

# Disease Burden of Hepatitis B Infection and Vaccination Trends in Healthcare Workers: A Prospective Cohort Study

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## ABSTRACT

**Introduction:** Hepatitis B Virus (HBV) infection is an important occupational hazard for Healthcare Workers (HCWs), with an approximately four-fold increased risk of acquiring this infection compared to the normal population. The horizontal mode of transmission is the predominant mode among HCWs. Additionally, vaccination trends among HCWs have been disappointing, with paramedics reported to have a higher risk of HBV transmission and receiving HBV vaccination less often than doctors.

**Aim:** To determine the burden of hepatitis B infection and vaccination trends among HCWs.

**Materials and Methods:** This cross-sectional study was conducted at Pandit Bhagwat Dayal Sharma PGIMS, Rohtak Haryana, India, from March 2019 to January 2020, enrolling 250 HCWs. The study included 80 junior residents, 17 house surgeons, 123 nursing staff, 18 Laboratory Technicians (LTs), and 12 Operation Theatre Assistants (OTAs). The subjects were divided into two groups: medical workers (Group-1; House Surgeons and Junior Residents) and paramedical workers (Group-2; Nursing staff, LTs, OTAs). The sample size was

calculated using Probability Proportion to Size (PPS) of HCWs. Descriptive statistics were performed.

**Results:** None of the subjects tested positive for Hepatitis B surface Antigen (HBsAg) during the study period. A total of 196 (78.4%) subjects were vaccinated, while 54 (21.6%) subjects remained Non-Vaccinated (NV). Out of the 196 vaccinated subjects, 140 (71.4%) were Completely Vaccinated (CV), and 56 (28.6%) were Incompletely Vaccinated (IV). The vaccination rate was highest among junior residents (95%) and lowest among LTs and OTAs (50%). Among the 80 junior residents, 76 (95%) were vaccinated, and 4 (5%) were NV. Among the 123 nursing staff, 89 (72.3%) were vaccinated, and 34 (27.7%) were CV. Among the 18 LTs, 6 (33.3%) were CV, 9 (50%) were NV and 3 were in category of IV. None of the 12 OTAs were CV, with 6 (50%) being NV.

**Conclusion:** HCWs are at a potential risk of contracting HBV infection as an occupational hazard. There is need to strengthen efforts towards vaccination and prevention of HBV infection.

**Keywords:** Caregiver, Hepatitis B virus, Immunisation

## INTRODUCTION

Among viral hepatitis illnesses, infection with HBV is a serious global public health problem and is currently the 7<sup>th</sup> leading cause of global mortality [1]. India accounts for an estimated burden of 10-15% of the entire pool of HBV carriers worldwide, with an estimated prevalence of 1.3-7% [2]. HBV infection an important occupational hazard for HCWs, with an approximately four-fold increased risk of acquiring this compared to the normal population [3,4]. According to the World Health Organisation (WHO), 5.9% of HCWs are exposed to blood-borne HBV infection each year, corresponding to about 66,000 infections worldwide [5].

The horizontal mode of transmission is the predominant mode of transmission among HCWs due to the transmission of the virus through body fluids, particularly blood. Although HBV infection in HCWs is largely attributed to percutaneous exposure, many studies have shown that most infected HCWs could not recall any overt percutaneous injury, further complicating the scenario [6]. In addition, the immunisation trends among HCWs have been disappointing. Hepatitis B vaccination coverage among HCWs varies from 18% (Africa) to 77% (Australia and New Zealand) [5]. In India, there is wide variation in vaccination trends among HCWs, with only 16-60% reported to have complete HBV immunisation [7]. Paramedics are reported to have a higher risk of HBV transmission and receive HBV vaccination less often than doctors [8,9]. These malpractices regarding vaccination further add to the existing risk of HBV infection among HCWs.

The hospital where the study is conducted is one of the largest tertiary care centers in North India. The authors regularly received calls from hospital employees regarding needlestick injuries and

post-exposure prophylaxis for Hepatitis B. When inquiring about the vaccination status, many of them reported non-vaccination or incomplete vaccination. Moreover, HBsAg/Anti-HBs Antibodies estimation has not been a part of regular medical examination at the time of employment in many centers in India, including the present study center.

Recently, a part of the existing study was published by the authors on Knowledge, Attitude, and Practices (KAP) towards Hepatitis B Infection, its prevention, and vaccination among HCWs [10]. Considering these facts, this study aimed to determine the burden of hepatitis B infection in 250 HCWs through HBsAg estimation, assess vaccination trends by inquiring about the schedule followed, and explore the reasons for incomplete/non-vaccination among them. The study emphasises the need for this exercise at every institute/hospital level to prevent Hepatitis B transmission among HCWs.

