

Adherence to multidose Hepatitis B vaccination in a Tertiary Care Centre: A Retrospective Cohort Study

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Abstract

Background: Globally out of 200 crore population who are getting exposed to the hepatitis B virus (HBV), about 350 million are chronically carrying it resulting in 0.5 to 1.2 million deaths each year. These mortalities are due to chronic hepatitis, cirrhosis, and hepatocellular carcinoma (HCC). Horizontal transmission in early childhood and parental transmission at any age are the important routes of transmission. This study was conducted with following objectives.

- (a) To assess the prevalence of adherence to Hepatitis vaccination.
- (b) To associate this adherence with demographic factors.

Methodology: After receiving approval from the Institutional Ethics Committee a record based retrospective cohort study was conducted at Gastroenterology and Hepatology OPD of IMS and SUM Hospital, Bhubaneswar. Data regarding all the patients who have received First dose of Hepatitis Vaccine from January 2019 to December 2019 were followed up till June 2020 to find out how many of them have revisited to obtain second dose as well as third dose of vaccine. Their demographic characteristics collected from the immunisation register. Data was entered and analysed using SPSS vs 21 using appropriate statistics.

Results and conclusion: Total 1134 subjects have received the first dose of Hepatitis B vaccine. Mean age of the participants is 36±15yrs. First dose taken by 453(39.9%) people, 324(28.6%) had completed the schedule by taking the final dose of vaccine. Hardly one third of the patients adheres to the schedule and completes it. Inadequate vaccination makes the patients vulnerable to risks of Hepatitis B and its morbidities.

Key-words- Hepatitis B Virus (HBV), Vaccination, Health care workers (HCW), Hepato-cellular Carcinoma (HCC)

Introduction and Problem Statement:

HBV DNA virus that belongs to Hepa-dna-viridae family causes Hepatitis B infection. It is both acute

and chronic in nature. Acute hepatitis B results in acute inflammation and hepatocellular necrosis. Due to persistent stay of hepatitis B surface antigen [Hbs Ag] in the blood or serum for more than six months, chronic hepatitis B results which may or may not be associated with active viral replication and hepatocellular injury. Among neonates young children the risk of chronicity is (90%) and (20-60%) respectively as compared to (5%) among adults.^{1,2} Hepatitis B infection can result in liver cirrhosis and cancer which are most of the times fatal.^{3,4}

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It accounts for (15 to 40)% of infected cases.⁴

Burden in World: Hepatitis B Virus (HBV) infection is a global public health problem and the tenth leading cause of deaths globally. It has been estimated, nearly 2 billion of the population is infected with HBV worldwide that results in 350million chronic cases and 2 million annual deaths.^{2-3,5-10}

According to WHO around 257 million people are living with hepatitis B surface antigen positive.^{11,12} From a meta-analysis, the prevalence of HBV among general population was reported to be 2.4% and among tribal population 15.9%.¹³

Globally, Chronic viral hepatitis is responsible for almost 1 million deaths .⁴ Hepatitis of all types in toto contributes as seventh leading cause of worldwide mortality. According to The 2015 WHO Global hepatitis report about 3.5% of the general population i. e 257 million population are infected with Hepatitis B virus out of which 68% of the persons live in sub- Saharan African and Western Pacific regions (4)At the other hand The 2016 Polaris Observatory study found that around 3.9% of the World's population i. e 292 million persons are suffering from Hepatitis B infection. It was further estimated by the collaborators that out of total infected persons only 10% (29 million) were detected to be infected and among them only 1.4% (1.8 million) were in children who aged less than 5 years. African, Western Pacific, and Southeast Asia regions contribute to about 80% of the cases worldwide.⁴

HBV infection resulting in cancer attributes to million deaths worldwide annually.¹⁰

In 2015, 887,000 deaths occurred worldwide due to complications related to chronic HB virus infection.¹²

Burden In India:

