

## Hepatitis B Immunization Status of Health Care Personnel

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**Abstract:** Background & objectives: Post-vaccination anti-HBsAg antibody titer measurements among Health Care Personnel (HCP) are not being done routinely at present. The present study was carried out to assess the post vaccination immunization status of HCP and to find an association between demographic & host factors and level of immunity. Methods: Cross-sectional prospective study was conducted at Shree Krishna Hospital, Karamsad. Information on Hepatitis B Virus (HBV) vaccination status and demographic details of HCP were collected using a structured proforma through verbal interviews and hospital information system. Anti-HBs antibody titre was determined by Enzyme Linked Immunofluorescent Assay (ELFA). Results : They were analysed using Pearson Chi<sup>2</sup> test and Fisher's exact test. Results: Among 505 participants, 96.4% developed protective antibody titres ( $\geq 10$  mIU/ml) after primary vaccination. Following revaccination of participants with insufficient titres, 100% developed protective antibodies. There were no non-responders in the study. There was a significant association between anti-HBs antibody titres and duration after last dose of vaccine ( $p = 0.01$ ) whereas no correlation was found between antibody titres and gender, age group, BMI & category of HCP. conclusions: HBV vaccination showed an excellent response following primary vaccination. For HCP with insufficient titres after primary vaccination, re-vaccination and re-testing is recommended. [Khristi P, Natl J Integr Res Med, 2018; 9(4):37-43]

**Key Words:** Health Care Personnel, HBV, anti-HBs antibody titre

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**Introduction:** Hepatitis B virus (HBV) has been long recognized as an occupational risk for health care personnel (HCP) including health care profession trainees and students. HCP do not recognize all exposures as potentially infectious blood or body fluids.<sup>1</sup> In an unvaccinated individual, the risk of acquisition of HBV infection after single exposure of HBV infected blood or body fluid ranges from 6% to 30%.<sup>2</sup> In serological studies conducted in the United States in 1970s, HCP had prevalence of HBV infection approximately 10 times greater than the general population.<sup>1</sup> Vaccines to prevent HBV infection were licensed in 1981, and have been commercially available since 1982.<sup>3</sup> The protective efficacy of hepatitis B vaccination is directly related to the development of antibody to Hepatitis B surface antigen (anti-HBs).<sup>4</sup> Vaccine induced sero-protection is a useful surrogate of vaccine efficacy.<sup>5</sup> Immune response to HBV vaccine is assessed by measuring antibody levels after 6-8 weeks of completion of 3 doses. Hepatitis B surface antibody level more than 10 mIU/ml is generally taken to be protective.<sup>4</sup> The seroconversion rate is influenced by a number of factors such as gender, BMI, smoking, alcohol intake, obesity, chronic diseases, HIV infection, and certain HLA haplotypes.<sup>1</sup> The group of non-responders to HBV vaccine poses a special problem due to their false sense of security after HBV vaccination.<sup>6</sup> Post vaccination serological testing for anti-HBs antibody identifies vaccine non-responders. Revaccination with

$\geq 1$  dose of HBV vaccine for non-response subsequent to the primary series increases the proportion of persons achieving vaccine induced sero-protection.<sup>4</sup> The duration of immunity after HBV vaccination is not known. The level of anti-HBs antibody does wane after vaccination, quite rapidly within the 1<sup>st</sup> year and more slowly thereafter.<sup>7</sup> About 10% of the patients who receive and respond to vaccination lose anti-HBs antibody after 5 years and 50% lose anti-HBs antibody after 10 years.<sup>8</sup> As there are no data to support the need for booster doses of Hepatitis B vaccine in immunocompetent individuals who respond well to primary doses, however some authorities recommend regular booster doses to maintain seropositive anti-HBs antibody titers.<sup>9</sup> Since a high percentage of HCP do not exhibit detectable anti-HBs antibody titres and post-vaccination anti-HBs antibody testing is not performed to define non-responders, there may be a substantial population of HCP who are at risk for contracting HBV infection.<sup>8</sup> Therefore, post immunization serology should be performed to ensure seroconversion and to guide further immunization and post-exposure prophylaxis.<sup>10</sup> Thus, the purpose of this study was to assess the anti-HBs antibody titres in the vaccinated HCP and to investigate the probable association between anti-HBs antibody titres and demographic and host factors.