## MATERIALS AND METHODS

This cross-sectional study was conducted among HCWs from different departments at Pandit Bhagwat Dayal Sharma PGIMS, Rohtak, Haryana, India, from March 2019 to January 2020. The study enrolled 250 HCWs from different departments, preferentially selecting those who were in direct contact with patients and clinical materials with a potential high-risk of horizontal transmission.

The study protocol was approved by the institutional ethics committee (IEC/18/Th-Med/10 dt. 09.02.2019).

**Sampling of HCWs:** Out of the 250 HCWs, 80 were junior residents, 17 were house surgeons, 123 were nursing staff, 18 were LTs, and 12 were OTAs, according to PPS [Table/Fig-1].

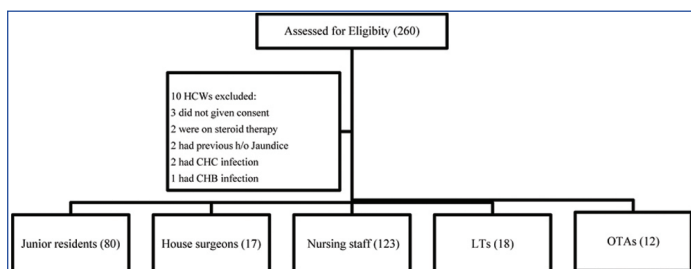
S. No.	Category of HCW	Number in health facility (N)	Calculated proportion	Number allocated to study (n)
1.	Junior residents	708	$708/2208 \times 250 = 80$	80
2.	House surgeons	150	$150/2208 \times 250 = 17$	17
3.	Nursing staff	1088	$1088/2208 \times 250 = 123$	123
4.	Laboratory technicians (LTs)/Operation Theatre Assistant (OTAs)	262	$262/2208 \times 250 = 30$	30
5.	Total	2208		250

**[Table/Fig-1]:** Sampling of HCWs by probability proportional to size.

After explaining the objectives of the study, written informed consent was obtained from the participants. For data interpretation, the subjects were divided into two groups: medical workers (Group-1; house surgeons and junior residents) and paramedical workers (Group-2; nursing staff, LTs, OTAs). Blood samples were collected from the participants for HBsAg estimation. To explore the reasons for incomplete/non-vaccination among HCWs, the authors formulated a questionnaire in a structured proforma, available in Hindi and English (forward and backward translation was done), and all HCWs were asked to fill it.

Hepatitis B infection was assessed by HBsAg estimation using Enzyme Linked Immunosorbent Assay (ELISA) in the Department of Microbiology at our institute. Anti-HBs/Anti-HBc antibodies were not estimated due to non-availability at the institute level. The HBsAg positive participants underwent further investigations and were managed according to the Indian National Association for the Study of the Liver (INASL) Position statements on prevention, diagnosis, and management of HBV Infection in India [11]. Vaccination status was defined as complete vaccination (CV; subjects receiving three vaccines as per schedule at 0, 1, 6 months), incomplete vaccination (IV; subjects receiving atleast one dose of vaccination), and non-vaccinated (NV; no vaccination received).

**Inclusion criteria:** Medical workers (house surgeons and residents), Paramedical workers (nursing staff, LTs, OTAs) [Table/Fig-2].



**[Table/Fig-2]:** Enrollment of subjects in study.

LT: Laboratory technician; OTA: Operation theatre assistant; CHC: Chronic hepatitis C; CHB: Chronic hepatitis B

**Exclusion criteria:** Those HCWs with HIV infection, cirrhosis of the liver, chronic kidney disease or those with previously known chronic Hepatitis B/Hepatitis C virus (CHB/CHC) infection or those HCWs on immunosuppressants/chemotherapeutic agents or those subjects who did not give consent for participation were excluded from the study.

The primary outcome of the study was to estimate the hepatitis B disease burden among HCWs. The secondary outcomes included vaccination trends and reasons behind incomplete/non-vaccination among HCWs.

## STATISTICAL ANALYSIS

The data were documented in pre-designed proformas. Computer files were created in Microsoft excel for Windows. Data analysis was performed using STATA version 11 and SPSS version 17.0 software. Normally distributed variables were expressed as mean  $\pm$  standard deviation (SD), and continuous variables with skewed

distribution were expressed as median (range). Descriptive statistics were performed.

