

SERO-EPIDEMIOLOGICAL SURVEY OF HEALTH CARE WORKERS IN MAHARASHTRA

THESIS SUBMITTED
UNIVERSITY OF MUMBAI

FOR THE DEGREE OF
MASTER OF SCIENCE
IN
MICROBIOLOGY

SUBMITTED BY
S. TAISHETE

UNDER THE GUIDANCE OF
DR. ABHAY CHOWDHARY

DEPARTMENT OF VIROLOGY
HAFFKINE INSTITUTE FOR TRAINING, RESEARCH & TESTING
BOMBAY

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Ms Sushma Taishete

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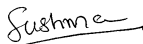
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STATEMENT BY THE CANDIDATE

As required by the University Regulation Number 2190, I wish to state that the work embodied in this thesis titled “**Sero-epidemiological survey of health care workers in Maharashtra**” forms my own contribution to the research work carried out under the guidance of **Dr. Abhay Chowdhary**, Director, Haffkine Institute for Training, Research and Testing, Parel, Mumbai-400012. The work has not been submitted for any other degree of this or any other university. Whenever references have been made to previous works of others, it has been clearly indicated as such and included in the Bibliography.



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1. INTRODUCTION

- 1.1 It is a well known fact that the health care structure has been expanding with rapid gains for the public. Due to the nature of the work the Health Care Workers (HCWs) undertake, it makes them highly vulnerable to work related injuries like wounds, cut & Needle Stick Injuries (NSIs) in turn exposing them to infected blood and body fluids. The infections that could be transmitted following sharps' injuries are due to viral, bacterial and fungal pathogens.
- 1.2 Due to the recognized risk of NSIs, safeguards have been put in place to attempt to lessen the risk of injury (45). These include the policy of universal precautions and needleless systems to connect with intravenous tubing. Several strategies have been adopted such as neutral zone in which to pass sharps, use of blunt tip needles etc. Wearing two pairs of gloves is a practice which protects HCWs from patient's blood and body fluids. A recent study conducted in 2010 found that in 82% of cases when the outer gloves was perforated, the inner gloves had been found to protect the wearer's hand from contamination (45). However, discomfort, restriction of dexterity and impaired sensation of touch were reported to outweigh the benefits afforded by double gloving. Blunt needles require much greater force to induce glove perforation than sharp needles which can protect surgeons from needle-stick injuries. In the USA, the Centers for Disease Control and Prevention (CDC) recommends the use of universal precautions to minimize exposure to blood borne pathogens (15). Nevertheless, the health technology supply industry has not been able to successfully develop cost-effective devices by which to protect the HCWs and so not routinely used in the developing countries such as India. Using needle protective devices or double gloving may be cost effective in the long term. However, there is a need to undertake more cost-effective analysis to determine further validation.
- 1.3 More than 20 infections can be transmitted through needle sticks, including tuberculosis, syphilis, malaria and herpes. Amongst, the viral

infections, Hepatitis B virus (Relative Risk –RR=18-30%) is most common followed by Hepatitis C virus ($RR \leq 0.5\%$) and HIV ($RR \leq 0.3\%$) (59). Though HIV is presently one of the most dreaded viruses, Hepatitis B virus is also of the great importance because of its morbidity and mortality. Ten Percent of the Acute Hepatitis B cases progress to the chronic stage and over a period of 30 to 50 years, to Hepato-Cellular Carcinoma (HCC) eventually leading to death (23). HCC is one of the ten most frequent tumors in the world and there is considerable evidence that 80% of them are caused by chronic infection with HBV (88). The concentration of HBV in blood and body fluids is also much greater than HIV. Nosocomial infection is therefore consequently a greater problem (88). During an active stage, DANE particles (complete 42 nm virus) are so numerous that as little as 0.00001 ml of blood can transmit the infection. This means that minor abrasions or cuts can serve as a portal of entry for such minute quantity of infective material (20). Hepatitis B has been an important cause of occupational infections in HCWs (88). There exists a potent HBV vaccine giving protection against HBV infection in almost 90% of the vaccinees that is unique in being the vaccine that can prevent malignancy. The frequency of nosocomial HBV infection has been greatly reduced by widespread immunization of HCWs (88) However, 5-10% of the vaccinees do not attain adequate protective levels, leaving them at a possible risk of acquiring the HBV infection. Hence this study has been undertaken to understand the knowledge, attitude and practice of associated risks and infection control measures to protect HCWs and to evaluate protective antibodies in HBV vaccinated HCW's and to identify the non-responders which have the highest risk amongst the high risk health care workers, and recommend measures to avoid infections and create suitable work environment for them.

- 1.4 The study conducted at the Safdarjung Hospital, New Delhi published in Indian Journal of Medical Research in March, 2010 (54) has shown that 60% of HCWs are not aware of precautionary options available to them in hospitals and 75% nursing students did not seek help when exposed to NSIs. The most common clinical activity to cause the needle stick injury was blood withdrawal (55%), followed by suturing (20.8%) and vaccination (11.7%). The study has also highlighted the menace caused by the practice of recapping needles after use. About 66.8% HCWs responded positively to recapping needles after use. Only 11.4% HCWs admitted to have bent the needles before discarding.
- 1.5 Generally, interventions around healthcare occupational injuries fall into two major categories, those using double-gloving or blunt needles and those providing educational messages. Interventions using double-gloving or blunt needles are often implemented in different hospital departments or in different operations. In contrast, educational interventions provide information about the negative consequences of healthcare occupational injuries or provide strategies to change attitudes to the occupational injuries. Occupational health and safety is a cross-disciplinary area concerned with protecting the safety, health and welfare of people engaged in work or employment. The goal of all occupational health and safety programmes is to foster a safe work environment. As a secondary effect, it may also protect co-workers, family members, employers, customers, suppliers, nearby communities, and other members of the public who are impacted by the workplace environment. It may involve interactions among many subject areas, including occupational medicine, occupational (or industrial) hygiene, public health, safety engineering, chemistry, health physics etc.

- 1.6 The HCWs are needed to be trained repeatedly on- the- job on the occupational hazards of handling blood, bloody body fluids, sputum etc. with careful attitude. Sensitization of the HCWs on the precautions to be taken on the duty should be highlighted. Sensitization should not only involve loading information on them but to identify the gaps in their knowledge through participatory communication approach and convincing them on the importance of taking precautions for a safer environment for themselves as well as for their co-workers and patients. Attitudinal change in the HCWs, especially those at the bottom rung of the health care delivery is must as they are the crucial transmission agents due to their active handling of body fluids of the patients. Necessity of creation of safe working environment by protecting oneself by using proper gadgets as well as by abiding to cleanliness needs to be stressed upon. Training modules are needed to be developed accordingly for filling up of the knowledge gaps for on- the- job training of these HCWs. Standard operating procedures need to be developed to deal with NSIs to educate HCWs on the hazards of needle-stick injuries, on what they can do to protect themselves and what they need to do in case they are so injured. They can also proactively immunize all HCWs against hepatitis.
- 1.7 Hospitals involved in the network can try whenever possible to switch to safety devices that are specially designed to ensure that sharp objects such as needles are covered with a protective sheath after use. They can also install software eg. EPINet (Exposure Prevention Information Network) to help them further improve their efficiency in tracking and analyzing needle-stick injuries. EPINet provides standardized methods for recording and tracking injuries and blood and body fluid contacts. The system consists of mechanisms to report various injuries and exposures to blood or body fluids and also has a program to help hospitals analyze the data.

- 1.8 Therefore this study was planned among HCWs in the public sector across the State of Maharashtra to understand their awareness level and HBV vaccination status and to make efforts to boost their awareness and enhance safe working practices to create infection safe environment in health care set-up.

2. REVIEW OF LITERATURE

- 2.1 Occupational exposure to pathogenic microbes as a result of needles and other sharps is an important public health concern. In the health care setting transmission of disease from patients to HCWs can occur through percutaneous injuries such as accidental needle stick and sharps injuries. HCWs that come in contact with medical devices such as sharps including syringes or scalpels are at risk of injuries that can lead to serious blood borne infections. Although there are reports of bacteria, viruses (herpes, cytomegalovirus, Epstein Barr virus), fungi, protozoa (malaria) and even tumor cells being transmitted by percutaneous exposures, most studies focus on the main blood borne pathogens as Hepatitis B virus (HBV), Hepatitis C virus (HCV), and Human Immunodeficiency Virus (HIV).

The definition as adopted by the International Labour Organization (ILO) and the World Health Organization (WHO) of Occupational Health reads: "Occupational Health should aim at: the promotion and maintenance of the highest degree of physical, mental and social well-being of workers in all occupations. The prevention amongst workers of departures from health caused by their working conditions; the protection of workers in their employment from risks resulting from factors adverse to health; the placing and maintenance of the worker in an occupational environment adapted to his physiological and psychological capabilities; and, to summarize, the adaptation of work to man and of each man to his job" (56).

2.2 Causative Factors behind Transmission

Viral hepatitis may be caused by either hepatic virus or may occur incidentally during many viral infections, such as yellow fever, Lassa fever, Marburg fever and infections involving Epstein-Barr, cytomegalovirus, herpes simplex, varicella zoster, measles, rubella, HIV or Coxsackie virus. The term viral hepatitis refers to primary infection of

the liver by one of them. Features common to them are hepatotropism and ability to cause icteric illness. All are RNA viruses except HBV which is a DNA virus .

After a needle stick exposure to an infected patient, a HCWs risk of infection depends on the pathogen involved, the immune status of the worker, the severity of the needle stick injury, and the availability and use of appropriate post exposure prophylaxis.