In India, HBsAg prevalence among the general population ranges from 2 to 8%, which places India in an intermediate HBV endemicity zone and India with 50 million cases, is also the second largest global pool of chronic HBV infections.^{6,7,9}

India falls in the intermediate endemicity zone with an average prevalence of 4%. Pockets of higher endemicity are found in tribal areas where the high burden is maintained through intra-caste marriages, tribal customs, illiteracy and poor exposure to health care resources.⁷ In India it is estimated that 2 to 10% of the population are infected with Hepatitis B virus which accounts to 40 million .^{1,8} Annually over 100,000 Indians die because of disease related with HBV infection.⁸

Next to Hepatitis E, HBV is the most common cause for acute hepatitis in India being responsible for nearly one-third of acute viral hepatitis patients.⁹

Viral hepatitis is one of major public health problems in India. On an average about (3-4) % of the population carry Hepatitis B virus antigen. In India, 40% of Hepato-cellular Carcinoma (HCC) and 20-30% cases of cirrhosis are due to chronic HBV infection. About 4.7% population i. e 56.5 million are carrier for Hepatitis B carrier rate in India.¹

Risk factors:

Blood to blood contact, mother to child transmission, unprotected sexual intercourse and sharing salon equipments are the most important routes of transmission of Hepatitis B from one individual to another.⁸

Sexually active heterosexual adults with more than one sex partner in the prior 6 months ,man or woman having history of sexually transmitted disease; men having sex with men; illicit injection drug users, haemodialysis patients and persons at occupational risk of infection are vulnerable to get infected with Hepatitis B.^{1,5}

Similarly, recipients of multiple blood/ blood products transfusion, prisoners, migrants and truckers and first degree relatives and family members like mother, siblings, spouse and children, of persons affected with viral hepatitis are also at risk of acquiring the infection.¹

Horizontal transmission in early childhood (mostly from family contacts) and to lesser extent by perinatal transmission are most common modes of transmission

in India. Due to contact of non-intact skin or mucous membranes with tears, saliva or blood containing HBV-infected secretions or through sharing of toothbrushes horizontal transmission occurs.¹⁴

There is even chance that patients remain asymptomatic for years and unknowingly may transmit the infection to others via perinatally, percutaneously, sexually, or through close person-to-person contact (e.g., open cuts and sores).⁴

Health care workers (HCW):

Health care workers (HCW) are defined as persons whose activities involve contact with patients or with blood or other body fluids from patients in health care or laboratory settings. They are at occupational risk of exposure to blood borne pathogens like Hepatitis B virus (HBV). In developing countries only 40-60% HBV infections in HCW are attributed to percutaneous occupational exposure due to sharp injuries.^{10,15} Healthcare workers always have a high risk of getting exposed to many blood-borne pathogens like HIV, Hepatitis B, and Hepatitis C.⁶ There is severe risk of infection among HCWs because of too many virus carriers in the surrounding population, frequent exposure to blood and other body fluids as well as high contagious nature of HBV. Performance of invasive procedures, mucocutaneous exposure while examining the patients physically as well as accidental exposures due to improper disposal of sharps makes HCWs vulnerable to Hepatitis B infection.⁹

Amongst all the body fluids blood has the highest amount of HBV titres and hence is the major vehicle for transmission in the healthcare setting.^{6,11}

Due to inadequate sterilisation process and improper hospital waste management there has been rise and spread of hepatitis B as 10 to 20% health care waste is generated to cause hazards.⁸ There has been rise and There is (6 to 30)% risk of acquisition of HBV infection in non- vaccinated person after single exposure.¹¹

Health-care delivery is responsible for transmission of hepatitis B virus (HBV) to both health-care staff as

well as patients. The risk of transmission is dependent on frequency of exposure as well as to how much extent an individual has come in direct contact with human blood and body fluids. HCWs are susceptible to acquire infections from the patients as well as vice versa. The prevalence of HBV infections among HCWs is 14.4%. Dentists, physicians nursing staff, dialysis, and laboratory staff are at highest risk of getting infected.¹⁰