**Methods:** The cross sectional prospective study, approved by Institutional Ethics Committee (IEC) of H.M. Patel Centre for Medical Care and Education,

Karamsad was carried out at Shree Krishna Hospital, Karamsad during the period of January 2015 to June 2017. A total of 505 health care personnel i.e. consultant doctors, resident doctors, nursing staff, technicians, attendants and assistants were included in the study. All HCP who had completed their 3 doses of Hepatitis B vaccine were eligible for detection of anti-HBsAg antibody titres only if they can produce HBV-vaccine card or any other such evidence showing dates of vaccination. Defaulters (not completed the schedule) were included 6-8 weeks after the complete full course of vaccine, as the case may be, during the study period. Participants were further subdivided into the following groups:

**(i) Group A:** Primary vaccinated and titres done within 1-2 months of the last dose of vaccination.

**(ii) Group B:** Primary vaccinated and titres done between 2 months to <5 years of the last dose of vaccination.

**(iii) Group C:** Primary vaccinated and titres done at >5 years of interval after last dose of vaccine and those who had not taken any booster dose of vaccine.

**(iv) Group D:** Primary vaccinated and titres done at >5 years of interval after last dose of vaccine and those who had received a booster dose.

After informed consent, the serological test for anti-HBs antibody titre (AHBS) was done by Enzyme Linked Fluorescent Assay (ELFA) method in the mini-VIDAS (by Biomerieux, France). Anti-HBs levels  $\geq 10$  mIU/ml was considered as anti-HBs positive and anti-HBs level  $< 10$  mIU/ml was considered as anti-HBs negative. HCP with anti-HBs antibody titre  $< 10$  mIU/ml; as per recommendations, were counseled and encouraged to take additional dose of vaccine/s and re-tested for the titre as per the CDC guidelines.<sup>1</sup> All the data regarding HCP vaccination schedule and titres were collected from the Hospital information system. Additional required information such as height, weight, BMI [calculated by formula, weight (kg)/height (m<sup>2</sup>)], history of smoking, alcohol intake, chronic diseases, or immunosuppression and booster dose or previous vaccination were taken from the HCP after interviewing them. The statistical analysis of the results was done using Pearson Chi<sup>2</sup> test and Fisher's exact tests as appropriate and p values of less than 0.05 were considered significant. In our analysis, p value was derived for each of the different variables (gender, age, category of HCP, BMI and duration after the last dose of HBV vaccine) of the study population. Also results for each variable were compared with the

anti-HBs titre distribution, to find out the association between the variable and the anti-HBs antibody titre.

**Results:** Out of 525 eligible participants in our study, six (1.18%) participants did not comply for the further follow up of their titres, whereas 14 (2.77%) of them left the institute during the study period. Thus, a total of 20 (3.96%) participants were excluded from the study. A total of 505 participants were included in the present study and were divided into four groups as described in methods.

Of the 505 health care personnel included in the study, 473 (93.66%) were already primarily vaccinated. A total of 14 (2.77%) participants had history of incomplete HBV vaccination at the time of enrolment in the study; however, all of them had received complete three dose series of HBV vaccine during the study period and thus were included in the present study.

Out of 505, 487 (96.4%) participants were found to have successful immunization with anti-HBs antibody titre of  $\geq 10$  mIU/ml whereas 18 (3.56%) participants were found to have their anti-HBs antibody titre of  $< 10$  mIU/ml. All 18 participants underwent repeat vaccination with three doses of HBV vaccine. Post vaccination with three additional doses of HBV vaccine, these 18 participants were successfully seroconverted and achieved anti-HBs antibody titre  $\geq 10$  mIU/ml. Thus, there were no non-responders detected in the present study.