In case of HIV, risk of HIV transmission gets increased when the HCW is exposed to a larger quantity of blood from the patient, as indicated by a visibly bloody device, a procedure that involved placing a needle in a patient's vein or artery, or a deep injury. Such high-risk needle stick injury may have a substantially greater risk of disease transmission per injury. Post-exposure prophylaxis for HIV is recommended for HCWs occupationally exposed to HIV under certain circumstances (49).

The rate of HBV transmission to susceptible HCWs ranges from 6% to 30% after a single needle stick exposure to an HBV-infected patient. However, such exposures are a risk only for HCWs who are not immune to HBV. HCWs who have antibodies to HBV either from pre-exposure vaccination or prior infection are not at risk. In addition, if a susceptible HCW is exposed to HBV, post-exposure prophylaxis with hepatitis B immunoglobulin and initiation of hepatitis B vaccine is more than 90% effective in preventing HBV infection (49).

2.3 Geographic Spread of Viral Hepatitis

Approximately 1 in 12 persons worldwide, or some 500 million people, are living with chronic viral hepatitis. Viral hepatitis is among the top 10 infectious disease killers and the leading cause of liver cancer and cirrhosis. In order to raise awareness of this silent epidemic, the World Health Assembly designated July 28th, 2011 as the World Hepatitis Day. Organizations around the world, including the World Health Organization (WHO) and the Centers for

Disease Control (CDC) used the day to raise awareness and challenge the globe to meet the need for viral hepatitis prevention and control (9).

One million of those who are infected globally die each year, primarily from cirrhosis or liver cancer resulting from their hepatitis B and hepatitis C infections. Many of those who are chronically infected with viral hepatitis are unaware of their infection as the virus can go 20 to 30 years before they develop symptoms or feel sick. As a result, even though a person has no symptoms and may appear healthy, the virus can still be detected in the blood and damage to the liver can still be occurring.

As far as chronic Hepatitis C is concerned, it affects an estimated 170 million people worldwide and causes approximately 35 million deaths each year. Unfortunately there is no vaccine available to prevent hepatitis C, but research is being done to develop one. Most infections are associated with inadequate infection control and unsafe injection practices, which are estimated to account for as many as 4.7 million cases of hepatitis C annually. An estimated 50 million cases of Hepatitis C every year may also occur as a result of many countries not properly screening donated blood.

2.4 Chronic Hepatitis B

An estimated 350 million people are living with chronic Hepatitis B worldwide. About a quarter of them become HBV carriers and a quarter of these develop serious liver diseases, including chronic hepatitis, cirrhosis and primary hepatic cancer (81). Approximately two billion people or one third of the world's population have serological evidence of past or continuing infection with the virus. The WHO estimates that HBV infection causes more than a million deaths worldwide mostly from the sequel of chronic hepatitis. Globally, an estimated 78% of primary liver cancer and 57% of liver cirrhosis cases are caused by viral hepatitis each year .

- 2.5 The virus is common in many areas across the world, especially Asian and African countries. The proportion of persons living with viral hepatitis

is greatest in Asia, sub-Saharan Africa, and Egypt; however, prevalence of HCV infection is high among subpopulations (e.g., IDUs and persons living in correctional settings) in almost all parts of the world. Based on the prevalence of hepatitis B carrier state in the general population, countries are classified as having high (8% or more), intermediate (2-7%), or low (less than 2%) endemicity. Geographic regions with high HBV endemicity with HBsAg prevalence of >8% consists of regions with following countries (11)-

1. Africa: All countries except Algeria, Djibouti, Egypt, Libya, Morocco and Tunisia
2. Southeast Asia: All countries except Malaysia
3. East Asia: Hong Kong, Mongolia, North and south Korea and Taiwan
4. Australia and South Pacific: All except Australia, Guam and New Zealand
5. Middle East: Jordan and Saudi Arabia
6. East Europe: Albania, Armenia, Azerbaijan, Bulgaria, Croatia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Turkmenistan and Uzbekistan
7. West Europe: Malta and Greenland
8. North America: Alaska and North Canada
9. South America: Bolivia, Brazil, Colombo, Peru and Venezuela, Caribbean, Turks and Calicos

Despite the success of the hepatitis B vaccine, only about 1 in 5 infants globally receive a birth dose of Hepatitis B vaccine, which is necessary to prevent mother's infected with hepatitis B from spreading it to their newborns (9). Also, many adults who are at risk for getting hepatitis B remain unvaccinated, including 50% of adults at risk in the United States. Inadequate screening of donated blood in many parts of the world causes up to 8 million hepatitis B infections every year and unsafe

injection practices, many of which are linked to injection drug use may result in as many as 16 million hepatitis B cases annually (9).

In the rich and developed countries infection occurs mostly in the adolescents and youngs through contaminated syringes and needles (among drug addicts) and sex (mostly homosexuals). In the poor and less developed countries infection occurs usually at younger ages either perinatally from mother to baby or horizontally among children. Perinatal and horizontal infection in infants and neonates leads to asymptomatic infection with circulating HBeAg and HBV DNA without any rise in transaminase levels. This is due to their inability to mount virus immune response. Such cases become chronic carriers with higher chances of HCC in later life (24).

Figure 1: Worldwide rates of chronic Hepatitis B

Worldwide Rates of Chronic Hepatitis B



2.6 Hepatitis in India

Hepatitis B is a major health problem in India. On HBV endemicity, India is at the intermediate endemic level of hepatitis B, with hepatitis B surface antigen (HBsAg) prevalence between 2% and 10% among the populations studied. The prevalence does not vary significantly by region in the country. The number of HBsAg carriers in India has been estimated to be over 40 million with carrier rate of 4% which is the second largest, next only to China. About a quarter of the carriers in India are HBe Ag positive i.e., super carriers. This carrier state is more common among the males (51).

In India, of the 25 million infants born every year, over one million run the lifetime risk of developing chronic HBV infection. Estimates indicate that annually over 10 million Indians die due to illnesses related to HBV infection.

Wide variations in social, economic and health factors of different regions may explain variations in carrier rates from one part of the

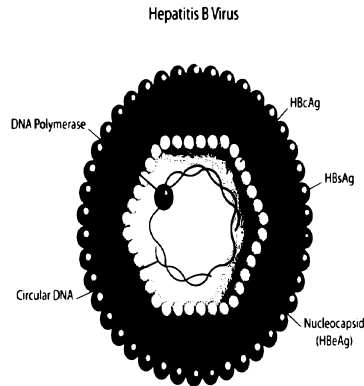
country to another. Professional blood donors constitute the major high-risk group for HBV infection in India, with a hepatitis surface antigen B positivity rate of 14%. Blood transfusions represent the most important route of HBV transmission among adults. However, most of India's carrier pool is established in early childhood, predominantly by horizontal spread due to crowded living conditions and poor hygiene. HBV is reported to be responsible for 70% of chronic hepatitis cases and 80% of cirrhosis of liver cases. About 60% of those cases with hepatocellular carcinoma are HBV marker positive. Co-infection with hepatitis c virus or hepatitis delta virus is comparatively uncommon (51).

The prevalence of hepatitis C has ranged from 10.8% to as high as 48.5% (13). The study that reported the highest prevalence of hepatitis C had a hepatitis B prevalence of 69.5% suggesting that co-infection of HBV and HCV is indeed a significant problem in India (4). A significantly high prevalence of co-infection rate of 24.7% was noted in the report from Punjab (4). In Mumbai, the prevalence rate of Hepatitis C is 1-2%. Mumbaiers' lack of hygienic eating habits and exposure to contaminated drinking water may have been contributing in increasing number of hepatitis A and E (which are water borne diseases) cases in the city (4).

The lowest prevalence rate of Hepatitis B has been observed in Chandigarh in northern India (51) and highest prevalence rate has been observed in Chennai in south India (51). Anti-HBs anti-body positivity, indicating past infection, follows the same epidemiological pattern as that of HBsAg and about 14% of health volunteer blood donors are estimated to be anti-HBs positive. Limited studies of rural versus urban population suggest that their HBV carrier and infection rates are similar. But a recent study on the systemic review and meta-analysis of the prevalence of hepatitis B in India confirms that in tribal and non-tribal populations of India, it is 15.9% and 2.4% respectively (51). It is understood that only a large national epidemiological study can give a final answer as to the overall prevalence of hepatitis B in India. In the

absence of such a national sample survey, a meta-analysis of all the studies from India provides the best evidence.

Figure 2: Structure of Hepatitis B virus



2.7 Hepatitis B virus structure

Hepatitis B virus (HBV) is a member of the Hepadnavirus family (81). The virus particle, virion consists of an outer lipid envelope and an icosahedral nucleocapsid core composed of protein. The nucleocapsid encloses the viral DNA and a DNA polymerase that has reverse transcriptase activity. The outer envelope contains embedded proteins that are involved in viral binding of, and entry into, susceptible cells. The virus is one of the smallest enveloped animal viruses, with a virion diameter of 42 nm, but pleomorphic forms exist, including filamentous and spherical bodies lacking a core. These particles are not infectious and are composed of the lipid and protein that forms part of the surface of the virion, which is called the surface antigen (HBsAg), and is produced in excess during the life cycle of the virus (81).