Needlestick injuries (NSIs) have been defined by The National Institute for Occupational Safety and Health, Centres for disease control and prevention(CDC), as “those injuries caused by needles such as hypodermic needles, blood collection needles, intravenous (IV) stylets, and needles used to connect parts of IV delivery systems.” Out of 35 million health-care workers (HCWs) around 2million sustain NSIs every year, as a result of which they are at risk of exposure to blood-borne infectious agents including HBV.¹⁴

Through NSIs risk of transmission of HBV is (6%–30%).^{5,14}

As compared to adult general population, HCWs are four fold more at risk of acquiring the Hepatitis B infection.^{3,5,11}

After percutaneous exposure to blood the risk of infection with hepatitis B is about 30%.⁵

The risk of HBV infection is determined by the degree of contact with blood in the workplace and also HBsAg to the hepatitis B-e antigen (HB-e Ag) status of the source person. There is evidence that HBV is able to survive in dried blood, at room temperature, on environmental surfaces, for a long time. It is found in several other body fluids, including breast milk, bile, cerebrospinal fluid, faeces, nasopharyngeal washings, saliva, semen, sweat, and synovial fluid. Degree of exposure to the infected body fluids or blood-contaminated sharps such as needles and other medical instruments, and the duration of employment in an occupational risk category are important determining factors.⁶

It has been estimated that about a million HCWs are suffering from cut and puncture injuries per year. As

per the report of The Department of Health and Human Services, Centres for Disease Control and Prevention (CDC) United States “the risk of infection is depends on the no. of HBV carriers prevalent ,how frequently the HCWs are exposed to blood and body fluids and how infective is the virus”.³

Vaccination:

A vaccine against hepatitis B has been available since 1982 with the efficacy 85-90% in preventing infection.⁸ Routine immunization against hepatitis B has led to a significant reduction in the prevalence of chronic HBV infection among many countries. Based on the global experience, it is liable that an effective childhood immunization program will reduce the burden of infection in this country.⁹

Immunisation along with strict adherence to infection control protocol is one of the most effective prevention strategies for the protection against hepatitis B infection, especially in high-risk groups including the HCWs.^{6,10}

As it indirectly helps in the prevention of hepatocellular carcinoma it is considered as the first anticancer vaccine.^{8,10}

As per the standard schedule vaccine has to be administered in three doses at 0-, 1-, and 6-month interval. There should be at least 4weeks gap between 1st and 2nd dose and 8weeks gap between 2nd and 3rd dose respectively. It has to be injected through intramuscular route in the deltoid region with a 1–1.5-inch long needle.¹⁰

Compulsory availability of hepatitis B vaccination services at all hospitals along with postexposure prophylaxis (PEP) can only prevent HCW from getting infected with hepatitis on occupational exposure.¹⁰ The above strategy has infact drastically reduced the occupationally acquired HBV infection in many countries.^{10,12}

World Health Assembly in 2016 through its The Global Health Sector Strategy on viral hepatitis called for the elimination of viral hepatitis by 2030. WHO

recommends that Hepatitis B vaccine to be administered at birth followed by two or three doses .¹²

In India Hepatitis B vaccine was introduced in the Universal Immunization Program (UIP). It was initially started in 2002-2003 on a pilot basis in 14 cities and 33 districts.

In Phase I it was expanded to ten states in 2007–2008. In Phase 2 i. e 2011–2012 is then extended to the entire country. Vaccine coverage in India has thus increased from 28.9% in 2007–2008 to 62.8% in 2015–2016.^{7,12} Self-reported hepatitis B vaccination coverage among adults at risk for HBV infection which was 30% in 1981 increased to 45% in 2002-2004 . It has probably resulted in 35% reduction (from 3.7 to 2.4 per 100,000 populations) in acute hepatitis B incidence during this period. This justifies the need of people at risk of getting infected with Hepatitis B to get vaccinated.

