2, 20.4) compared to 9.2 (95% CI= 8.6, 9.9) among non-Saudis (Table 3).

**Table 3. Reported cases of hepatitis B virus infection and incidence rates, by year and nationality, Kingdom of Saudi Arabia, 2009 – 2013**

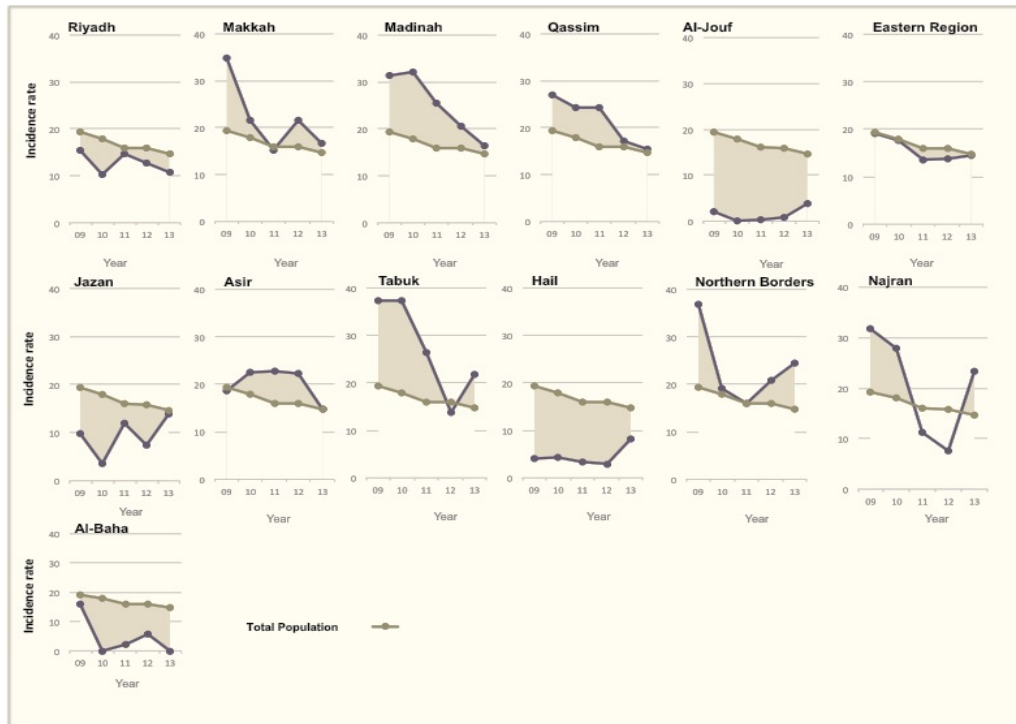
Year	Saudi		Non-Saudi	
	# Cases (IR <sup>o</sup> )	95%CI*	# Cases (IR <sup>o</sup> )	95%CI*
2009	4361 (24.2)	23.5 – 25	659 (8.2)	7.6 – 8.9
2010	4115 (22.9)	22.2 – 23.6	739 (9.2)	8.6 – 9.9
2011	3758 (19.8)	19.2 – 20.4	736 (9.2)	8.6 – 9.9
2012	3899 (20.5)	19.9 – 21.2	710 (7.9)	7.3 – 8.5
2013	3731 (18.7)	18.1 – 19.3	528 (5.9)	5.4 – 6.4
Total	19,864		3,372	

<sup>o</sup>IR = incidence rate per 100,000 population

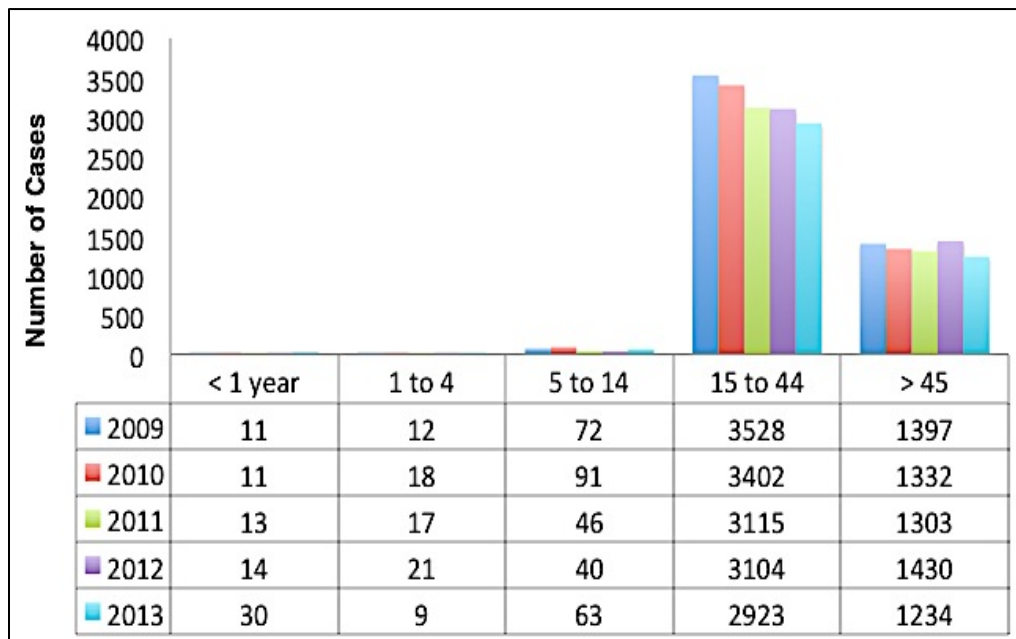
\*CI = confidence interval

Breaking down the hepatitis B incidence rates by administrative region, we found massive variations (Figure 1). The highest incidence rate for over the 5-year surveillance period was found in Tabouk region (37.4 in 2009, 37.2 in 2010, 26.3 in 2011, 13.7 in 2012, and 21.8 in 2013); the second highest overall was Madinah region. The lowest IR over the study period was seen in Al-Jouf region, followed by Al-Baha and Hail regions (Figure 1).