Genome

The genome of HBV is made of circular DNA, but it is unusual because the DNA is not fully double-stranded. One end of the full length strand is linked to the viral DNA polymerase. The genome is 3020–3320 nucleotides long (for the full-length strand) and 1700–2800 nucleotides long (for the short length-strand). The negative-sense, (non-coding), is complementary to the viral mRNA. The viral DNA is found in the nucleus soon after infection of the cell. The partially double-stranded DNA is rendered fully double-stranded by completion of the (+) sense strand and removal of a protein molecule from the (-) sense strand and a short sequence of RNA from the (+) sense strand. Non-coding bases are removed from the ends of the (-) sense strand and the ends are rejoined. There are four known genes encoded by the genome, called C, X, P, and S. The core protein is coded for by gene C (HBcAg), and its start codon is preceded by an upstream in-frame AUG start codon from which the pre-core protein is produced. HBeAg is produced by proteolytic processing of the pre-core protein. The DNA polymerase is encoded by gene P. Gene S is the gene that codes for the surface antigen (HBsAg). The HBsAg gene is one long open reading frame but contains three in frame "start" (ATG) codons that divide the gene into three sections, pre-S1, pre-S2, and S. Because of the multiple start codons, polypeptides of three different sizes called large, middle and small (pre-S1 + pre-S2 + S, pre-S2 + S, or S) are produced. The function of the protein coded for by gene X is not fully understood but it is associated with the development of liver cancer. It stimulates genes that promote cell growth and inactivates growth regulating molecules (81).

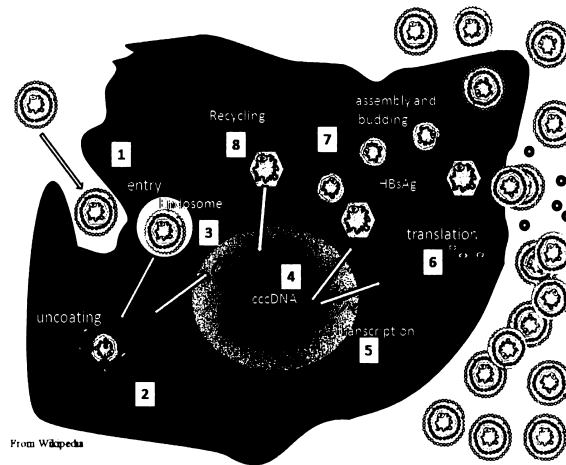
2.8 Life cycle of Hepatitis B

The life cycle of hepatitis B virus is complex (81). Hepatitis B is one of a few known non-retroviral viruses which use reverse transcription as a part of its replication process.

Attachment

The virus gains entry into the cell by binding to a receptor on the surface of the cell and enters it by endocytosis. The cell surface receptor has yet to be identified however, it is suspected to be a member of the ovalbumin family of serine protease inhibitors.

Figure 3: Life Cycle of Hepatitis B



Penetration

The virus membrane then fuses with the host cell's membrane releasing the DNA and core proteins into the cytoplasm.

Uncoating

Because the virus multiplies via RNA made by a host enzyme, the viral genomic DNA has to be transferred to the cell nucleus by host proteins called chaperones. The core proteins dissociate from the partially double stranded viral DNA which is then made fully double stranded and transformed into covalently closed circular DNA (cccDNA) that serves as a template for transcription of four viral mRNAs.

Replication

The largest mRNA (which is longer than the viral genome) is used to make the new copies of the genome and to make the capsid core protein and the viral DNA polymerase.

Assembly

These four viral transcripts undergo additional processing and go on to form progeny virions which are released from the cell or returned to the nucleus and re-cycled to produce even more copies.

Release

The long mRNA is then transported back to the cytoplasm where the virion P protein synthesizes DNA via its reverse transcriptase activity.

2.9 Transmission of Viral Hepatitis

HBV is a blood borne virus and infection is transmitted by parental, sexual and perinatal modes. DANE particles are so numerous that as little as 0.00001ml of blood can transmit infection. Therefore minor cuts and abrasions can serve as a portal of entry for such minute amounts of infective material (64). Hepatitis B virus (HBV) is transmitted primarily by infected blood and body fluids. Perinatal, percutaneous, and sexual transmission account for the majority of cases of acute and chronic HBV infection worldwide. Viral titers are highest in blood and serum; they are intermediate in semen, vaginal fluid, and saliva; and they are lowest in urine, feces, and breast milk (27).

Vertical transmission refers to the transmission of hepatitis B virus (HBV) from mother to infant immediately before or after birth. Also called mother-to-infant transmission or perinatal transmission, vertical transmission is very efficient and the most important mode of HBV transmission in highly endemic areas (12). Among infants born to hepatitis B e antigen (HBeAg)–positive mothers with high HBV DNA levels ($> 7.3 \log_{10}$ IU/mL) at the time of delivery, 70% to 90% acquire HBV infection (37).

Horizontal transmission refers to transmission of hepatitis B virus (HBV) from person to person, usually in the same age group. In sub-Saharan Africa, horizontal transmission is a major route of transmission among children. This may result from contact with blood from scrapes, breaks in mucous membranes, or interfamilial contact. To prevent horizontal transmission, HBV-infected persons should be counselled on precautions they should take to prevent transmission. These include covering open cuts and scratches, cleaning blood spills with detergent or bleach, and not sharing toothbrush or razor (81).

Sexual transmission is the major route of hepatitis B virus (HBV) transmission in the United States and Western Europe, as well as other geographic areas where the prevalence of HBV infection is low (23). Sexual transmission accounts for approximately 38% of cases of acute HBV infection in the United States, and 25% are estimated to occur among men who have sex with men (2). The risk of sexual transmission is directly related to number of lifetime sexual partners, use of paid sex, and a previous history of sexually transmitted diseases (2).

Percutaneous transmission is an important mode of transmission among injection drug users. Estimates of the global prevalence of hepatitis B surface antigen (HBsAg) in injection drug users range from 5% to 10% (23). Worldwide, it is estimated that 1.2 million injection drug users (range: 0.3 million-2.7 million) are HBs Ag-positive (50). The risk for acquiring hepatitis B virus infection has been found to increase with the number of years of drug use, with the frequency of injection, and with sharing of drug-preparation equipment (50). Vaccination of all patients at high risk including injection drug users is recommended (78).

In the hospital setting, transmission of hepatitis B virus (HBV) generally occurs from patient to patient, patient to HCWs via contaminated instruments or accidental needlestick and rarely, from healthcare personnel to patient due to tears in safety gloves, suturing accidents, or through use of contaminated multiuse vials. The risk of acquiring HBV infection after an accidental needlestick is related to the degree of contact with blood and the hepatitis B e antigen (HBeAg) status of the source patient. The risk for clinical hepatitis if, the source patient is HBeAg-positive is 22% to 31% vs 1% to 6% if the source patient is HBeAg-negative (53). Therefore, HCWs are strongly advised to receive immunization against HBV.

Transmission of hepatitis B virus (HBV) has been reported after transplantation of solid organs such as kidneys and livers (31). The CDC recommends screening of all potential organ donors for high-risk

behavior and testing for hepatitis B surface antigen (HBsAg) prior to donation. To prevent transmission, persons testing HBsAg-positive should not donate organs.

About 25% of adults who become chronically infected during childhood later die from liver cancer or cirrhosis. The rate of progression from acute to chronic HBV infection is approximately 90% for perinatally acquired infection, 20 to 50% for infections between the age of 1 and 5 years, and less than 5 % for adult acquired infection (81).

The average transmission rates are highest for percutaneous injuries from Hepatitis B (22-31%) that is positive for both hepatitis B surface antigen and hepatitis B envelop antigen (8). The probability of transmission varies depending on whether the exposure is with a hollow bore needle or a solid needle due to higher fluid content and pathogen load.

Needle stick injuries (NSI) can occur during a variety of procedures including needle recapping, injuries sustained in the operating room, during blood collection or intravenous line administration, suturing, checking blood sugar, careless disposal in garbage bags due to inadequate segregation at source, etc. A lack of knowledge about the seriousness of NSI, a careless attitude as well as indifference and apathy towards the subject is prevalent. Surprisingly, even basic first aid treatment after a NSI was found to be wanting and inadequate. There is thus a huge scope for improvement (8).

Blood of carriers is the most important source for transmission. Carriers are those persons who have detectable HbsAg in blood for more than 6 months. Super- carriers are highly infectious and have a high titer of HBsAg, DNA polymerase and HBV in circulation. The virus may also be present in saliva, breast milk, semen, vaginal secretions, urine, bile and feces. Only semen and saliva are known to transmit the infection, others may do so but less efficiently than blood. Feces are not known to be infectious.

Measurement of serum antibody levels of anti-HBs, one month after the immunization is imperative. Those who achieve protective levels of > 10 mIU /ml are protected for life and do not need repeat antibody level estimation or even booster immunization. Under Post-exposure Prophylaxis (PEP), hospitals should make it obligatory for a defined policy to record and report all NSIs with an active ongoing PEP programme in place. For effective implementation of this programme, a policy needs to be formulated at the institutional level to establish a system for reporting injuries, performing relevant baseline tests for both the HCW and the source (if not known) and administering prophylaxis if, required. The risk of transmission is assessed by taking into account the degree of exposure and the evaluation of the source patient. PEP for HBV positive sources for exposed HCWs, who are anti HBs negative, warrants hepatitis B vaccination and a full course of passive immunization with hepatitis B immunoglobulin preferably within 24 hours. PEP for NSIs from HIV positive sources includes 2 or 3 anti-retrovirals and warrants logistic support in terms of ready availability of a "starter pack" of drugs being kept in the Emergency Room (ER) with sufficient drugs for 48 hours so that injuries on weekends can immediately be initiated on treatment. All this requires financial support and commitment as also counselling and reassurance. Follow up of all injuries should also form a vital part of the PEP programme (8).

Routes of transmission vary by geographic prevalence. In regions of high endemicity, HBV is primarily transmitted vertically or perinatally. In regions of intermediate prevalence, transmission occurs mostly through horizontal transmission via household contact or childhood interaction that allows exposure to bodily fluids. Conversely, in areas of low endemicity, transmission is mostly percutaneous, occurring primarily in late adolescence or young adulthood via high risk behaviors such as injection drug use and unprotected sexual intercourse(53).