Sero- protection i. e (Anti-HBs level \$10 m IU/ml) has been determined to be 20-30%, 75-80%, and 90- 95%, following first, second and third dose respectively.⁶

Policy of administration of Hepatitis B vaccine to at risk individuals has been widely implemented in countries such as UK, USA, and Israel .³

Almost all of the children and adults who are receiving the three dose schedule of the vaccine are developing protective antibodies. It has been recommended by the Advisory Committee on Immunization Practices (ACIP) that hepatitis B vaccine should be administered to every individual below 18 years as well as to those above 18 years who are at risk of getting infected.⁵

As per estimates of WHO, in developing countries, on an average (18-39) % of HCWs are vaccinated against Hepatitis as compared to (67-79%) in developed nations.¹⁵

Objectives:

1. To assess the prevalence of adherence to Hepatitis vaccination.
2. To associate this adherence with demographic factors.

Methodology

After receiving approval from the Institutional Ethics Committee a record based retrospective cohort study was conducted at Gastroenterology and Hepatology OPD of IMS and SUM Hospital, Bhubaneswar. Data regarding all the patients who have received First dose of Hepatitis Vaccine from January 2019 to December 2019 were followed up till June 2020 to find out how many of them have revisited to obtain second dose as well as third dose of vaccine as per the schedule. During their visit to the immunization unit, they were explained about the disease and the benefit of completion of three doses of vaccination, and on the day they received the first dose, a vaccination card mentioning the dates was provided to them. Their demographic characteristics i.e age and gender was also collected from the immunisation register.

Data was entered and analysed using SPSS vs 21 using appropriate statistics.

Results

Total 1134 persons have got vaccinated with the first dose of Hepatitis B vaccine from January 2019 to

December 2019.

Table I Illustrates the demographic profile. Among them, 729(64.3%) are males. Mean age of the participants is 36±15yrs.Half of the participants aged from 20 to 40yrs.

Table II indicates the month wise distribution of beneficiaries of first dose of Hepatitis vaccine (n=1134). Most of the beneficiaries had taken their first dose in February (13.8%), March (11.5%), April (11.6%) and November (11.5%).

Table III indicates the distribution of patients according to receipt of the three doses of vaccine. Out of the 1134 first time vaccines 453(39.9%) had taken second dose and 324(28.6%) had completed the schedule by taking the final dose of vaccine

According to Table IV, Out of 1134 candidates, only 324(28.6%) completed the three dose schedule.

Table V infers that No significant association was found with age groups with completion of schedule. Table VI shows that No significant association was found with gender with completion of schedule.

Table-I Demographic profile of beneficiaries(n=1134)

Gender wise distribution	
Male	729(64.3%)
Female	405(35.7%)
Mean Age= 36.4+-15.3years	
Age group wise distribution	
0-9 yrs	10(0.9%)
10-19 yrs	129(11.4%)
20-40 yrs	569(50.2%)
41-60 yrs	347(30.6%)
61-75 yrs	71(6.3%)
>76 yrs	8(0.7%)

Table II Month-wise distribution of vaccination(n=1134)

Jan	103(9.1%)
Feb	156(13.8%)
March	130(11.5%)
April	132(11.6%)
May	42(3.7%)
June	51(4.5%)
July	58(5.1%)
Aug	94(8.3%)
Sept	54(4.8%)
Oct	108(9.5%)
Nov	130(11.5%)
Dec	76(6.7%)

Table-III Distribution of beneficiaries according to receipt of vaccines (n=1134)

Dose	Taken	Not taken
I	1134(100%)	0(0%)
II	453(39.9%)	681(60.1%)
III	324(28.6%)	810(71.4%)

Table-IV Status of three dose schedule(n=1134)

Schedule completed	324(28.6%)
Schedule not completed	810(71.4%)

