Prevalence of Hepatitis B Virus in Blood Donors born before and after the Implementation of Universal Hepatitis B virus Vaccination in Egypt at Qena University Hospital

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Abstract

Background: In 1992, the ministry of health in Egypt implemented a universal hepatitis B virus (HBV) vaccination program to reduce infection rates, especially among newborns. This study investigates the prevalence of HBV among blood donors born before and after the vaccination programs to assess their long-term effectiveness in reducing HBV transmission.

Objectives: To determine the prevalence of HBV in blood donors born before and after the implementation of universal HBV vaccination in Egypt.

Materials and methods: A cross-sectional study was conducted on 1000 blood donors at Qena University Hospital's blood banks from March 15, 2024, to September 15, 2024. The blood donors were divided into two groups based on their birth year and the vaccination program (pre-1992 and post-1992). All participants underwent serological testing for HBsAg.

Results: The study identified significant associations between HBsAg positivity and variables like birth year, occupation, marital status, HBV vaccination status, booster dose, surgical history, and hospital admissions ($p < 0.05$). Blood transfusion, family history, and habits such as tattooing or cupping showed even stronger significance ($p < 0.0001$). Predictors were assessed using statistical models to evaluate their influence on HBsAg results, considering demographic, medical, and behavioral factors. These findings highlight the impact of vaccination programs and preventive measures in reducing HBV infection risk.

Conclusion: HBV prevalence in Egypt has significantly decreased, particularly among younger blood donors, due to the national vaccination program. To continue reducing transmission, expanding vaccination in high-risk groups, raising public awareness, and maintaining stringent infection control measures are essential.

Keyword: HBV; Blood donors; Prevalence; Vaccination; Egypt, Immunization.

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Introduction

Hepatitis B virus (HBV) represents a major global health challenge, affecting approximately 296 million individuals worldwide and causing 820,000 deaths annually, as of 2019 **(Jeng et al., 2023).**

The prevalence of HBV varies significantly across regions, with the highest rates observed in sub-Saharan Africa and parts of the Western Pacific. According to the most recent Egyptian Health Issues Survey (EHIS) conducted in 2015 by **El-Zanaty and colleagues**, the estimated prevalence of HBV infection is 1% based on HBsAg seroprevalence among 26.047 healthy participants aged 1–59 years and 1.56% among 16.003 healthy participants aged 15–59 years **(Azzam et al., 2023).**

The transmission of HBV through transfusion appears to be influenced by a variety of factors. These factors include the volume of plasma in the infected blood components that are transfused, the immune status of both the recipient and the donor in relation to HBV, and potentially the strength of the infecting HBV strain **(Candotti et al., 2017).**

The hepatitis B vaccine is the most effective protection against chronic HBV infection and its complications. It is included in routine childhood vaccinations in many countries. The vaccine has been available since 1982 and became widely used. The hepatitis B vaccine has proven to be the most effective measure in preventing chronic HBV infection and its complications. Integrated into routine childhood immunization programs globally, it became more widely accessible after 2000. Numerous studies affirm its success in significantly lowering HBV transmission rates, particularly among high-risk groups, including newborns and healthcare workers. **(Stasi et al., 2020).**

The aim of this study is to compare the prevalence of HBV infection in blood donors born before and after the implementation of the universal HBV vaccination program in Egypt and identify factors associated with HBV transmission in this population.

Materials and methods

This was a cross-sectional study involving 1000 blood donors. The ethical code: SVU-MED-CCP031-1-24-3-829.

The inclusion criteria were: All blood donors attending in a period of 6 months from 15/3/2024 to 15/9/2024.

Exclusion criteria were: All blood donors who refuse to participate in this study.

Study Setting: South Valley University Hospital's blood banks at the Clinical Pathology Department.

Target population: This study was conducted on blood donors attending blood banks at Clinical Pathology department at Qena university Hospital in a period of 6 months from 15/3/2024 to 15/9/2024.

The studied individual divided into 2 groups:

• Group A: blood donors born after implementation of universal hepatitis B virus vaccination in Egypt in 1992.

• Group B: blood donors born before implementation of universal hepatitis B virus vaccination in Egypt in 1992.

All blood donors included in the study underwent comprehensive assessments through detailed questionnaires and blood sample analysis.