In forty percent of the new cases infection is acquired through sexual mode. Sexual transmission is probably the single most important mode of HBV transmission in developed countries, where the prevalence of

infection is low. Men who have sex with men are at particularly high risk of HBV infection and accredited to 20% of all reported cases of HBV infection (2). Factors associated with a thigh risk of viral acquisition in this patient population include multiple sexual partners, anal-receptive intercourse and duration of sexual activity. Recently, the risk has fallen markedly, probably because of modification of sexual behavior in response to acquired immunodeficiency syndrome (AIDS) epidemic (50). Heterosexual sex also accounts for majority of cases of HBV infection in developed countries.

In developed countries, intravenous drug abuse also remains a very important mode of HBV transmission (23). The risk of HBV infection increases with duration of drug use so that serologic markers of ongoing or prior HBV infection are almost universal after five years of drug abuse.

As hepatitis B is 100 times more transmissible than HIV and 10 times more transmissible than HCV. Therefore, immunization of HCWs against HBV assumes great importance and is universally recommended. This is best done at the time of employment and should be mandatory.

2.10 Risk Factors

High Risk Group term applies to people who by reason of their country of birth, way of life or type of work are at a higher than average risk of getting infected or passing it on. HCWs and public safety workers fall into the high risk group. Amongst these, surgeons, emergency physicians, dentists, laboratory staff and paramedics working with them are at the greatest risk as they are directly exposed to blood. Barbers amongst the nonmedical occupational group also fall in the high risk group. Other risk factors for HBV infection include transfusion and dialysis, acupuncture, tattooing, travel abroad and residence in an institution. Ritual circumcision, ear or nose piercing are also common modes of transmission. Infection by direct contact with open skin lesion such as pyoderma, eczema, cuts and scratches is very common among

young children in developing countries. HBV is said to survive for 2 week in mosquitoes, however, they do not appear to transmit HBV. Although the risk of transfusion associated HBV infection has been greatly reduced with the screening of blood as well as exclusion of donors who engage in high risk activities, nosocomial spread of HBV infection in hospitals, particularly in dialysis units as well as dental units, has been well described, even when current infection control practices are followed. HBV infection has been linked to multiple-use heparin vials. As with other models of transmission, HBV remains infectious in the environment for 7 days or longer, so that contaminated surface may account for transmission in the absence of a known exposure (18).

HBV infection in liver graft recipients when donor has anti-HBc and no other serological markers can be observed in 50% of the cases (23). Sharps injuries especially needle stick injuries constitute a major source of transmission amongst HCWs(20). The WHO estimates that each year in Europe 30 million HCW's are exposed to at least one percutaneous injury with a sharp object contaminated with HBV, 15 million are exposed to HCV and 2.2 million to HIV.

2.11 Hepatitis B Markers

The Virus contains several antigens to which an infected person can make immune response. These antigens and their antibodies are important in identifying Hepatitis B virus and are collectively called "markers of HBV infection"(36).

- HBsAg: Primary diagnosis of hepatitis B is based on presence of HBsAg which is a general marker of infection.
- Anti HBs: Antibody to hepatitis B surface antigen is a marker of immunity. Its presence indicates an immune response to HBV infection, an immune response to vaccination, or the presence of passively acquired antibody. It indicates recovery and/or immunity.
- HBcAg: Hepatitis B core antigen is a marker of infectivity. Its presence indicates either acute or chronic HBV infection.
- Anti-HBc(total): Antibody to hepatitis B core antigen is a nonspecific marker of acute, chronic, or resolved HBV infection. It is not a marker of vaccine induced immunity. It may be used in prevaccination testing to determine previous exposure to HBV infection.
- IgM anti-HBc: IgM antibody is a subclass of anti-HBc. Positivity indicates recent infection with HBV (within the past 6 months). Its presence is an indicator of acute infection.
- IgG anti-HBc: IgG antibody is a marker of past or chronic infection.
- HBeAg: Hepatitis B 'e' antigen is a marker of a high degree of HBV infectivity with active replication of virus and it correlates with a high level of HBV replication. It is primarily used to help determine the clinical management of patients with chronic HBV infection.
- Anti-HBe: It indicates that virus is no longer replicating Antibody to hepatitis B 'e' antigen may be present in an infected or immune person. In persons with chronic HBV infection, its presence suggests a low viral titer and a low degree of infectivity.
- HBV DNA: It indicates active replication of virus, more accurate than HBeAg especially in cases of escape mutants which is used mainly for monitoring response to therapy.

- Hepatitis B Immunoglobulin (HBIG): HBIG are found in the serum of a person within 48 hrs of incident of being exposed and in the neonates whose mothers are HBsAg and HBeAg positive.
- 2.12 The biochemical and blood cells whose varying levels indicate Hepatitis B infection are as described below (16, 26)-
1. Serum Transaminases level typically ranges between 200 to 2000U/L. Peak levels vary from 400 to 4000U/L or more at the time when the patient is clinically icteric. Acute level of these enzymes however does not correlate well with the degree of liver damage.
 2. Plasma bilirubin reflects the degree of liver damage. When jaundice appears serum bilirubin typically rises to 5 to 20mg/dL. The serum bilirubin may continue to rise despite falling transaminase levels. Bilirubin levels > 20 mg/dL late in the course of viral hepatitis is associated with severe disease. In certain patients with underlying hemolytic anemia such as G-6-P-D deficiency and sickle cell anemia high (up to 30 mg/dL) level of bilirubin have been observed.
 3. Alkaline phosphatase is rarely twice the upper limit of normal.
 4. A mild elevation of gamma-globulins is common in the acute viral hepatitis.
 5. Serum IgM and IgG are elevated in about one- third of the patients.
 6. Mild steatorrhea, microscopic haematuria and minimal proteinuria may be seen.
 7. Prolongation of Prothrombin replication time also indicates severity of hepatitis, but rarely exceeds 25 seconds (except in acute liver failure). Prolonged PT may reflect a severe hepatic synthetic, signifying extensive hepatocellular damage.
 8. White cell counts are normal with relative lymphocytosis. Atypical lymphocytes are (varying between 2 and 20%) are common during the acute phase. Neutropenia and lymphopenia are transient.

Biochemical tests are indicative, but serological tests confirm the etiology of infection to be Hepatitis B.

2.13 Diagnosis of Viral Hepatitis

Diagnosis of HBV is made by detection of HbsAg in the serum. Infrequently levels of HbsAg are low and in such cases diagnosis may be established by the presence of IgM anti-HBc. HbsAg appears within four weeks of exposure to infection. Titer of HbsAg bears little relation to severity of the disease. In fact there is an inverse relation between severity of the disease and the degree of liver damage. Titers are highest in immunosuppressed patients, lower in chronic liver disease higher in mild chronic than in severe chronic hepatitis and very low in patients with acute fulminant hepatitis. In HBV, the degree of liver cell damage and clinical course are related to patient's immune response rather than the circulating HbsAg. HbsAg precedes elevation of transaminases and becomes undetectable 1 to 2 months after the onset of jaundice and rarely persists beyond 6 months.

HBeAg generally appears within six weeks of exposure and disappears within three months of infection (i.e. 18-20 weeks). Anti-Hbe appears generally by the 20th week and this reflects the end of replicative phase. (only tubular and spherical forms of HBV circulate). HBeAg is a qualitative marker of replication of Hepatitis B virus.

HbcAg is sequestered within the coat of HbsAg and not detectable routinely. Anti-HBc is demonstrable 1-2 weeks after the appearance of HbsAg (i.e. 6 weeks after exposure). IgM anti-HBc predominates during the first 6 months and IgG anti-HBc beyond 6 months. False positive IgM anti-HBc may be encountered in patients with high titer Rheumatoid Arthritis (RA) factors.

Anti-HBs is rarely detectable in the presence of HbsAg. It is rarely detectable in the presence of HbsAg in patients with acute hepatitis but 10% to 20% of the patients with chronic HBV may harbour low level of anti-HBs.

Following exposure to hepatitis B virus (HBV), two third of patients present with an asymptomatic, subclinical infection and one third present with an acute hepatitis with jaundice, of whom a minority (< 1%) develop fulminant hepatitis (58). The outcome of acute infection is largely dependent on age at exposure: 90% to 95% of individuals who acquire the infection as infants progress to chronic infection compared with 25% of those infected during childhood, and $\leq$ 5% of those infected as adults (24).

Acute hepatitis B infection is more likely to resolve in patients who present with jaundice or who are not immunosuppressed at the time of infection compared with those who present with a subclinical infection or who are immunosuppressed. With sensitive assays for hepatitis B virus (HBV) DNA, low-level viral replication can be detected in up to 15% to 20% of persons who recover from acute HBV. Indeed, it is now believed that low-level viral replication probably occurs throughout an individual's lifetime and is held in check by the immune system. This explains why reactivation of hepatitis B might occur if the immune system becomes compromised by chemotherapy, bone marrow or stem cell transplantation or HIV infection.

The outcome of chronic hepatitis B is variable and dependent on a complex interplay between the level of viral replication and the host immune response. Approximately one half of individuals transition to an inactive carrier state, 30% progress to cirrhosis, and the remainder have varying degrees of chronic hepatitis (24). Although all patients with chronic hepatitis B are at risk for hepatocellular carcinoma, the rate is highest for those with cirrhosis or persistently high viral replication (23). Understanding the natural history of chronic hepatitis B virus (HBV) infection is crucial for determining who requires therapy, when to initiate treatment, and establishing realistic therapeutic goals. In general, chronic HBV infection consists of 4 phases: an immune-tolerance phase, an immune clearance phase, an inactive phase, and a reactivation phase in a proportion of patients. Serum HBV DNA, alanine

aminotransferase and hepatitis B e antigen (HBeAg) status are used to define these different phases of chronic infection.