## RESULTS

A total of 83 (33.2%) were males and 167 (66.8%) were females, with nursing staff and junior residents accounting for the majority of participants: 123 (49.2%) and 80 (32%) subjects, respectively. The mean age (SD) of the participants was  $31.8 \pm 9.1$  years. Eighty (32%) junior residents and 17 (6.8%) house surgeons were included in Group-I (97; 38.8%), while 123 (49.2%) staff nurses, 18 (7.2%) LTs, and 12 (4.8%) OTAs were included in Group-II (153; 61.2%). None of the participants had any features suggestive of cirrhosis, intake of immunosuppressive medicines in the last year, CHB, CHC, or HIV infection. The demographic characteristics are shown in [Table/Fig-3].

Variables	No. of subjects (n=250) n (%)
Age (mean $\pm$ SD) (in years)	31.8 $\pm$ 9.1
Sex (Male:Female)	83:167 (1:2)
<b>Occupation</b>	
Junior residents	80 (32)
House surgeons	17 (6.8)
Nursing staff	123 (49.2)
Laboratory Technicians (LTs)	18 (7.2)
Operation Theatre Assistant (OTAs)	12 (4.8)
Medical workers (junior residents and house surgeons)	97 (38.8)
Para medical workers (nursing staff, LTs,OTAs)	153 (61.2)
<b>Co-morbid conditions</b>	
Cirrhosis of liver	0 (0)
immunosuppressive medicines use	0 (0)
Positive HBsAg/ Anti-HCV Ab/HIV	0 (0)

**[Table/Fig-3]:** Demographic profile of subjects.

HBsAg in subjects: HBsAg estimation was done using the ELISA method in all subjects to check for the presence of any Hepatitis B infection. However, none of the participants tested positive for HBsAg. The authors did not estimate the presence of Anti-HBs/Anti-HBc antibodies in the subjects.

A total of 196 (78.4%) subjects were vaccinated, with 54 (21.6%) subjects being NV. Out of the 196 vaccinated subjects, 140 (71.4%) received Complete Vaccination (CV), and 56 (28.6%) received Incomplete Vaccination (IV). The vaccination rate was highest among junior residents (95%) and lowest among LTs and OTAs (50%). Among the 80 junior residents, 76 (95%) were vaccinated, and 4 (5%) were non-vaccinated. Among the vaccinated junior residents, 59 (77.7%) received CV, and 17 (22.3%) received IV. Similarly, out of the 17 house surgeons, 16 (94.1%) were vaccinated (15 [93.7%] CV, 1 [6.3%] IV), and 1 (5.9%) was non-vaccinated. Among the 123 nursing staff, 89 (72.3%) were vaccinated, and 34 (27.7%) were non-vaccinated. Among the 89 vaccinated nursing staff, 60 (67.4%) received CV, and 29 (32.6%) received IV. Among the 18 LTs, 6 (33.3%) received CV, 3 (16.7%) received IV, and 9 (50%) were non-vaccinated. None of the 12 OTAs received CV, 6 (50%) received IV, and 6 (50%) were non-vaccinated. The vaccination status among the HCWs is shown in [Table/Fig-4].

Among the 56 subjects with incomplete vaccination, 41 (73.2%) missed the third dose of the vaccination schedule, while 15 (26.8%) HCWs received only a single dose of vaccination. A total of 49 (87.5%) subjects missed their scheduled visit and never visited the immunisation clinic again, while 7 (12.5%) HCWs had an upcoming schedule of visit [Table/Fig-5].

Among the 54 unvaccinated HCWs, 49 (90.7%) were paramedical workers, and 5 (9.3%) were medical workers. Nineteen (35.2%)

Total (n=250)	Vaccinated N (%)	Completed vaccination N (%)	Incomplete vaccination N (%)	Unvaccinated N (%)
	196 (78.4)	140 (71.4)	56 (28.6)	54 (21.6)
<b>Group-I (n=97)</b>				
Junior residents (n=80)	76 (95)	59 (77.7)	17 (22.3)	4 (5.0)
House surgeons (n=17)	16 (94.1)	15 (93.7)	1 (6.3)	1 (5.9)
	92 (94.8)	74 (80.4)	18 (19.6)	5 (5.2)
<b>Group-II (n=153)</b>				
Nursing staff (n=123)	89 (72.3)	60 (67.4)	29 (32.6)	34 (27.7)
Lab Technicians (LT) (n=18)	9 (50)	6 (33.3)	3 (16.7)	9 (50)
OT Assistants (OTA) (n=12)	6 (50)	0 (0)	6 (50)	6 (50)
	104 (67.9)	66 (63.4)	38 (36.6)	49 (32.1)

**[Table/Fig-4]:** Vaccination status among Health Care Workers (HCW).

	n=56 (%)
1 <sup>st</sup> dose only	15 (26.8)
Two doses	41 (73.2)
Upcoming schedule of visit	7 (12.5)
Missed the schedule of visit	49 (87.5)

