

## Anti HBs Titers in Health Care Persons of Clinical Laboratory.

Dr. Jaya Lakshmi L<sup>1</sup>, \*Dr. Alekhya P<sup>2</sup>, Dr. Sasikala G<sup>3</sup>

<sup>1</sup>Associate Professor, Department of Microbiology, Osmania Medical College, Hyderabad, India.

<sup>2</sup>Senior Resident, Department of Microbiology, Gandhi Medical College, Hyderabad, India.

<sup>3</sup>Professor & HOD, Department of Microbiology, Osmania Medical College, Hyderabad, India.

Corresponding Author: \*Dr. Alekhya P

**Abstract:** Antibodies to Hepatitis B surface antigen (Anti HBs) are protective antibodies against Hepatitis B virus (HBV) infection. Health care persons are vulnerable to laboratory acquired infections as they handle infectious clinical specimens. HBV is highly infectious and at least 85 – 90% of HBV associated deaths are vaccine preventable. The present study was aimed to determine the anti HBs levels in health care persons working in clinical laboratory including Microbiology, Biochemistry and Pathology at a tertiary care hospital, Hyderabad. The material included blood samples collected from 80 health care persons of clinical laboratory after taking informed consent and relevant history. Rapid card test was used in screening the sera for Hepatitis B surface antigen (HBsAg). Anti HBs was estimated using ELISA method. Among 80 participants 31 (38.75%) were completely vaccinated, 24 (30%) were incompletely vaccinated and 25 (31.25%) were not vaccinated. 62.5% samples showed protective levels of anti HBs, i.e. more than 10 mIU/mL. Monitoring of anti HBs levels in all health care persons helps in recognizing unprotected persons so that necessary precautions can be advised.

**Keywords:** Anti HBs levels, Health care persons, Vaccination, Protective antibody.

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### I. Introduction

Infection with hepatitis B virus (HBV) is a serious public health problem worldwide and persistent infection, is a major cause of chronic hepatitis, cirrhosis and hepatocellular carcinoma [1,2]. Natural infection occurs only in humans. The prevalence of hepatitis B carriers varies widely in different countries and India falls in the intermediate group [3]. The virus is highly infectious. For non-immune persons, disease transmission from a needle stick exposure is up to 100 times more likely for exposure to hepatitis B envelop antigen (HBsAg) positive blood than to HIV positive blood [4].

Laboratory associated infections (LAI's) are defined as all infections acquired through laboratory or laboratory-related activities regardless whether they are symptomatic or asymptomatic in nature [5]. LAIs are due to wide variety of bacteria, viruses, fungi and parasites. Hepatitis B virus, Hepatitis C virus and Human Immunodeficiency Virus – are common blood borne pathogens of LAI. Any workers who have reasonably anticipated contact with blood and body fluids during performance of their jobs are considered to have occupational exposure and to be at risk of being infected [6].

Health Care Persons (HCP) are defined as all paid and unpaid persons working in health-care settings who have the potential for exposure to patients and/or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces or contaminated air. HCP include (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the health-care facility and persons not directly involved in patient care (e.g., clerical, dietary, housekeeping, laundry, security, maintenance, administrative, billing, and volunteers) but potentially exposed to infectious agents that can be transmitted to and from HCP and patients [7].

Vaccines to prevent HBV infection contain Hepatitis B surface antigen and they became available since 1981 and was recommended by the Advisory Committee on Immunization Practices (ACIP) for HCP in 1982 [8]. At least 85-90% of HBV associated deaths are vaccine preventable as vaccine induce protective immunity by producing antibody to Hepatitis B surface antigen (anti HBs). The protective cutoff level of antibody to Hepatitis B surface antigen was set at 10 mIU/mL, based on vaccine efficacy studies [9]. The duration of vaccine induced immunity is uncertain but it is definitely long term [>15years].

Various studies have shown that prevalence of non-responsiveness to the initial 3-dose regimen ranges between 10 and 15%. Thus estimation of post-vaccination anti-HBs titers is of utmost importance in the protection of health care workers [10].

The aim of the present study was to determine the protective levels of anti HBs titre in health care personnel working in clinical laboratory departments of Microbiology, Biochemistry and Pathology, thus assessing their immunity to hepatitis B infection and to identify non immune and non responders.

## II. Material And Methods

After taking Institutional Ethical committee permission, blood samples from 80 healthcare personnel of clinical laboratory including Microbiology, Biochemistry, and Pathology were collected after taking informed consent. The details of year and month of primary vaccination schedule, booster dose, additional information about previous jaundice, blood transfusion, hospitalization were recorded. Serum was separated and stored at -20°C till tested and thawed completely before testing. Hepatitis B surface antigen (HBs Ag) screening of all the 80 serum specimens was done using rapid card test (Fig.1). Quantitative estimation of Antibody to Hepatitis B surface antigen was done using ELISA method (Dia.Pro Diagnostic, Bioprobe) and titres determined using calibration curve, calibrated against standard dilutions provided in the kit (Fig.2).



Fig 1. HBsAg Rapid Card Test



Fig 2. ELISA test for Anti HBs

## III. Results

Among 80 serum specimens of the study 44 (55%) were from female and 36 (45%) were from male participants. 48 (62.5%) samples were from Doctors and 32 (37.5%) were from laboratory technicians and their age ranged from 23 to 54 years. All the 80 specimens were negative for Hepatitis B surface antigen (HBsAg). 31(38.75%) specimens were from participants with complete three doses of Hepatitis B vaccination, 24(30%) from incomplete vaccinated and 25(31.25%) were from non vaccinated. More than 100 mIU/mL antibody to Hepatitis B surface antigen (Anti HBs) was detected in 33 specimens which include 21 from completely vaccinated and 12 from incompletely vaccinated participants. 2 (6.45%) samples among the 31 completely vaccinated, 8 (33.3%) samples among 24 incomplete vaccinated and 20 (80%) among 25 non vaccinated showed < 10 mIU/mL indicating lack of protective levels of anti HBs (Table 1 & 2).