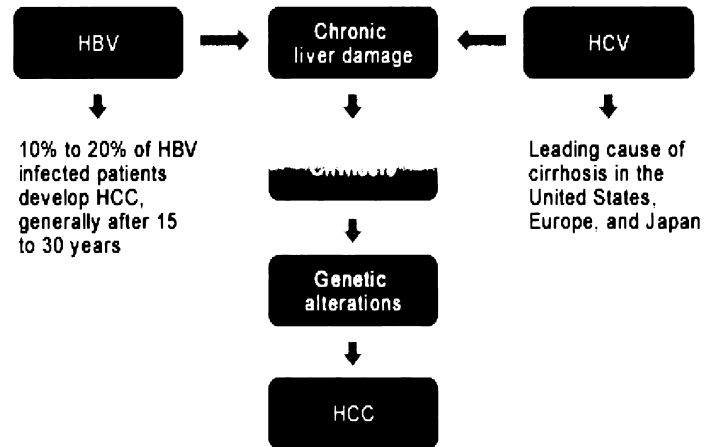
2.14 Pathogenesis

First stage of HBV pathogenesis is immune tolerance. Duration of immune tolerance for healthy adults is approx 2-4 weeks and duration for newborns is often decades. Second stage is inflammatory reaction with cytopathic effect in which HBeAg is identified in sera and decline observed in HBV DNA. Third stage in which the host can target the infected hepatocytes and there is no viral replication. In the fourth stage the virus cannot be detected and antibodies to viral antigen are produced. Successful control of hepatitis B virus (HBV) is dependent on the complex interplay between the innate, cellular, and humoral responses to the infecting virus. At the same time, the immune response may be responsible for mediating clinical hepatitis and disease progression. The exact role of the innate response in acute HBV infection is unclear. The nonspecific innate immune response involves production of interferon, activation of natural killer cells, and activation of Kupfer cells, all of which may help to control viral replication and limit the spread of the virus during the early stages of infection (79,87).

The roles of the cellular and humoral responses are better defined. The T-cell response during acute, self-limited HBV infection is characterized by a strong, polyclonal, multispecific cytotoxic and helper T-cell response (27). Clinical hepatitis is associated with an influx of inflammatory cells, including both HBV-specific and non-HBV-specific T cells (27). In particular, CD8+ T cells that mediate cytolytic activity against HBV-infected hepatocytes correlate with an increase in serum alanine aminotransferase level (27). By contrast, the CD4+ and CD8+ response in chronic carriers is feeble or undetectable (80). However, their presence in the peripheral blood and liver of chronically infected persons with elevated alanine aminotransferase levels suggest a pathogenic role for the cellular immune response. Therefore, the cell-mediated immune response is a doubled-edged sword: a vigorous

response leads to viral clearance, whereas an ineffective response leads to hepatocellular injury. HBV-specific CD8⁺ cytotoxic T cells appear to be important for initiating liver injury. Upon activation, they secrete a number of cytokines, including interferons that recruit a variety of nonspecific inflammatory cells in the liver, resulting in more extensive liver injury. Infiltrating macrophages probably mediate most of the hepatic damage .

Figure 4 : Parthenogenesis of HBV Infection



HBV: Hepatitis B virus

HCV: Hepatitis C virus

2.15 Evaluation of Serologic Markers

Serologic assays for 2 viral antigens (hepatitis B surface and e antigens) and 3 antibodies (anti-HBc, anti-HBs, and anti-HBe) form the basis of diagnosis of acute and chronic hepatitis B virus infection. Three types of assays are available: enzyme immunoassays (EIAs), microparticle EIAs, and chemiluminescence assays.

2.15.1 Hepatitis B Surface Antigen and Anti-HBs

Hepatitis B surface antigen (HBsAg), the serologic hallmark of hepatitis B virus (HBV) infection, usually appears in serum 1-10 weeks following exposure to HBV and approximately 4-6 weeks before the onset of symptoms or elevation of serum aminotransferase levels. Persistence of HBsAg for > 6 months indicates chronic infection. Conversely, resolution of infection is characterized by loss of HBsAg and detection of anti-HBs, which usually persists for life (17). Anti-HBs, the only neutralizing antibody induced by vaccination confers protection against HBV infection. In rare circumstances, anti-HBs may not be detectable for some weeks to months in an individual destined for recovery and in whom HBsAg has already cleared. During the "window period" in which neither HBsAg nor anti-HBs are detectable in serum, the only serologic marker of infection is hepatitis B core antibody (anti-HBc) IgM. Occasionally, HBsAg and anti-HBs may coexist. It is believed in this situation that the anti-HBs is directed against one of the subtypical determinants and not the common 'a' determinant of the antibody and therefore, it is not neutralizing (19). These individuals should be regarded as chronically infected (78, 68,40).

2.15.2 Anti-HBc

Hepatitis B core antigen is an intracellular viral antigen that is present in infected hepatocytes but cannot be detected in serum. Antibody to hepatitis B core antigen, which is detectable in serum, is present in acute and chronic infection and persists after recovery. Anti-HBc usually appears after hepatitis B surface antigen (HBsAg) but before the rise in serum alanine aminotransferase. The presence of anti-HBc IgM typically indicates acute infection, but the antibody is also occasionally detectable during exacerbation of chronic hepatitis B. This can lead to confusion as to whether the presentation is acute or chronic. Isolated detection of anti-HBc can occur in 4 settings: a false-positive test result; during the window period of acute hepatitis B when the anti-HBc is predominantly IgM; many years after recovery from acute hepatitis B when anti-HBs has fallen to undetectable levels; and after many years of chronic HBV infection when the HBsAg titer has decreased below the cutoff level for

detection. Among populations with a high HBV prevalence, an isolated anti-HBc positive result is likely to reflect a previous infection; however, among groups with low HBV prevalence, isolated anti-HBc positivity is likely to reflect a false-positive result (72).

For persons in whom acute hepatitis B is suspected, the diagnosis is based on the detection of hepatitis B surface antigen (HBsAg) and anti-HBc IgM in serum. In the uncommon situation of a patient presenting in the window period, anti-HBc IgM is the only serologic marker of infection. Fulminant hepatitis is an example of a situation where only anti-HBc IgM may be present because of rapid viral clearance. Recovery is diagnosed by the detection of anti-HBc IgG and anti-HBs (72).

The diagnosis of chronic hepatitis B is based on the detection and persistence of HBsAg in serum for > 6 months. To better characterize patients and provide information on prognosis and response to treatment, supplemental testing for hepatitis B e antigen (HBeAg) and hepatitis B virus (HBV) DNA is performed. If case is negative for anti-HBc IgM and HBV DNA, vaccination test needs to be initiated after 30 days of 1st dose. An anti-HBs titer exceeding 50mIU/mL indicates anamnestic response. Such cases have resistance to HBV re-infection and do not need to complete vaccination. If anti-HBs titer is <50IU/mL 30 days after 1st dose of vaccination, it (vaccination) schedule needs to be completed. If anti-HBs titer exceeds 10 IU/mL thirty days after the 3rd dose of vaccine, it indicates a primary response. In case of and exposure to an HBsAg positive source, isolated anti-HBc case needs to be treated as susceptible (72).

2.16 Table 1: Interpretation of HBV Ag & Abs

TESTS	RESULT	INTERPRETATION	VACCINATION
HBsAg Anti-HBs	Negative Negative	susceptible	Vaccinate, if indicated
HBsAg Anti-HBs	Negative positive with >10IU/ml	Immune	No vaccination necessary
HBsAg Anti-HBs	Negative Positive	Immune due to natural infection	No vaccination Necessary
HBsAg IgM anti- HBc Anti HBs	Positive positive negative	acutely infected	No vaccination Necessary
HBsAg IgM anti-HBc Anti-HBs	Positive negative negative	chronically infected	No vaccination Necessary
HBsAg IgM anti-HBc Anti-HBs	Negative positive negative	four interpretations possible*	Use clinical judgment

- *1. May be recovering from acute HBV infection
2. May be distantly immune, but test may not be sensitive enough to detect a very low level of anti-HBs in serum.
3. May be susceptible with a false positive anti-HBc.
4. May be chronically infected and have an undetectable level of HBsAg present in serum (36).

2.17 Action Strategy

Extending screening, referral, and contact vaccination services to persons identified as HBsAg positive can help prevent serious sequel in person with chronic infection and enhance vaccination strategies to eliminate HBV transmission (3). HBsAg positive persons should be referred for evaluation to a physician experienced in the management of chronic liver disease.

Unvaccinated sex partners, household and needle-sharing contacts should be tested for susceptibility to HBV infection. Susceptible and incompletely vaccinated persons should be completely vaccinated. If they have demonstrable immunity (i.e. anti-HBs > 10 mIU/ml) or previous infection (i.e. anti-HBc positive). Use of preventive measures (like condoms) might also reduce the risk of HIV and other STD's. To protect liver from further harm they should be advised to avoid or limit alcohol, refrain from taking any new medicines, including over the counter drugs and obtain hepatitis A vaccination if chronic liver disease is present (27). To prevent transmission to others, HBsAg positive persons should be advised about the risks of perinatal transmission to infants, transmission to household, sex and needle-sharing contacts and the need for such contacts to receive vaccine.

HBsAg positive should be advised to notify their sex partners about their status, use methods to protect non-immune sex partners, cover cuts / wounds to prevent spread through secretions and blood, refrain from donating blood, plasma, tissue or semen, refrain from sharing household articles that could become contaminated with blood.