Complete History taking included:

• **Personal History**: age, sex, marital status, occupation, address, place of birth, and Special habits (tattooing or cupping).

• **Medical History and Surgical History**: vaccination history, surgical operation, history of hospital admission, and blood transfusion history.

• **Family History:** if any family member has

an HBV infection.

• **Drug History.**

• **Obstetric History** for female cases.

• **Travel History** to endemic countries with HBV infection.

Laboratory investigations

• **Blood sampling:** A 3 ml venous blood sample in the plain tube was collected under aseptic conditions for serology tests. The serum sample was obtained by centrifuging the clotted blood at 3000 × g for 10 min at room temperature.

• **Serology tests:** Hepatitis B surface antigen (HBsAg) was measured using the Elecsys HBsAg II kit (Cat. No. 08814856190) on the Cobas e analyzers, manufactured by Roche Diagnostics GmbH, Germany. HIV antigen/antibody (HIV Ag/Ab) was detected using the Elecsys HIV combi PT kit (Cat. No. 0924163190) on the Cobas e analyzers, manufactured by Roche Diagnostics GmbH, Germany. Syphilis antibody testing was performed using the Elecsys Syphilis kit (Cat. No. 09014977190) on the Cobas e analyzers, manufactured by Roche Diagnostics GmbH, Germany. Hepatitis C virus antibody (anti-HCV) was detected using the Elecsys Anti-HCV II kit (Cat. No. 08836981190) on the Cobas e analyzers, manufactured by Roche Diagnostics GmbH, Germany.

Statistical analysis

Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS), version 26. Descriptive statistics were used to summarize the demographic and clinical characteristics of the study population. The normality of quantitative data was assessed, and suitable parametric tests were applied based on the data distribution. Univariate analysis was conducted using chi-square tests for categorical variables and t-tests for continuous variables. Variables with a p-value < 0.05 were considered statistically significant. Multivariate logistic regression analysis was then applied to identify independent risk factors associated with HBsAg positivity, incorporating 19 categorical binomial independent variables, with the dependent variable being HBsAg result. This comprehensive statistical approach allowed for an in-depth assessment of the factors influencing HBV infection rates among blood donors.

Results

Our study included 1000 blood donors aged 18 to 60 years; 57% were born after 1992, and 43% were born before 1992. 5% were female, 95% were male. 3% were employed in the health sector, while 97% worked in non-health-related fields. 57.2% were married, 42.8% were single. 4.1% engaged in activities like tattooing or cupping. 57.5% were vaccinated, 42.5% were unvaccinated. 60.6% regularly donated blood, and 39.4% did so for the first time. 19.2% had surgery. 16.3% had prior hospitalizations.

3.7% of the sample had a family history of HBV infection, 1.8% mentioned parenteral medication use, and 3.6% reported prolonged drug use or drug abuse. 72% of women had multiple or single births, 58.3% underwent C.S. delivery, and 41.7% had vaginal deliveries. 8.4% reported a travel history, and the age categories were 57% (18-32), 37.2% (33-45), and 5.8% (46-60), **(Table.1).**

Table 1. Demographic data of included subjects

Variables	Level	Frequency	Percent (%)
Birth year	After 1992	570	57
	Before 1992	430	43
	Total	1000	100

Gender	Male	950	95
	Female	50	5
	Total	1000	100
Occupation	Health workers	30	3
	Non-health workers	970	97
	Total	1000	100
Marital status	Married	572	57.2
	Unmarried	428	42.8
	Total	1000	100
Special habits	Positive	41	4.1
	Negative	959	95.9
	Total	1000	100
Vaccination	Vaccinated	575	57.5
	Unvaccinated	425	42.5
	Total	1000	100
Booster dose	Positive	13	1.3
	Negative	987	98.7
	Total	1000	100
Blood receiving	Positive	9	0.9
	Negative	991	99.1
	Total	1000	100
Blood donation	First time	394	39.4
	Frequently	606	60.6
	Total	1000	100
History of surgical operations	Positive	192	19.2
	Negative	808	80.8
	Total	1000	100
History of hospital admission	Positive	163	16.3
	Negative	837	83.7
	Total	1000	100
Family history of HBV infection	Positive	37	3.7
	Negative	963	96.3
	Total	1000	100
Parenteral drug administration	Positive	18	1.8
	Negative	982	98.2
	Total	1000	100
Prolonged drug use or abuse	Positive	36	3.6
	Negative	964	96.4
	Total	1000	100
Parity (females only)	Multi/Uni	36	72
	Null	14	28
	Total	50	100
C.S delivery	Positive	21	42