There were 337 (66.7%) male and 168 (33.3%) female participants in the study. 323 (63.96%) participants had anti-HBs antibody titres of  $> 500$  mIU/ml, 103 (20.4%) had titres between 101 – 500 mIU/ml, 61 (12.1%) between 10 – 100 mIU/ml and 18 (3.56%) had anti-HBs titres of  $< 10$  mIU/ml, after primary vaccination. Out of 505 participants, 241 (47.7%) participants belonged to age group 20 – 30 years, 148 (29.3%) between 31 – 40 years, 83 (16.4%) between 41 – 50 years and 33 (6.5%) were of more than 50 years of age. There were 319 (63.16%) nurses, 99 (19.60%) doctors, 37 (7.32%) technicians, 30 (5.94%) assistants, and 19 (3.76%) attendants in the present study. 37 (7.3%) participants had a BMI of  $< 18.5$  (Underweight), 402 (79.6%) had BMI between 18.5 – 24.9 (Normal), 52 (10.2%) between 25 – 29.9 (Overweight) and 14 (2.7%) had a BMI of  $> 30$  (Obese). Out of 505 participants, 50 (9.9%) participants got their anti-HBs antibody titres measured between 1 – 2

months of last dose of vaccination, 244 (48.3%) between two months and five years, 109 (21.5%) after five years (without a booster dose) and 102 (20.1%) after five years (with booster dose).

**Table 1: Association between Gender & Age group and anti-HBs antibody titre (n = 505)**

	AHBS >10 mIU/ml (n=487) (%)	AHBS <10 mIU/ml (n=18) (%)	Total No.	p Value
<b>Gender</b>				
Female	324 (66.5)	13 (72.2)	337	1 sided Fisher's exact =0.412, p=0.800*
Male	163 (33.5)	05 (27.8)	168	
<b>Age (years)</b>				
20-30	232 (47.6)	09 (50)	241	Pearson Chi2=0.7476 p=0.862*
31-40	144 (29.6)	04 (22.2)	148	
41-50	79 (16.2)	04 (22.2)	83	
>50	32 (6.6)	01 (5.6)	33	

**Table 2: Association between category of HCP & BMI and anti-HBs antibody titre (n = 505)**

	AHBS >10 mIU/ml (n=487) (%)	AHBS <10 mIU/ml (n=18) (%)	Total No.	p Value
<b>Category of HCP</b>				
Doctors	95 (19.5)	04 (22.2)	99	Pearson Chi <sup>2</sup> =1.4945 p=0.828*
Nurses	308 (63.2)	11 (61.1)	319	
Assistants	30 (6.2)	02 (11.1)	32	
Technicians	36 (7.4)	01 (5.6)	37	
Attendants	18 (3.7)	00 (0.0)	18	
<b>BMI (kg/m<sup>2</sup>)</b>				
<18.5	35 (7.9)	02 (11.1)	37	Pearson Chi <sup>2</sup> =6.5839 p=0.086*
18.5-24.9	391 (80.3)	11 (61.1)	402	
25 - 29.9	49 (10.1)	03 (16.7)	52	
>30	12 (2.5)	02 (11.1)	14	

**Table 3: Association between duration after the last dose of vaccine and anti-HBs titre (n = 403)\***

Duration of anti-HBs titre done after last dose of vaccine	AHBS >10 mIU/ml (n=385) (%)	AHBS <10 mIU/ml (n=18) (%)	Total No. (403)	P Value
1-2 months	50 (12.4)	00 (0.00)	50	Pearson Chi <sup>2</sup> =8.80 61 p=0.01
2 months - < 5 years	236 (58.6)	08 (1.9)	244	
>5 years without booster	99 (24.6)	10 (2.5)	109	

\*Analysis did not include 102 participants whose duration after the last dose of primary vaccination series was more than five years and had taken a booster dose.

All 18 participants whose anti-HBs antibody titres were found to be < 10 mIU/ml following primary vaccination were further studied to find an association between variables (gender, age, BMI, category of HCP and duration after the last dose of vaccination) and anti-HBs antibody titre. Association between variables (gender, age group, category of HCP & BMI) and anti-HBs antibody titres was not found to be significant (Table 1, Table 2). Association between duration after the last dose of vaccine and anti-HBs antibody titres was found to be significant at 95% confidence interval but not at 99% confidence interval by Pearson Chi<sup>2</sup> test (Table 3).