**Table 1:** Vaccination status and Antibodies to Hepatitis B surface antigen (anti HBs) concentration in serum specimens of 80 Health care personnel

Vaccination status	Anti HBs concentration in sera			Total
	>100 mIU / mL	10 – 100 mIU / mL	< 10 mIU / mL	
Complete vaccinated (n=31)	21 (67.74%)	8 (25.8%)	2(6.45%)	31
Incomplete vaccinated (n=24)	12 (50%)	4 (16.6%)	8(33.3%)	24
Non vaccinated (n= 25)	---	5(20%)	20(80%)	25
Total (n=80)	33 (41.25%)	17 (21.25%)	30 (37.5%)	80

**Table 2:** Time of vaccination and serum concentration of anti HBs in 31 completely vaccinated participants.

years after vaccination	No.of specimens	Serum anti HBs		
		>100mIU/mL	10-100mIU/mL	<10mIU/mL
< 5 years	14	13 (92.85%)	1(7.15%)	--
5 – 10 yrs	8	7 (87.5%)	--	1 (12.5%)
10 – 15 yrs	1	--	1(100%)	--
>15 yrs	8	1 (12.5%)	6 (75%)	1 (12.5%)
Total	31	21 (67.74%)	8 (25.8%)	2 (6.45%)

Decline in the anti HBs to unprotective level of <10 mIU / mL was observed in 2 samples, one each from 5-10 yrs and more than 15 years after complete vaccination. 93.55% of vaccinated, 66.6% of incompletely vaccinated and 20% of non vaccinated showed protective levels of anti HBs with serum levels of >10 mIU / mL.

**Table 3:** Mean value (Average) of Anti HBs titres in sera of 80 participants.

Vaccination Status	Male		Female		Total	
	No.	Mean value	No.	Mean value	No.	Mean value
Complete vaccinated (n=31)	10	207.3043	21	215.5477	31	212.8885
Incomplete vaccinated (n=24)	13	125.3375	11	173.1725	24	147.2619
Non vaccinated (n= 25)	13	11.89168	12	12.55952	25	12.21224

Geometric mean concentration (GMC) is a type of mean or average indicating the central tendency or typical value of a set of numbers by using the product of their values thus GMC can give a meaningful average to compare two or more characters(table -4).

**Table 4:** Quantitative anti HBs levels presented as Geometric mean concentration (GMC)

Vaccination Status	Male		Female		Total	
	No	Geometric Mean	No	Geometric Mean	No	Geometric Mean
Complete vaccinated (n=31)	10	89.136	21	129.6304	31	114.2857
Incomplete vaccinated (n=24)	13	37.6986	11	135.8363	24	67.7663
Non vaccinated (n= 25)	13	1.07192	12	2.08518	25	1.4752

#### IV. Discussion

It is estimated that there are 300 million HBV carriers and as many as 1 million deaths annually due to HBV infection worldwide. Various therapies for persistent HBV infection, such as interferon-  $\gamma$  or antiviral agents have been developed but the goal of eradicating HBV globally depends largely on efforts to prevent new infection. HBV infection is vaccine preventable [11]. In an attempt to reduce the global impact of HBV infection, in 1991 the WHO recommended that HBV vaccine should be integrated into national immunization programs by the year 1997(CDC). HBV vaccination induces protective level of antibody after complete course of vaccination. Despite completing vaccination, non-responsive subjects are more at risk of acquiring the infection with potential progression to fatal sequelae. Various studies have shown that prevalence of non responsiveness to the initial 3-dose regimen ranges between 10 and 15%[10] and in the present study 6.45% of vaccinated did not show protective level of anti HBs i.e. >10 mIU / mL.

Occupational Health and Safety Administration (OHSa) recommends HBV vaccination of all HCW followed by confirmation of vaccine response in all HCW by 'initial' anti-HBs assay within 1-3 months of primary vaccination and advice booster dose if the anti-HBsAg titre is negative[6]. Previous studies carried out in dental students, medical students, medical safety personnel, homosexuals, dialysis patients and organ transplant patients evaluated the anti HBs levels following immunization [12,13,14,15]. Present study was carried out in a group of clinical laboratory workers of departments of Microbiology, Biochemistry and Pathology because clinical laboratory personnel are considered at high risk as they are exposed to blood and body fluids. There are some known factors like gender, smoking and obesity which influence immune response [16]. Such difference was not observed in the present study as there were no smokers or obese individual in our study group which parameters usually affects antibody level.

**Table 5:** Comparison of anti HBs levels in vaccinated persons in various studies

S.No	Study	completely vaccinated persons		
		>100 mIU / mL	10 – 100 mIU / mL	< 10 mIU / mL
1	Chakraborty et al 2011 [11]	63%		
2	Chathuranga et al 2013 [12]	66.4%	23.7%	9.9%
3	T.V.Rao et al 2008 [17]	75%	25%	--
4	Present study 2015	67.74%	25.8%	6.45%

In non vaccinated individuals Chakraborty[11] et al in 2011 reported 100% had less than <10 mIU/ml where as in the present study it showed 20% had levels 10 -100mIU/ml and 80% had levels <10mIU/ml. this could be because the HCW would have developed antibodies following professional exposure to the HBs antigen from the clinical specimens.

#### V. Conclusion

The present observational study was cross sectional in nature and emphasizes on assessment of anti-HBs level after HBV vaccination and periodic monitoring of anti-HBs assay for all health care workers. Thus in persons without protective anti HBs levels revaccination and necessary precautions can be advised.

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