	Negative	29	58
	Total	50	100
Vaginal delivery	Positive	15	30
	Negative	35	70
	Total	50	100
Travel history	Positive	84	8.4
	Negative	916	91.6
	Total	1000	100
Age categories	18–32	570	57
	33–45	372	37.2
	46–60	58	5.8
	Total	1000	100

Out of 1,000 blood donors, 32 individuals (3.2%) tested positive for HBs antigen, while 968 individuals (96.8%) tested negative. Among the positive cases, 4 (0.4%) had a titer between 1 and 100, 2 (0.2%) had a titer between 100 and 1,000, and 26 (2.6%) had a titer of 1,000 or higher. **(Table. 2, Fig.1).**

Table 2. Distribution of HBs(Ag) Results and Titre Categories Among 1000 blood donors.

Response Variable	Category	Frequency	Percent (%)
HBs(Ag) result	Positive	32	3.2
	Negative	968	96.8
	Total	1000	100
HBs Ag titre categories	<1	968	96.8
	From 1 up to <100	4	0.4
	From 100 up to <1000	2	0.2
	≥1000	26	2.6
	Total	1000	100

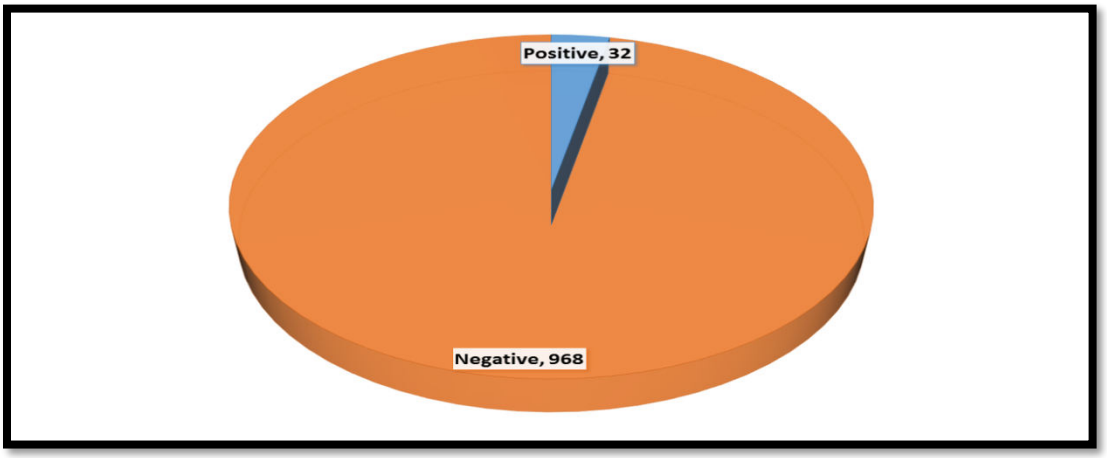

Fig.1. Pie chart of HBsAg result

The analysis revealed notable differences in HBsAg positivity across various factors. A higher prevalence was observed among males, individuals born before 1992, those with positive special habits such as tattooing or cupping, and individuals with a history of surgical operation or hospital admission. Conversely, vaccination and receiving a booster dose were associated with a lower prevalence of HBsAg positivity. Statistically significant associations were found for several variables, including birth year ($p = 0.002$), occupation ($p = 0.005$), vaccination status ($p = 0.001$), booster dose ($p = 0.01$), history of surgical operations ($p = 0.001$), and history of hospital admission ($p = 0.01$). Factors such as blood transfusion, family history of HBV infection, and certain habits showed even stronger significance ($p = 0.0001$). However, variables like gender, blood donation frequency, parenteral drug administration, prolonged drug use or abuse, parity, cesarean delivery,marital status, and travel history did not reach statistical significance ($p > 0.05$). These findings provide a comprehensive overview of the associations between independent variables and HBsAg positivity, highlighting areas for further investigation, **(Table. 3).**