**Discussion:** Health Care Personnel are at a greater risk of various blood borne infections, including infection with HBV. It has been found that vaccination is effective in protecting against HBV infection in about 90-95 % of adults.<sup>11</sup> The effectiveness of protection is determined by measuring anti-HBs antibodies that are produced in response to the vaccination. Anti-HBs antibody, thus, serves as an important serological marker to assess the HBV vaccine induced immunity and therefore sero-testing after HBV vaccination is recommended in many countries worldwide.<sup>12</sup> Protective levels of anti-HBs antibodies are not developed in certain percentage of individuals. In healthy population, the rate of subjects with low or undetectable anti-HBs antibody titre after primary vaccination is 2% to 15%, therefore, making them susceptible to HBV infection.<sup>13</sup>

The present study was aimed to determine the anti-HBs antibody titres of the HCP at Shree Krishna – a tertiary care hospital in Karamsad, Gujarat, India and to investigate an association between demographic profile as well as duration after the last dose of vaccination and observed anti-HBs antibody titre.

In the present study, a total of 505 health care personnel who received complete three doses of HBV vaccination were evaluated for their anti-HBs antibody titres. The overall immune response was 96.4% irrespective of the categories studied where titres were found to be  $\geq 10$  mIU/ml. Globally, seroconversion rate following three doses of HBV vaccination has been found between 55 – 100%.<sup>2,14-23</sup> In present study, it was found that 334 (66.13%) participants had anti-HBs antibody titre  $>500$  mIU/ml. In present study, a titre of  $<10$  mIU/ml was seen in 18 (3.56%) out of total 505 participants. Seroconversion rate among these participants following three doses of revaccination was 100% where 15 (83.3%) participants had anti-HBs titre  $>500$  mIU/ml. Li Zhang *et al* found seroconversion rate of 89.24% following third dose of re-vaccination.<sup>18</sup> Although there were no non-responders in the present study, we evaluated the reason for low titres ( $< 10$  mIU/ml) with respect to their demographic profile as well as duration after the last dose of vaccination.

In present study, successful immune response was found in 97% males and 96% females. Previous studies have shown successful immune response ranging from 87 – 97% in males and 89 – 97% in females.<sup>24,25</sup> As shown in Table 1, there was no significant association between gender and failure to respond to primary vaccination ( $P = 0.8$ )

In present study, the rate of seroconversion following primary vaccination ranged from 95% - 97% in various age groups. Contrary to this was results observed by N Kollathodi *et al*, where they reiterated the inverse relation between age and vaccine immunogenicity with younger individuals showing higher response compared to older people.<sup>24</sup> CN Chaudhari *et al* also had similar results where they found 93.8% response in age group  $<30$  years compared to 77.5 % in those age  $>50$  years.<sup>25</sup> In contrast to our study, other study reported older age group as an important factor in the reduced immunogenicity of the HBV vaccine.<sup>2</sup> As shown in Table 2, we did not find any association

between age group and failure to respond to primary vaccination ( $P = 0.8$ ).

Present study demonstrated a successful immune response of 96.43% among various HCP. In contrast to these V Batra *et al*, in their study found that 30% of the vaccinated health care workers mainly doctors had low anti-HBs titre  $<10$  mIU/ml.<sup>11</sup> As shown in Table 3, we did not find any significant association between category of HCP and failure to respond to primary vaccination ( $P = 0.8$ )

As shown in Table 4, we could not establish any statistical significance between the BMI and failure to respond to primary vaccination ( $P = 0.08$ ). Similar results were seen in the study done by N Kollathodi *et al* where BMI did not significantly contribute in low titres.<sup>24</sup> In study by AJ Roome *et al*, BMI over 35 is shown as risk factor for vaccine failure.<sup>26</sup>