**[Table/Fig-5]:** Hepatitis B vaccination doses among Incomplete Vaccinated (IV) HCWs and reasons for IV.

HCWs (5 in Group-I and 14 in Group-II) stated that they were never offered hepatitis B vaccination by the department/administration during their service. Fourteen (25.9%) subjects reported non-availability of the vaccine at their workplace, 8 (14.8%) stated that they were very careful and maintained standard precautions at their workplace, while 8 (14.8%) subjects avoided vaccination due to fear of side effects, and 5 (9.3%) HCWs were not vaccinated due to a lack of knowledge regarding the occupational risk of hepatitis B transmission. Since the vaccine is available free of cost to all patients and HCWs in the hospital vaccination clinic, the cost of the vaccine was not an issue among the subjects. The reasons for non-immunisation are depicted in [Table/Fig-6].

Reasons for non-vaccination	(n=54) N (%)	Group-I (n=5) N (%)	Group-II (n=49) N (%)
Fear of side-effect	8 (14.8)	0 (0)	8 (16.3)
Lack of knowledge regarding occupational risk of transmission	5 (9.2)	0 (0)	5 (10.2)
Department/administration did not offered vaccine at any time	19 (35.2)	5 (100)	14 (28.6)
Costly	0 (0)	0 (0)	0 (0)
I was found infected on initial screening	0 (0)	0 (0)	0 (0)
I am very careful, I maintain all the standard precaution measures	8 (14.9)	0 (0)	8 (16.3)
Vaccine is not available at my working place	14 (25.9)	0 (0)	14 (28.6)

**[Table/Fig-6]:** Reasons for non-vaccination among Health Care Workers (HCW) (n=54).

\*other data was also collected; however the available data was sketchy and could not be interpreted in the study context

## DISCUSSION

Occupational exposure has been well-recognised as a risk factor for HBV infection among HCWs. Generally, it is assumed that HCWs, by virtue of their proximity to healthcare facilities, should have adequate knowledge of the causation and prevention of communicable diseases like HBV infection. However, on the contrary, literature has shown a high prevalence of HBV infection among HCWs compared to the normal population [12]. In this

study, we aimed to explore the disease burden of hepatitis B and the vaccination status among HCWs.

This study was conducted among 250 HCWs. The subjects were selected according to PPS, and the number of nursing staff was the highest (123; 49.2%) among the subjects. As females predominate as nursing staff almost everywhere in the country, we had almost twice as many females (167; 66.8%) compared to males (83; 33.2%). False negative HBsAg positive status was ruled out as none of the enrolled subjects had chronic liver disease, a positive HIV status, or were receiving immunosuppressive agents that could have influenced the HBsAg estimation.

In this study, none of the subjects tested positive for HBsAg, unlike what has been reported in the literature [4,8,13-15]. This might be attributed to more than three-fourths (78.4%) of the subjects being vaccinated (see below). Since we did not estimate Anti-HBc antibodies, we cannot comment on whether any proportion of the subjects had previous HBV infection.

A total of 196 (78.4%) HCWs were vaccinated, and these estimates of hepatitis B vaccination coverage in HCWs are much better than those reported by Singhal V et al., [15]. In another study conducted at GB Pant Hospital in Delhi, only 1198 (55.4%) out of 2162 HCWs were vaccinated against Hepatitis B [8]. The percentage of vaccinated HCWs in our study was much higher than the estimate reported by the WHO in 2003 (18% in the South-East Asian Region) [5]. We expect a high coverage of vaccination among HCWs in our country compared to what the WHO has reported, owing to the marked efforts for hepatitis B vaccination that have been taken in the past two decades. However, we stress that our vaccination coverage estimates are from a single center in North India with a small number of subjects, and they cannot be representative of the country-wide vaccination status among HCWs.

We had a 56% complete coverage of immunisation in our subjects, which was higher than the 42.2% reported by Kumar KA et al., [13]. Even in the most developed countries, the situation is not satisfactory. In the United States, according to one study, 75% of HCWs at risk had received three or more doses of the hepatitis B vaccine [16]. In Sweden, 79% of HCWs had received at least one dose of the vaccine, but only 40% were reported to be fully vaccinated [17]. These estimates reflect that HCWs, despite having knowledge of vaccination and initiating the vaccination process, are not completing the vaccination schedule.