Some counseling messages which needs to be propagated are-

- HBV is not spread by breastfeeding, kissing, hugging, coughing, ingesting food and water, sharing utensils or drinking glasses, or casual contact.
- Persons should not be excluded from work on the basis of HBs Ag status.
- Children should not be excluded from school, play, child care, or other setting unless they are prone to biting.

The support groups are available for patients to cope with their chronic HBV infection.

Changes in sexual practices in response to HIV infection have probably contributed to falling incidence of HBV infection and improved screening measures of blood products in blood bank have reduced the risk of transfusion associated Hepatitis B. Other primary measures to avoid needle exchange habit in intravenous drug users are more difficult to implement. Behavior modification is unlikely to be beneficial in countries where neonates and young children are at the greatest risk of acquiring infection. In these groups immunoprophylaxis both active and passive will be effective.

2.18 Strategy for management of occupational exposure

Immediate response-

- Percutaneous exposure- encourage bleeding and wash with soap and water.
- Cutaneous contamination- wash with soap and water.
- Mucus membrane contamination- flush with water.
- Eyes- irrigate with clean water, saline, or sterile antiseptic solution.
- Antiseptic/disinfectant use is not contraindicated as both viruses are enveloped and supposed to be sensitive to many chemical agents.

- Application of caustic agent or injection of antiseptic/disinfectants onto the wounds is not recommended (59).

2.19 Risk Assessment Criteria

In case of an occupational exposure to at risk blood infection baseline HBV, HCV, HIV immune status of the exposed HCW should be available (74).

- For medico legal reasons baseline plasma & serum of the HCW should be stored.
- Evaluation of the exposure's potential to transmit HBV and HIV based on the type of exposure and body material involved should be done.
- Serological status of HCW for antibodies against HIV, HCV and for HBsAg needs to be evaluated.
- In case of needle stick injuries, it is needed to check if HCW is vaccinated. If HCW has been vaccinated then the source should be tested for anti-HIV and anti-HCV.
- If HCW is unvaccinated then the source needs to be tested for HBs Ag and the HCW needs testing of HBs Ag and anti-HBs.
- If the source is HBsAg positive and the recipient is unvaccinated and negative for both HBsAg and anti-HBs the recipient needs to be vaccinated with 3 doses, 1st dose of hepatitis B vaccine, followed by 2nd and 3rd dose at 1 and 6 months respectively. Without intervention, there is a 20% chance of the recipient contracting acute hepatitis B.

The comprehensive strategies to prevent Hepatitis B should include behavior modification and creation of awareness, educational programmes and training, passive immunoprophylaxis and active immunoprophylaxis.

HCWs need to be educated about the importance of avoiding needle stick injuries and exposure to body fluids, open blood and blood products. If they are working in high-risk areas and have cuts, bruises and open wounds they should take adequate precautions to protect themselves against infection and in turn avoid infecting those whom they are treating or nursing. The importance of Immunoprophylaxis should be stressed upon to the entry-level medical and nursing graduates.

All HCW's should be informed, educated and trained about the possible risk of prevention of blood borne infections after occupational exposure, measures to prevent blood borne pathogen exposure, implementation of standard precautions, implementation of safer procedures and HBV vaccination. They should be provided with sufficient personal protective equipments and safety devices.

Table 2: Safety Aspect of HCWs at Work-Place

The Gap and Solutions concerning safety aspect of HCWs in Hospitals are as tabulated below (42)-

Sr.No.	The Gap	Solutions
1	Inadequate availability of gears and equipment	• Provision of aprons, gloves, needle destroyer and hand washing facility. • Impart training on need, scope and options for personal protection • Create awareness by IEC & BCC • Health & Hospital Administrator sensitized • Hospital staff immunized regularly
2	Error-prone practice of handling blood and tissue samples in laboratories	• A system for the identification and traceability of samples • A label on sample containers • A system of cross verification of test results
3	Biomedical waste Management (BMW) rules not followed	• A process owner for BMW management • Identify locations for BMW bins • Procure BMW equipments, materials & supplies • Sorting out the waste in color coded containers • Training to personnel for handling BMW • A record maintained for amount of waste collected with time of collection • Untreated BMW not stored beyond 48 hrs • Storage site covered
4	X-Ray machines operating without atomic energy regulatory board clearance	The hospital management to follow AERB Guidelines strictly
5	Not observing all legal stipulations /statutory requirements	• Create awareness on statutory and legal requirements • Fix responsibility and accountability • A review system for monitoring the compliance
6	Disposal of non-operational material not done	• A committee to review the status of equipment • Rules on disposal of obsolete items followed
7	Health surveillance of workers not practiced	• To provide the services of a physician for all HCWs • All HCWs be subjected to general medical examination • Special tests for workers • Counseling of pregnant workers

2.21 Immunoprophylaxis

Active Immunoprophylaxis (AI)

Active immunoprophylaxis is done by using HBV vaccine. Hepatitis B vaccine is prepared in two ways:-

By concentrating and inactivating infectious particles in circulation from blood of persons who are Hepatitis B carriers (13). These have been the first commercially available vaccines but concerns about transmission of other infectious agents have led to their discontinuation and are no longer routinely available (47) .

Recombinant vaccines are produced by DNA technology (genetic engineering) to produce the surface antigen (S.gene) in yeast cell lines. The yeast cells are grown in which large amount of HBsAg is produced. The HBsAg nucleotide sequence is purified to 95% by adsorption of the purified antigen in cellular extract to colloidal silica followed by its desorption, ion exchange chromatography and ultracentrifugation. The vaccine is then prepared by adsorbing the purified HBsAg onto aluminum hydroxide gel. Thiomersal is used as preservative.

Pichia pastoris is the most advanced 2nd generation yeast strain with proven advantages used over the other yeast strains like *Saccharomyces cerevisiae*. It can grow at a highly acidic pH that becomes a barrier for growth of many contaminating microbes during the process of fermentation (21).

Passive immunoprophylaxis (PI)

Passive immunoprophylaxis is provided by Hepatitis B Immunoglobulin (HBIG). It provides passively acquired anti-HBs and temporary protection (i.e 3-6 months) when administered in the standard doses. HBIG is typically used as an adjunct to hepatitis B vaccine for post exposure to prevent HBV infection. HBIG is prepared from the plasma of donors with high concentrations of anti-HBs. The plasma is screened to eliminate donors, who are positive for HBsAg, antibodies to HIV and hepatitis C virus (HCV).

Postexposure prophylaxis is recommended for all persons who are exposed to hepatitis B virus (HBV) and are not vaccinated. Both the hepatitis B immune globulin plus the hepatitis B vaccine and the hepatitis B vaccine alone are highly effective in preventing infection after exposure to HBV. Guidelines for postexposure prophylaxis for adults with occupational and nonoccupational exposures to HBV have been developed (74).

The effectiveness of postexposure prophylaxis is dependent on early administration of the initial dose of vaccine and effect diminishes the longer after exposure it is initiated (74). Ideally, persons without contraindication to HBV vaccination should receive the first dose within 24 hours and not later than 7 days following exposure.

- 2.22 Protection with HBV Vaccine is considered to be achieved when the concentration of anti-HBs antibody titer is 10mIU/ml, one to two months after the last dose of vaccine. Non-responders are those with an anti-HBs titer equal to 10mIU/ml, Responders are those with an anti-HBs titer between 10mIU/ml and 100mIU/ml, High responders are those with an anti-HBs titer between 100mIU/ml and 1000mIU/ml and Hyper responders are those with an anti-HBs titer above 1000mIU/ml.

Currently no vaccine exists to prevent HCV infection, and neither immunoglobulin nor antiviral therapy is recommended as post-exposure prophylaxis. HCWs with known exposure should be monitored for sero-conversion and referred for medical follow up, if seroconversion occurs (49).

In conclusion, although exposure to HBV poses a high risk for infection, administration of pre-exposure vaccination or post-exposure prophylaxis to workers can dramatically reduce this risk. Such is not the case with HCV and HIV. Preventing the NSI is the best approach to preventing these diseases in HCWs and it is an important part of any blood borne pathogen prevention program in the workplace.

2.23 Non-Responders to Vaccine

Although the currently available hepatitis B virus (HBV) vaccines are highly effective, it is estimated that approximately 5% to 15% of healthy individuals fail to respond to the 3-dose series (6). Some risk factors for non responses are male sex, older age, cigarette smoking, obesity, immunodeficiency, renal failure, intragluteal vaccination, chronic diseases, certain HLA haplotypes (43) and celiac diseases (55).

Vaccination of non-responders is done by administering 4th dose and testing for response 1 to 2 months later. If there is no response still 5th and 6th dose (70) is completed then tested for response 1 to 2 months again. Other strategies are giving three intra-dermal doses of standard vaccine every two weeks or administering high-doses of standard vaccine (57) by giving combined Hepatitis A and Hepatitis B vaccine. Nucleic Acid Vaccine or DNA Vaccines are the vaccine to prevent and treat viral hepatitis and hepatitis B (63). DNA vaccine seems to induce protective antibody responses in human non-responders to conventional vaccination.

According to the CDC (65), individuals who have anti-HBs levels < 10 mIU/mL following the primary HBV vaccine series should be

revaccinated with 3 doses according to the appropriate schedule and should be retested for anti-HBs 1-2 months following the third dose. Individuals with anti-HBs levels < 10 mIU/mL following revaccination, should be tested for hepatitis B surface antigen to determine if they are infected with HBV. If the test is negative, they should be considered susceptible to HBV infection and should be counseled on precautions to avoid becoming infected and the need for hepatitis B immunoglobulin.

2.24 **Vaccination Program/ Regulation**

The following persons should receive routine hepatitis B vaccination according to CDC:

- All newborns at birth prior to hospital discharge
- All children and teens ages 0 through 18 years
- All persons who wish to be protected from hepatitis B virus (HBV) infection

CDC states that it is not necessary for the patient to disclose the risk factor to receive hepatitis B vaccine (9).