Anti-HBs antibody titres tend to decline with increase in the duration after the last dose of vaccination.<sup>1</sup> Protective levels of antibodies are maintained for long duration as found in study conducted by V Gilca *et al* where 60% individuals had persistent protective levels of anti-HBs antibodies after 22 years of primary vaccination.<sup>27</sup> In the present study, protective titres were found in all 68 (100%) participants who underwent anti-HBs antibody titre measurement within one to two months after the last dose of vaccination. The protective titres decreased with increase in the duration after the last vaccination where 236 (96.7%) participants maintained protective titres between two months to five years duration after the last vaccination and 99 (90.8%) participants maintained protective titres beyond five years after the last dose of vaccination without taking additional booster dose. In the present study, there were eight participants in the period between two months to five years and 10 participants in the period beyond five years where the titres were found to be insufficient. However, all 10 participants falling in period of more than five years had no history of booster dose. None of the participants was found to have insufficient titre in the duration group of one to two months. As shown in Table 5, there was a significant association between duration after the last dose of vaccination and anti-HBs antibody titres where the titres tend to fall with increase in the duration after the last dose of vaccination ( $P = 0.01$ ). Similar findings were observed by N Kollathodi *et al* and CN Chaudhari *et al* where



anti-HBs antibody titre declined with regards to duration since last dose of vaccination.<sup>24,25</sup> A long term follow up study by CW Wang *et al* also had reported loss of antibody titres over the years.<sup>28</sup>

The term “booster dose” has been used to refer to a dose of Hepatitis B vaccine administered after a primary vaccination series to provide rapid protective immunity against significant infection. The proportion of responders to a challenge dose might vary by population and age at receiving the primary Hepatitis B series. HCP with a response  $\geq 10$  mIU/mL following a challenge dose are considered protected, regardless of future declines in anti-HBs. Further studies are required to conclude response to a challenge dose of vaccine.<sup>1</sup>

There are some known factors like gender, smoking, obesity which influence immune response. H Willacy *et al* found that those above 40 years, obese and smokers are more likely to fail to respond.<sup>29</sup> In a study by N Kollathodi *et al*, 98.2% of the non-smokers responded, whereas only 66.7 % smokers had protective antibody levels.<sup>24</sup> However, in present study, there were only two participants with history of smoking but these two had responded to primary vaccination. Similarly, we did not have significant numbers of participants with history of alcohol, diabetes, hypertension and thyroid disorders. Moreover, all 18 participants who did not have protective titres following primary vaccination, had no history of smoking, alcohol consumption, diabetes, hypertension or other chronic diseases. Other factors that could affect antibody titres are type of vaccine, brand of vaccine and route of administration,<sup>30</sup> however; it was not possible to collect this information from the participants in the present study.

Post vaccination anti-HBs titre measurement is recommended one to two months after last vaccine dose as per CDC guidelines.<sup>1</sup> In the present study, all 18 participants whose titres were below protective levels had not undergone measurement of titres after one-two months of primary vaccination. As per the CDC guidelines, completely vaccinated HCP with anti-HBs  $\geq 10$  mIU/mL are considered hepatitis B immune. Immunocompetent persons have long-term protection and do not need further periodic testing to assess anti-HBs levels.

Limitations of the study: We could not comment on the efficacy of the vaccines used as we did not have the data about the brands of the vaccine, type of vaccine and route of administration used by the different group of the participants. Also, Geometric Mean Titre (GMT) of anti-HBs was not measured, as we could not perform the dilutions of the samples with  $>500$  mIU/ml value due to the cost restraints.

Future Scope: Considering different types and brands of Hepatitis B vaccine that are available in the market, we recommend a long term follow up study comparing them for its long-term efficacy.

**Conclusion:** From the finding of the present study it is concluded that an excellent immune response was noted in the HCP where 96.4% participants developed protective antibody levels after primary series of vaccination. All 100% participants developed protective levels of antibodies after secondary series of vaccination. There were no non-responders in the present study. Insufficient levels of antibodies after primary vaccination had significant association with duration after the last dose of vaccination whereas there was no significant association found between insufficient levels of antibodies and factors like gender, age group, category of HCP and BMI. Anti-HBs antibody titres measurement after HBV vaccination is strongly recommended in HCP. For HCP with titres below protective level, revaccination with one or more doses of vaccine and re-testing for anti-HBs titre is advised.

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