Table 3.Comparison between HBsAg positive cases and negative cases

Variables	**Level**	**HBsAg Positive Count (%)**	**HBsAg Negative Count (%)**	**P-Value**
Birth Year	After 1992	9 (1.58%)	561 (98.42%)	0.002**
	Before 1992	23 (5.35%)	407 (94.65%)	
Gender	Male	31 (3.26%)	919 (96.74%)	0.234
	Female	1 (2.00%)	49 (98.00%)	
Occupation	Health workers	2 (6.67%)	28 (93.33%)	0.005**
	Non-health workers	30 (3.09%)	940 (96.91%)	
Marital Status	Married	29 (5.07%)	543 (94.93%)	0.11
	Unmarried	3 (0.70%)	425 (99.30%)	
Special habits	Tattooing/cupping	6 (14.63%)	35 (85.37%)	0.000***
	None	26 (2.71%)	933 (97.29%)	
Vaccination	Vaccinated	9 (1.57%)	566 (98.43%)	0.001**
	Unvaccinated	23 (5.41%)	402 (94.59%)	
Booster dose	Yes	0 (0.00%)	13 (100.00%)	0.01*
	No	32 (3.24%)	955 (96.76%)	
Blood receiving	Yes	2 (22.22%)	7 (77.78%)	0.00***
	No	30 (3.03%)	961 (96.97%)	
Blood donation	First time	7 (1.78%)	387 (98.22%)	0.5
	Frequently	25 (4.13%)	581 (95.87%)	
History of surgical operation	Yes	10 (5.21%)	182 (94.79%)	0.001**
	No	22 (2.72%)	786 (97.28%)	
History of hospital admission	Yes	6 (3.68%)	157 (96.32%)	0.01*
	No	26 (3.11%)	811 (96.89%)	

Family history of HBV	Yes	14 (37.84%)	23 (62.16%)	0.00***
	No	18 (1.87%)	945 (98.13%)	
Parental drug administration	Yes	0 (0.00%)	18 (100.00%)	0.5
	No	32 (3.26%)	950 (96.74%)	
Prolonged drug use/abuse	Yes	1 (2.78%)	35 (97.22%)	0.320
	No	31 (3.22%)	933 (96.78%)	
Parity	Multi/Uni	1 (2.78%)	35 (97.22%)	0.296
	Null	0 (0.00%)	14 (100.00%)	
C.S. Delivery	Yes	1 (4.76%)	20 (95.24%)	0.437
	No	0 (0.00%)	29 (100.00%)	
Vaginal Delivery	Yes	0 (0.00%)	15 (100.00%)	0.494
	No	0 (0.00%)	35 (100.00%)	
Travel history	Yes	3 (3.57%)	81 (96.43%)	0.543
	No	29 (3.17%)	887 (96.83%)	
Age Categories	18–32	9 (1.80%)	561 (98.20%)	0.52
	33–45	21 (4.74%)	351 (95.26%)	
	46–60	2 (3.45%)	56 (96.55%)	

Discussion

Our study revealed that 32 out of 1000 blood donor samples (3.2%) tested positive for HBsAg, indicating a significant prevalence of HBV infection among blood donors in Qena, Egypt. This infection rate aligns with regional studies but shows variability when compared to findings from other areas. **Azzam et al. (2023)** reported a lower prevalence of 1.8% in Egypt, while **Al-Alousi et al. (2023)** observed a similar rate of 2% in Thamar, Yemen. Conversely, a higher prevalence of 4.8% was reported by **Fatma et al. (2023)** in the Gaziantep region, Turkey. Our study findings are consistent with those of **Jannat et al. (2023**), who reported a 1.07% positivity rate for HBsAg in males compared to just 0.02% in females in Rangpur, Bangladesh. Among our sample of 1000 blood donors, 3.26% of male donors tested positive for HBsAg, which is significantly higher than the 2% observed in females. Additionally, **Uneke et al. (2005),** who reported that the prevalence of HBsAg was slightly higher in males (14.6%) than in females (12.9%) among the blood donors, although they noted that this result may have been influenced by the challenges their study faced in recruiting a sufficient number of female participants.