Table -V Association of age groups with status of completion of vaccination schedule

Age groups	Not completed	completed	X2	P
0-9years	7(70%)	3(30%)		
10-19 years	88(68.2%)	41(31.8%)		
20-40years	410(72.1%)	159(27.9%)	8.132	0.149
41-60years	258(74.4%)	89(25.6%)		
61-75 years	43(60.6%)	28(39.4%)		
³ 76 years	4(50%)	4(50%)		

Table VI- Association of gender with status of completion of vaccination schedule

Gender	Not completed	completed	X2	P
Male	518(71.1%)	211(28.9%)		
Female	292(72.1%)	113(27.9%)	0.139	0.382

Discussion

No studies have been yet done to assess the compliance of general population to multidose Hepatitis B Vaccination. Most of the studies discuss the adherence of healthcare workers to the vaccination schedule.

In a study by Choudhry et al it was found that out of 254 HCWs recruited for the study, 48 (18.9%) were doctors, 93 (36.6%) were nursing staff, 104 (40.9%) were paramedics and rest 9(3.5%) were housekeeping professionals. Among them, 146 i.e 57.5% HCW had received vaccination against HBV. It was analysed that 77% of medical professionals and 43% of the paramedics were compliant towards vaccine. On the contrary housekeeping personnel were not compliant to vaccine. Adherence to vaccine was present among 77(51%) males and 69 (67%) females. Study subjects

aged from 19 to 54 years. The mean age at which medical professionals got vaccinated was 30.5 ± 7.3 years whereas that for nursing professionals was 24.7 ± 6.1 years.¹⁵

Siraj et al in their study found that, among 150 cases 69 were medical professionals and 81 were Para-Medical workers. Out of 55(79.7%) medical staff who were vaccinated, 29 (42.02%) had taken 3 doses whereas 26(47%) had taken only 2 doses. Among the 48(59.25%) paramedical staff who were vaccinated 24(50%) and 18(37.5%) had taken 3 doses and 2doses respectively.⁸

In a study by Mangaiyarkarasi et al, out of the 83 HCWs, 37(44.5%) had completed the schedule of HBV vaccine, 15(18.1%) were incompletely vaccinated whereas 31(37.3%) were completely unvaccinated. Out of the 15 who were partially vaccinated, 9(60%) have

received two doses whereas and 6(40%) were vaccinated with only one dose.¹⁴

Kumar S et al in their study found that 46.2%, 12%, 41% HCW fully vaccinated, partially vaccinated, not vaccinated respectively.¹⁶ Hussain S et al had complete immunization rate of 57.6%, partial 18.5% and non vaccinated 24% respectively.¹⁷ Chandra S et al revealed that 48.5% had got completely vaccinated, 21.8% incompletely vaccinated and 29.7% unvaccinated with hepatitis B vaccine.¹⁸

Conclusion: Hardly one third of the patients adheres to the schedule and completes it. Failure to complete the schedule makes the patients vulnerable to risks of Hepatitis B associated consequences like Chronic Hepatitis B, Cirrhosis, and Hepatocellular Carcinoma. There is need to raise awareness among public regarding the fact that these adverse events are preventable through three dose vaccination. It has to be supplemented by well organised and clear policies for screening of Hepatitis B and vaccination against it among at risk population.

Limitations-As it is a record based study, hence much information could not be collected. There is scope of Prospective cohort studies in which we can proceed along time and follow up the vaccine recipients to explore the associations of outcomes of Chronic Hepatitis B and its complications with the vaccination status of the patients.