By age group, those in the 15-44 year old age range had the majority of hepatitis B cases over the 5-year study period. There were a total of 16,072 hepatitis B cases among this group, representing about 70% of cases in all age groups. In the over-45 age group, there were 6,696 cases; among those aged 5-14 years, there were 312 cases; among those aged 1-4 years, there were 77 cases; and among those under one-year old, there were 79 cases (Figure 2).



**Figure 1. A Comparison of Trends of Incidence Rates of Reported Cases of Hepatitis B Infection to the Total Population, by Region, Kingdom of Saudi Arabia, 2009 – 2013.**



**Figure 2. Reported Cases of Hepatitis B Virus Infection, by Year and Age Category, Kingdom of Saudi Arabia, 2009 – 2013.**



## Discussion

The current study aims to analyze changes in hepatitis B IR during 5 years of surveillance from 2009 to 2013. In addition, it aims to study the distribution of these IR according to gender, nationality, and region. The number of cases by age group is also examined.

The IR showed a gradual decrease during the five years of surveillance, dropping to fewer than 15 per 100,000 people in 2013. The incidence rates among males and females were equal during the first three years of surveillance; however, males had a higher IR during the last 2 years. Saudi citizens had a two- to three-times higher IR than non-Saudis during the entire 5-year surveillance period. There were also huge differences in the IR among the 13 administrative regions. By age, those in the 15 – 45 year old age group had the highest number of cases, followed by those in the over-45 age group. There were low numbers of cases among the other age groups.

The decline in the overall IR can be explained by the various preventive measures that have been carried out by the MoH; these include the introduction of a hepatitis B vaccine as part of the Expanded Program on Immunization (15), investigation of blood donations, maternal screening, pre-marital screening, and health education efforts. Moreover, the MoH has begun implementing an electronic surveillance system, using the internet to monitor and manage diseases and epidemics and provide healthcare workers and decision-makers accurate information that enables them to offer a high level of health services (16). This system enables better notification of infectious diseases and prevents data duplication through the use of a specific identification number for each patient.

The difference in the IR between males and females can be explained by the fact that males are prone to engage in riskier behavior, such as the use of injection drugs and unsterilized equipment. To a lesser extent, females are also predisposed to other types of risky behavior.

Non-Saudi workers have to undergo medical examinations in their countries of origin at accredited centers prior to their arrival in any Gulf Cooperation Council (GCC) country and are reexamined when they enter the country (17). This may explain the lower

IRs among the non-Saudi population. However, the lower rate could also be attributed to underreporting; many non-Saudis may choose not to seek medical advice if they suspect they are infected due to fear of having their employment contracts terminated and being sent back to their countries of origin.

The lack of adult hepatitis vaccination programs, the greater number of years of potential exposure, and a lack of awareness concerning the HBV infection in earlier decades could explain the higher number of cases among the 15-44 and over-45 age groups as compared to the younger age groups.

The strength of the current study is that it involves data from the entire kingdom compared to other studies that were conducted only in specific regions or specific health facilities. Moreover, this study includes the most current data obtained from the surveillance system; therefore, it is a suitable tool for policymakers. However, this study has some limitations. First, the population data for 2009 was based on census estimates from a baseline KSA census taken in 2007, and the population data for 2010, 2011, 2012, and 2013 were based on census estimates from a baseline KSA census taken in 2010. In 2009, there were no calculations of growth rate across regions. Therefore, there was an overestimation of the IR across the regions (less than 5%) compared to the IR in the total population. In 2010, 2011, 2012, and 2013 the total population and regional population figures were in alignment. However, these estimates were not as precise as those that would have been derived from an annual census. Second, we examined confirmed cases reported to the MOH according to the WHO definition of a confirmed case. A stronger surveillance program is necessary to detect every suspected case and test the confirmation of these cases; without that, we may underestimate the incidence rate. Third, the hepatitis B screening program only includes blood donors, couples registering for marriage, and high-risk groups. Including the entire population would provide an accurate estimate of the incidence rate.

In conclusion, hepatitis B has significant consequences, including mortality, morbidity, negative impact on health-related quality of life, and increased healthcare expenditures (18). The status of HBV in KSA should be a source of concern to all sectors involved in public health, particularly those involved in strategic planning and decision-

making. In view of this, we recommend continuous monitoring and evaluation of surveillance and prevention strategies, implementation of a range of strategies and preventive measures to control the HBV infection, and the launch of well-designed research programs by the MOH and various regions of the Kingdom to improve planning and define priorities. Furthermore, we recommend further studies to examine the hypotheses generated by the current study, such as those concerning the differences in incidence rates between males and females and between Saudis and non-Saudis, as well as those pertaining to the huge variations in incidence rates among different regions of KSA.

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