According to our study, individuals born after 1992 had a significantly lower HBsAg positivity rate (1.58%) compared to those born before 1992 (5.35%), with a ($p = 0.002$). This finding is consistent with a study by **Jin et al. (2020)**, which reported a significantly lower HBsAg positivity rate in individuals born after 1992. The positivity rates were 0.58% in 2004 and 0.57% in 2017 for this group, compared to much higher rates of 5.45% in 2004 and 6.47% in 2017 for those born before 1992 in China.

In our study, we found that the rate of HBsAg positivity was non-significantly among married individuals (5.07%) compared to unmarried individuals (0.7%) ($p=0.11$). This finding is consistent with the results of **Fakruddin et al. (2013)**, who reported HBsAg positivity rates of 8.32% among married individuals and 3.19% among unmarried individuals in Dhaka, Bangladesh.

In our study, we found that vaccinated individuals had a positivity rate

of 1.57%, which was significantly lower than the 5.41% observed in unvaccinated individuals, with a ($p = 0.001$). These findings are consistent with several other studies. According to **Azzam et al. (2023)**, the prevalence of HBV is significantly lower among children who received vaccinations during infancy, at 0.69% in Egypt. Similarly, **Komada et al. (2022)** reported that HBsAg prevalence decreased from 8.0% in adults to 2.0% in individuals aged 1-19 years after the implementation of a three-dose vaccination schedule in Vietnam. Finally, **Pattyn et al. (2021)** found that the prevalence of HBsAg in individuals under 20 years old decreased from 9.8% in 1984 to consistently below 1% in 2004 in Antwerp, Belgium.

In our study, individuals who received a booster dose of the Hepatitis B vaccine showed no HBsAg positivity (0%), indicating strong immunity with a ($p = 0.01$). These findings align with those of **Mohamud et al. (2024)**, who observed that individuals who received the booster dose of the Hepatitis B vaccine had a very low HBsAg positivity rate of approximately 4.35%, with 95.65% of them testing negative for HBV infection, in Mogadishu Somalia . **Bruce et al. (2016)** argued that no additional doses are necessary. Their research found that over 90% of participants still showed signs of protection thirty years later, with an anti-HBs level of 10 mIU or higher in Alaska, United States.

In our study, we found that the rate of HBsAg positivity was significantly higher among healthcare workers (6.67%) compared to non-healthcare workers (3.09%), with a ($p = 0.005$). These findings align with **Bangura et al. (2021)**, whose study in Sierra Leone reported that 10.3% of the screened healthcare workers were HBsAg positive, indicating chronic HBV infection.

Our study revealed that the positivity rate for first-time blood donors was lower (1.78%) compared to regular donors (4.13%), but this difference was not statistically significant with a ($p = 0.5$). However, in contrast,**Wei et al. (2024)** found that the percentage of positive HBsAg was higher in first-time blood donors (98.9%) compared to frequent donors, suggesting a higher risk of HBV infection among new donors in Chongqing, China.

Our study revealed that individuals who received blood transfusions had a significantly higher HBsAg positivity rate (22.22%) compared to those who did not (3.03%), with a ($p < 0.0001$). This finding is consistent with **Bello et al. (2022),** who found that 2.7% of blood samples initially identified as HBsAg non-reactive were later determined to be positive using PCR. This highlights the importance of using more sensitive testing methods in Nigeria.

In our study, we discovered that engaging in certain practices such as tattooing and cupping was strongly and significantly associated with a higher rate of HBsAg positivity (14.63%) compared to those who did not engage in these habits (2.71%). The p-value was (0.000). This finding aligns with a study by **Fathimoghaddam et al. (2011)**, which also reported a significant association between traditional cupping and HBsAg positivity ($p=0.005$) in Mashhad, Iran. However, a study by **Zhang et al. (2017)** did not find a direct link between HBsAg positivity and tattooing or cupping practices in China.

In our study, we observed that individuals with a history of surgical operations had a positivity rate of 5.21% for HBsAg, while individuals with no history of surgical operations had a rate of 2.72%. This suggests a significant association between surgical history and HBsAg positivity ($p = 0.001$). In contrast, a study by **Yigezu et al.**

(2022) conducted among 107 individuals with a history of surgical procedures found that only 2 tested positive for HBV, resulting in a positivity rate of 1.87%, which was not statistically significant (p = 0.247) in South Ethiopia.