The proportion of vaccinated HCWs differed among various occupational groups, with the highest proportion of vaccination (around 95%) observed in Group-I. Among Group-II, only 50% of both LT and OTAs were vaccinated, compared to 72.3% of staff nurses, with none of the OTAs having complete vaccination. These findings are similar to a study conducted by Batra V et al., where doctors had the highest vaccination rate of 92.5%, followed by medical students (62.4%), nursing staff (41.6%), technical staff (24.2%), administrative staff (12.1%), nursing students (8.5%), and Grade-IV/laundry staff (0%) [7]. This difference in the pattern of vaccination among various categories of HCWs may be attributed to their level of education, knowledge, and attitude regarding vaccination.

A total of 56 (22.4%) HCWs had incomplete vaccination. The reasons for incomplete vaccination included missed scheduled visits and upcoming visits. Addressing incomplete vaccination is important, particularly for those who have already missed their scheduled visits and are potential defaulters on the vaccination program, putting them at risk for infection. It is worth mentioning that protective antibody levels depend on the dosing of the vaccine, with antibody levels reaching up to 90-95% with the third dose of the vaccine, compared to 20-30% and 75-80% with the first and second doses, respectively. Since we did not estimate Anti-HBs antibody levels, we cannot comment on the efficacy of vaccination in our subjects. However, we strongly recommend full vaccination coverage among HCWs.

Among the 54 (21.6%) HCWs who did not take the vaccine, the predominant causes were not being offered the vaccine by the department/administration and lack of awareness regarding the availability of hepatitis B vaccination at the workplace. In addition, factors such as not adopting standard precautions at work, fear of side-effects, and lack of knowledge regarding the occupational risk of transmission were also identified. Other studies have also shown that not being offered the vaccination at the workplace [18] and unavailability of the vaccine [19,20] were among the main reasons for not being vaccinated. Based on previous studies, lack of knowledge regarding HBV infection [21,22], access to hepatitis B vaccination [23], and a lack of publicity were major hurdles to increased coverage [23-25]. Reports have shown that publicity campaigns regarding HCWs' vaccination yielded nearly complete protection rates [24,25]. Therefore, we believe that increased publicity for the vaccine would empower HCWs to demand the vaccine and know how to access it.

In our hospital, all employees are offered HBV vaccination free of charge. It is then the employee's responsibility to make the necessary appointment to receive the vaccine. This study found that although 78.4% of HCWs had received the HBV vaccine at some point in time, only 56.9% completed three doses of vaccination. Additionally, 35.2% of the unvaccinated HCWs agreed that they would accept vaccination if offered. This clearly shows that a more robust system is needed to ensure the implementation of national vaccination guidelines. All new HCWs should be questioned about their prior vaccination status, and if there are any uncertainties, antibody levels should be checked. We recommend storing the data in a secure central database and sending repeated reminders to defaulters. The subjects in this study were not subjected to occupational health checks for hepatitis B infection at the time of employment in the hospital, and in this regard, the authorities have been informed of the study findings. Now, every effort is being made for HBsAg screening at the time of employment and at six-month intervals.

Among the 54 unvaccinated HCWs, 89% (49/54) were paramedical workers. These findings reveal that the type of profession and level of education have a profound impact on vaccination status. The presence of a significant association between the type of profession and vaccination status has also been reported in other studies [7, 18]. In addition, HCWs' acceptance of the vaccine can be influenced by various factors, including their knowledge, attitudes, and beliefs [26,27].

The strength of this study includes the enrollment of subjects proportionately from different strata of HCWs. The study reflects vaccination trends and highlights various parameters that contribute to non-vaccination or incomplete vaccination among HCWs. Our findings should encourage hospitals and other medical institutes to adopt a robust system for hepatitis B vaccination and emphasise the mandatory screening for HBsAg, Anti-HBc antibodies, and Anti-HBs antibodies at the time of employment.

### Limitation(s)

The study has some inherent limitations. First, the sample size is small and from a single center in North India, so the findings cannot be representative of the disease burden among HCWs nationwide. Anti-HBc antibodies levels were not estimated, which might have reflected the presence of previous infection in subjects. The study focused on the disease burden in HCWs who were not aware of their disease status at any point in time, and HCWs with CHB infection were excluded from the study, so an assessment of the existing burden of disease was not conducted. The number of phlebotomies/procedures was not calculated among HCWs. The educational status of the subjects was not assessed, which might

have provided more insight into any correlation between vaccination rates and educational status.

## CONCLUSION(S)

In conclusion, HCWs are at potential risk of contracting Hepatitis B infection as an occupational hazard. The non-availability of vaccines at the workplace and the failure to offer the vaccine by the department/administration at any time have a profound effect on hepatitis B vaccination. There is an urgent need to strengthen organisational efforts towards the prevention of these occupational hazards and to motivate HCWs towards vaccination.

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