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Conflicts of Interest- None

References

1. Malhotra P, Malhotra V, Pushkar, Gupta U, Sanwariya Y. Prevalence of Hepatitis B and Hepatitis C in tertiary centre of Northern India. *Adv Res Gastroenterol Hepatol.* 2020;15(4):00140–3.
2. Madihi S, Madihi S, Syed H, Lazar F, Zyad A, Benani A. A Systematic Review of the Current Hepatitis B Viral Infection and Hepatocellular Carcinoma Situation in Mediterranean Countries. *Biomed Res Int.* 2020;2020.
3. Omotowo IB, Meka IA, Ijoma UN, Okoli VE, Obienu O, Nwagha T, et al. Uptake of hepatitis B vaccination and its determinants among health care workers in a tertiary health facility in Enugu, South-East, Nigeria. *BMC Infect Dis.* 2018;18(1):1–9.
4. Lim JK, Nguyen MH, Kim WR, Gish R, Perumalswami P, Jacobson IM. Prevalence of Chronic Hepatitis B Virus Infection in the United States. *Am J Gastroenterol.* 2020;115(9):1429–38.
5. Yousafzai MT, Qasim R, Khalil R. Hepatitis B Vaccination among Primary Health Care Workers in Northwest Pakistan. *Int J Health Sci (Qassim).* 2014;8(1):67–76.
6. Singhal V, Bora D, Singh S. Hepatitis B in Health Care Workers: Indian Scenario. *J Lab Physicians.* 2009;1(02):041–8.
7. Ray G. Current scenario of hepatitis b and its treatment in India. *J Clin Transl Hepatol.* 2017;5(3):277–96.
8. Siraj F, Fareed P, Mahajan N. Assessment of knowledge attitude and practice towards hepatitis B among health care workers in a tertiary care hospital. *Int J Reprod Contraception, Obstet Gynecol.* 2016;5(1):58–61.
9. Bedi R. Changing patient safety in India: Mandatory hepatitis B immunity. *Contemp Clin Dent.* 2015;6(1):1–2.
10. Kashyap B, Tiwari U, Prakash A. Hepatitis B virus transmission and health-care workers: Prevention, management, and awareness toward the disease. *Indian J Med Spec.* 2019;10(1):6.
11. Chanda DD, Chakravarty A, Upadhyay S. Prevalence of Hepatitis B Virus Infection among Non-Vaccinated Health Care Workers of Cachar region of North East India. 2020;7(May):110–3.
12. Murhekar M V., Santhosh Kumar M, Kamaraj P, Khan SA, Allam RR, Barde P, et al. Hepatitis-B virus infection in India: Findings from a nationally representative serosurvey, 2017-18. *Int J Infect Dis.* 2020;100:455–60.
13. Reddy DCS. Elimination of viral hepatitis: Evolution and India's response. *Indian J Public*

- Health. 2019;63(4):275–6.
14. Thiagarajan M, Ranganathan U, Shivekar S, Rangasamy G. Trends of voluntary reporting of needlestick injuries and hepatitis B vaccination status among health-care workers of a tertiary health care center in Puducherry. *J Lab Physicians*. 2019;11(04):352–5.
 15. Chaudhari CN, Bhagat MR, Ashturkar A, Misra RN. Hepatitis B immunisation in health care workers. *Med J Armed Forces India [Internet]*. 2009;65(1):13–7. Available from: [http://dx.doi.org/10.1016/S0377-1237\(09\)80046-4](http://dx.doi.org/10.1016/S0377-1237(09)80046-4)
 16. Kumar S, Begum R, Farooq U, Kumari P. Hepatitis B Seropositivity and Vaccination Coverage among Health Care Workers in a Tertiary Care Hospital in Moradabad , UP , India. *Int J Sci Study*. 2014;1(4):4–7.
 17. Hussain S, NA P, Sham R. Hepatitis B and C Prevalence and Prevention Awareness among Health Care Workers in a Tertiary Care Hospital. *Int J Pathol*. 2010;8(1):16–21.
 18. Chandra S, Joshi G, Y S. Hepatitis B vaccination status among healthcare workers in a tertiary care hospital in Haldwani City of Nainital,Uttarakhand,India. *Ann Trop Med Public Heal*. 2014;2(7):96–9.