Our study found that Individuals with a history of hospital admissions had a positivity rate of 3.68%, while those without had a rate of 3.11%, making this association significant (p = 0.01). This aligns with a study by **Mohamud et al. (2024)** which reported individuals with a history of hospital admissions had a significantly higher positivity rate of 43.8% compared to 19.7% among those without such a history (p = 0.001) in Mogadishu Somalia.

Our study revealed that individuals with a family history of Hepatitis B infection had a significantly higher positivity rate (37.84%) compared to those without a family history (1.87%) (p = 0.000). This finding is supported by a study conducted by **Mohamud et al. (2024)** in Mogadishu, Somalia, where individuals with a family history of Hepatitis B had a positivity rate of 27.1%.

In our study, we found no statistically significant association between HBsAg positivity and prolonged drug use or drug abuse (p=0.320). However, the positivity rate for HBsAg in individuals associated with prolonged drug use or drug abuse was 2.78%, while those with no association had a rate of 3.22%. These findings align with **Hussein. (2016)** reported that no statistically significant association between HBsAg positivity and a history of drug abuse (p = 0.103). The positivity rate for HBsAg in individuals with a history of street drug use was 5.08%, compared to 10% in those without such a history.

In our study, we did not find a significant link between HBsAg positivity and the use of injectable drugs (p= 0.5). In contrast, **Cappy et al. (2022)** , among the 81 donors with occult HBV infection (OBI), parenteral or nosocomial exposure was identified as a risk factor in 7 cases (12%), indicating a notable contribution of these exposures to HBV infection.

in our study, we discovered that the prevalence of HBsAg is low across all parity groups. Among women with multiple or single births, there is a small percentage of positive cases (2.78%), whereas among women with no previous births, there are no positive cases (0%). Although there is a lack of studies specifically addressing HBV infection rates in women based on parity, this could be attributed to the relatively low number of blood donors in various studies, as in our sample. However, studies such as **Fite et al. (2020)** suggest that blood donors with a history of childbirth may exhibit different HBV seroprevalence rates, influenced by factors such as maternal health, vaccination status, and screening practices during pregnancy. These factors are crucial in understanding the dynamics of HBV transmission in women of childbearing age.

Although no previous studies have specifically examined the prevalence of HBV among female blood donors based on the mode of delivery as a contributing factor, our study provides preliminary insights into this relationship, despite the small number of female participants. Our findings suggest that the method of delivery likely does not play a significant role in HBV transmission. Cesarean section delivery was associated with an HBsAg positivity rate of 4.76%, while no HBsAg-positive cases were observed among women who had vaginal deliveries. This indicates that vaginal delivery may not contribute to an increased risk of HBV transmission within the studied sample. These results highlight the need for further research with

larger sample sizes to explore this potential relationship comprehensively.

Our study found that there was no statistically significant association between HBsAg positivity and travel history (p=0.543). However, the positivity rate was 3.57% in people who have a travel history to endemic countries, compared to 3.17% in people who have no travel history to endemic countries. Similarly, **Moncharmont et al. (2000)** revealed that 26 out of 76 donors (34.21%) who were followed up had traveled to these endemic areas in France.

This study provides a basis for future research to investigate more detailed aspects of HBV transmission, such as the specific roles of parenteral drug use and frequency of blood donation, to refine preventive strategies and ensure effective HBV control.

Limitations

The study has several limitations, including a small sample size in certain subgroups, particularly for different delivery methods, which limits generalizability. Data collection at a single time point restricts conclusions about cause and effect. Additionally, factors like socioeconomic status and healthcare access weren't controlled for, and the findings may not be applicable outside the studied region. Finally, the lack of longitudinal data means we cannot assess the long-term effects of the variables on health outcomes.

Conclusion

The overall HBsAg positivity rate of 3.2% among the donors, highlighting the continued public health challenge posed by HBV. Key factors such as male gender, being born before 1992, having a history of surgical operations, and engaging in activities like tattooing or cupping were found to be associated with higher HBsAg positivity.

Vaccination, especially with booster doses, was strongly linked to lower infection rates, emphasizing the critical role of immunization programs in reducing HBV transmission.

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