Vaccine dose and mode of its administration for various categories of people is as given below (9)-

- For infant, children and adolescents the dosage is 10 mcg of the antigen in 0.5 ml suspension
- For adults above the age of 20 years, dosage is 20 mcg of the antigen in 1.0 ml suspension (75) .
- For haemodialysis and immunocompromised persons under the age 20 years is 10 mcg of the antigen in 0.5 ml suspension and for adults 20 years and above it is 40 mcg in 2.0 ml suspension (26).
- Hepatitis B should be administered by intramuscular injection. The deltoid muscle is the recommended site of administration of adults. Injection into buttock is associated with decreased immunogenicity (69).

- Intradermal administration can result in lower seroconversion rate and final concentration of antibody to hepatitis B surface antigen (anti-HBsAg) compared with intramuscular injection (7, 20).
- Hepatitis B vaccine administered by any route or site other than intramuscularly in deltoid muscle should not be counted as valid and should be repeated unless serologic testing indicates that an adequate response has been achieved (14).
- For persons at risk for hemorrhage (e.g., persons with hemophilia), the risk for bleeding after intramuscular injection can be minimized by using a 23-gauge (or smaller) needle, applying direct pressure to injection site for 1-2 minutes, and administering vaccine immediately after infusion of coagulation factor. Subcutaneous administration of vaccine can be considered for these persons but might result in lower response and increased local reaction.
- Hepatitis vaccine should be stored at 2-8° C and should not be frozen.
- For intramuscular injection the needle should be long enough to reach the muscle mass and prevent vaccine from seeping into subcutaneous tissue but not so long as to involve underlying nerves and blood vessels or bones (38).
- The appropriate needle length for adults is 1'-1 ½' (25-38mm)

A reliable vaccine history is defined as written, dated record of each dose of a completed series. Persons whose records cannot be located should be considered susceptible and started on an age-appropriate vaccine schedule. In STD clinics, HIV testing centers or correctional facilities, an oral record can be used to give vaccination. Those uncertain about their status should be vaccinated. Persons without written documentation should receive doses to complete age-appropriate vaccine series.

When vaccine series is interrupted it need not be restarted, if the series is interrupted after the 1st dose, the 2nd dose should be started as soon as possible. The 2nd and 3rd doses should be separated by an interval of at least 8 weeks. If only 3rd dose has been delayed, it should be

administered as soon as possible (38). The 3rd dose should follow the 1st dose by at least 16 weeks. The minimum interval between the 1st and 2nd dose is 4 weeks. Inadequate dose or doses received after a shorter than recommended dosing interval should be re-administered using the correct dosage or schedule (34). If an accelerated schedule (i.e. 0, 7 and 14 days) is used, booster should be administered at least 6 months after the start of the series to promote long term immunity. The US Food and Drug Administration (FDA) does not recommend administration of HB vaccine more than once in a month.

Booster dose of the hepatitis B virus vaccine is not recommended for individual with normal immune status (62). However, the CDC recommends that booster dose be administered in the following circumstances:

- Hemodialysis patients: assessing the need for booster dose by annual anti-HBs testing; administering a booster dose when anti-HBs levels decrease to < 10 mIU/mL
- Other immunocompromised individuals: requirement for booster dose is determined; when anti-HBs levels decrease to < 10 mIU/mL, annual anti-HBs testing and booster dose in persons with ongoing hepatitis B virus exposure risk is needed (15).

Similarly high risk persons like HCWs should be considered if on serologic testing, their anti-HBs levels shows to be below 10mIU/mL. Routine boosters are not recommended for known responders, even if anti-HBs levels become low or undetectable(33,6). Low or non-responders need to be identified and informed that they are not protected and advised to seek prophylaxis on accidental exposure (91,106).

2.25 Vaccine Immunology

Serologic Testing

Pre-vaccination Serologic Testing

Pre-vaccination serologic testing can be done with a single test (anti-HBc) or with a panel of tests (e.g. HBsAg and anti-HBs). When a single test is used, anti-HBc is preferred because it identifies all persons with previous HBV infection, including persons with chronic infection. If prevaccination for anti-HBs is used to identify immunity after previous HBV infection, HBsAg testing must be performed to identify persons with chronic HBV infection. However, serologic testing should not be a barrier to vaccination of susceptible persons. The first vaccine dose typically should be administered immediately after collection of blood sample for serologic testing.

Post- vaccination Serologic Testing

Post vaccination serologic testing is to be performed 1-2 months after administration of the last dose of vaccine. It is not necessary after routine adult vaccination. Testing after vaccination is recommended for HCWs and public safety workers who are at high risk for continued percutaneous / mucosal exposure to blood or body fluids, chronic haemodialysis, HIV and immunocompromised persons and sex partners of HBsAg positive partners. Persons found to have anti HBs >10mIU/ml after primary vaccine are considered immune-competent persons who have long term protection and need not be tested further. Only immunocompromised persons need annual testing.

Persons found to be having anti-HBs <10mIU/ml after primary vaccination need to be revaccinated. Persons who do not have protective antibodies after revaccination should be tested for HBs Ag. If HBs Ag is positive, he/she should receive appropriate management. If HBsAg is negative, he/she should be considered susceptible to HBV

infection and counseled about precautions to prevent HBV infection and need to obtain HBIG post-exposure prophylaxis. Anti-HBs is the only easily measurable correlate of vaccine induced protection. Immunocompetent persons achieve antiHBs concentration >10 IU/mL after pre-exposure. Vaccination has virtually complete protection against both acute disease and chronic infection even if anti-HBs concentration subsequently decline to <10 mIU/ml. Although immunogenicity is lower among immunocompromised persons, those who have and maintain a protective antibody response before exposure to HBV have a high level of protection from infection. Despite decline of anti-HBs level to <10 mIU/ml, nearly all vaccinated persons are still protected against HBV infection. The mechanism for continued vaccine induced protection is thought to be the preservation of immune memory through selective expansion and differentiation of clones of antigen specific B and T lymphocytes. Persistence of vaccine induced immune memory amongst persons who responded to a primary childhood vaccine series 13-23 year earlier but then had levels of anti-HBs below 10 mIU/ml has been demonstrated by an anamnestic increase in anti-HBs level in 67% --76% of these persons 2-4 week after administration of an additional vaccine dose. Although direct measurement of immune memory is not yet possible, data indicate that a high proportion of vaccine recipients retain immune memory and would develop anamnestic response upon exposure to HBV.

Limited data is available on the duration of immune memory after hepatitis B vaccination in immunocompromised persons (e.g., HIV-infected patients, dialysis patients, patients undergoing chemotherapy, hemopoietic stem cell transplant patients). No clinically important HBV infections have been documented among immunocompromised persons who maintain protective levels of anti-HBs. In studies of long-term protection among HIV-infected persons breakthrough infections occurring after a decline in anti-HBs concentration to <10 mIU/ml which is transient and asymptomatic.

2.26 **Adverse Reactions of Vaccination**

Some common adverse reactions of vaccination are mild soreness, induration and erythema at the injection site. Rare systemic adverse reactions are fatigue, low grade fever and malaise, musculoskeletal: arthralgia and myalgia. Adverse reactions seen in the digestive system are nausea, vomiting, diarrhea and abdominal pain. Abnormal liver function tests, dizziness and paresthesia are some other adverse reactions. Extremely rare adverse reactions are anaphylaxis, serum sickness, angioedema, erythema multiforme, musculoskeletal arthritis and hypotension. Other adverse reactions in the nervous system are neuropathy, neuritis, encephalitis and meningitis. Bronchospasm and adenopathy are also some of the adverse reactions(75).

2.27 **Recovery from Infection**

Full recovery occurs in 90-95% of adults following acute HBV infection. The remaining 5-10% develop chronic infection which usually continues for life time. Chronic infection is common in immunodeficient individuals like those with Down's syndrome or HIV infection. Recovery from HBV occurs within six months and is characterized by appearance of viral antibodies to antigens.

Prevalence of HBeAg beyond this time indicates chronic infection. Superinfection with HIV cause more aggressive disease. Most patients with chronic Hepatitis B are asymptomatic and develop complications such as cirrhosis and hepatocellular carcinoma after many years. Cirrhosis develops in 15% to 20% of the patients with chronic Hepatitis B over 5-20 years.

In a long term study of patients with chronic Hepatitis B, investigators found 5-year survival rate for 97% for patients with chronic persistent hepatitis, 86% for patients with chronic active hepatitis and only 55% for patients with chronic active hepatitis and post necrotic cirrhosis. The likelihood of spontaneously converting relatively replicative to non-replicative chronic HBV infection is approximately 10 to 15% per

year. Replicative and nonreplicative HBV infection has been defined by the detection of HBV DNA in serum. The replicative process of the hepadnaviruses is unique among animal DNA viruses in which reverse transcription is involved.

2.28 Implementation of Universal Hepatitis B Vaccination Programme

The introduction of immunization programmes in endemic regions has had a profound impact on the hepatitis B virus (HBV) carrier rate and on the incidence of hepatocellular carcinoma (HCC). Taiwan was the first country to introduce universal Immunization against HBV in 1984. In 1992, the World Health Organisation (WHO) recommended that all countries implement Universal Hepatitis B Vaccination Programme as part of their National Infant Immunization Schedule. In 2005, the WHO set forth a HBV control goal of reducing the seroprevalence of HBsAg to < 2% in children below 5 years of age by 2012. As of 2009, 92% of the world's countries had integrated HBV vaccination into their national Infant Immunization Programme (76). This is an important part of the global effort to eradicate an infection that causes liver failure and cancer.

Low prevalence countries (with 2% chronic HBV infection) that have already implemented the Hepatitis B vaccination for infants include Andorra, Australia, Austria, Belgium, Canada, Czech Republic, Estonia, France, Germany, Greece, Israel, Italy, Latvia, Luxembourg, Malta, Monaco, New Zealand, Poland, Portugal, San Marino, Slovakia, Spain, Switzerland, Turkey, and the United States. Low prevalence countries that have not introduced universal Hepatitis B vaccination for Infants include Denmark, Netherlands, Switzerland, Sweden, Norway, Finland, Ireland, Iceland, Japan and the UK (13).

African countries such as the Gambia, Tunisia, Egypt, Mauritius and Seychelles islands have >90% vaccine coverage, whereas the figure in Caribbean and Latin American countries is around 50%.

Overall, between 1990 and 2007, the incidence of acute hepatitis B in the United States declined by 82%, from 8.5 cases per 10 million population

to 1.5 cases per 10 million population (22). During that time, the incidence declined among all age groups, but the reduction was most pronounced among children younger than 15 years of age, highlighting the significant impact of the mandatory immunization program. Native Alaskan people, who had a prevalence of hepatitis B infection > 6% overall in the 1970s (95) have seen a remarkable decline in hepatitis B virus (HBV) infection. Indeed, among children younger than 20 years of age, the number of HBV-positive individuals declined from 657 in 1987 to 2 in 2008. In the United States, rates remain highest among adults, particularly men 25-44 years of age who have an incidence of > 3.0 cases per 10 million population (22).

2.29 Hepatitis B Vaccine in Universal Immunization Program in India - A Brief Scenario

The Hepatitis B Project was initiated in India in the year 2002 with support of Global Fund for Vaccines & Immunization (GAVI). An agreement was signed by Govt. of India, Inter Agency Cooperation Committee (IAC) & the GAVI for this project. The partners from IAC for this initiative include WHO, UNICEF, USAID, PATH, World Bank, DFID & European Commission (31). Government of India is now working towards a planned phasing-in of hepatitis B vaccine, based on the capacity of the states and districts and sustainable funding.

To date, the use of hepatitis B vaccine in Indian children has been fairly limited. A pilot hepatitis B vaccination programme was conducted in east Delhi beginning late 1996 using vaccine donated by the WHO. In this pilot project, between 20 to 30 million doses of hepatitis B vaccine were administered to infants. The objective of this pilot project was to assess the feasibility of including hepatitis B vaccine into Universal Immunization Program (UIP) and to assess the requirement of forms and educational material. In this pilot project, three-dose coverage rate among the target population was estimated to be around 60%. Following the pilot project, the Government of Delhi successfully introduced hepatitis B vaccine all over Delhi. Experience from this pilot project has been incorporated in the

proposed plan for phased introduction of hepatitis B vaccine in India. In addition, two states (Kerala and Haryana) began hepatitis B vaccination using a cost-recovery strategy. These programmes were however, discontinued because of logistic difficulties. These projects were endeavors of the state governments. Unfortunately, the experience of these projects and the lessons learnt from them were not documented. During the last few years, hepatitis B vaccine has been available in the private sector in urban areas for those who can afford it. The Indian Academy of Pediatrics, which is the highest professional body of pediatricians in the country, has advocated hepatitis B vaccine as a part of routine immunization schedule. Many doctors therefore administer hepatitis B vaccine to patients and children under their care. Many schools and non-governmental voluntary organizations have been organizing hepatitis B vaccination drive on a payment basis. Though these drives possibly reflect public acceptance and demand for hepatitis B vaccine, these have not reached the rural population and the urban poor. It is important to note that over 90% of routine immunization in India is provided by the public sector (17).

The state of Maharashtra has not introduced the Hepatitis B programme in the whole state. Hepatitis B Vaccine was introduced in Universal Immunization Program (UIP) in Pune and Mumbai Municipal Corporation slums during March, 2003. It was introduced in Satara, Ratnagiri & Chandrapur districts in September, 2003. From April, 2004 the vaccination started in the whole of Pune and Mumbai Municipal Corporation areas (17).

2.30 International Regulatory Bodies

Under Needle-stick Safety and Prevention Act, 1991, the Occupational Safety and Health Administration, United States (OSHA) issued a Standard regulating occupational exposure to blood borne pathogens, including the human immunodeficiency virus, (HIV), the hepatitis B virus (HBV), and the hepatitis C virus (HCV). Compliance with the Blood Borne Pathogens Standard has significantly reduced the risk that HCWs

contract a blood borne disease in the course of their work. Nevertheless, occupational exposure to blood borne pathogens from accidental sharps injuries in health care settings continues to be a serious problem. In March 2000, the CDC estimated that more than 38 million percutaneous injuries from contaminated sharps occur annually among HCWs in United States hospital settings. Estimates for all health care settings are that 60 million to 80 million needle stick and other percutaneous injuries occur among HCWs annually. Such injuries can involve needles or other sharps contaminated with blood borne pathogens, such as HIV, HBV, or HCV (49). In 1998, OSHA issued engineering and work practice controls to eliminate or minimize the risk of occupational exposure to blood borne pathogens due to percutaneous injuries from contaminated sharps. Numerous studies have demonstrated that the use of safer medical devices, such as needleless systems and sharps with engineered sharps injury protections, when they are part of an overall blood borne pathogens risk-reduction programme, can be extremely effective in reducing accidental sharps injuries. In March 2000, the CDC estimated that, depending on the type of device used and the procedure involved, 62 to 88 percent of sharps injuries can potentially be prevented by the use of safer medical devices. Training and education in the use of safer medical devices and safer work practices are significant elements in the prevention of percutaneous exposure incidents. Staff involvement in the device selection and evaluation process is also an important element to achieving a reduction in sharps injuries, particularly as new safer devices are introduced into the work setting (49).

2.31 Engineering Controls

Engineering controls are defined in OSHA's Blood Borne Pathogens Standard as controls that isolate or remove the blood borne pathogens hazard from the workplace. The Standard states "Engineering and work practice controls shall be used to eliminate or minimize employee exposure". Blunt-tip suture needles are identified by OSHA as an example of an engineering control to reduce percutaneous injuries as an

alternative to sharp-tip suture needles. Blunt-tip suture needles can be used to suture less-dense tissue such as muscle and fascia since as many as 59% of suture needle injuries occur during suturing of muscle and fascia. Evidence of effectiveness of Blunt-tip suture needles in decreasing percutaneous injuries has been reported. A CDC study of suture needles in gynecologic surgery found a statistically significant reduction of injury rates when blunt-tip suture needles were used. In addition, use of these devices resulted in minimal clinically apparent adverse effects on patient care and was generally accepted by participating surgeons (65).

The circumstances leading to a NSI also depends partly on the type and design of the device used. For example, needle devices that must be taken apart or manipulated after use are an obvious hazard and have been associated with increased injury rates. In addition, needles attached to a length of flexible tubing e.g., winged-steel needles are sometimes difficult to place in sharps containers and thus present another injury hazard. In addition to risks related to device characteristics, NSIs have been related to certain work practices such as recapping, transferring a body fluid between containers, and failing to properly dispose of used needles in puncture-resistant sharps containers. Recapping by hand has been discouraged for some time and is prohibited under the OSHA Blood Borne Pathogens Standard unless no alternative exists. Injury may occur when a HCW attempts to transfer blood or other body fluids from a syringe to a specimen container (such as a vacuum tube) and misses the target. Also, if used needles or other sharps are left in the work area or are discarded in a sharps container that is not puncture resistant, a NSI may result.

NSIs can be regarded as preventable if a needle was used unnecessarily. A safer work practice could have prevented the NSI, if a device was disposed off properly. NSIs that are caused by patient-related factors (e.g., a patient moved while the needle was being used or removed) are usually considered non preventable.



The introduction of any device must include training of staff in its proper use and follow-up to ensure a successful transition from conventional to safer devices. Employers of HCWs should implement the use of improved engineering controls to reduce NSIs by eliminating the use of needles where safe and effective alternatives are available, by implementing the use of devices with safety features and evaluating their use to determine which are most effective and acceptable. NSIs can best be reduced when the use of improved engineering controls is incorporated into a comprehensive programme involving HCWs.

It is sometimes easier to change technology than human behaviour. Safety devices are being used in several hospitals in developed countries, and this has shown to reduce NSIs. The incorporation of safer needle devices (SNDs) and better utilization of safety devices such as needleless sets, safety cannula, self-capping intravenous catheters, self retracting lancets for blood glucose monitoring, auto disposable syringes certainly help in reducing injuries but these come at a cost. SNDs today encompass a large variety that include safety syringes / needles for hypodermic devices, prefilled medication syringes, safety intravenous catheters and needle less intravenous systems, safe and closed system blood-collection devices, safety blades, scalpels, suture needles, and surgical sharps protection devices, hemodialysis safety needle sets etc. Cost effective practical and local solutions which can be rooted in the system need to be implemented.

OSHA intends to act to reduce the number of injuries that HCWs receive from needles and other sharp medical objects. Comprehensive programmes to prevent NSIs, safety and health issues can best be addressed in the setting that considers all aspects of the work environment and that has employee involvement as well as management commitment. Implementing the use of improved engineering controls is one component of such a comprehensive programme. Other prevention strategy factors that must be addressed include modification of hazardous work practices, administrative changes to address needle hazards in the environment (e.g. prompt

removal of filled sharps disposal boxes), safety education and awareness, feedback on safety improvements, and action taken on continuing problems. Several authors have noted the importance of a comprehensive approach (56). The critical role of appropriate training has been emphasized by several recent reports of increased patient bloodstream infections associated with improper care of needleless intravenous systems, primarily in the home health care setting (73).

Changes in HCWs education and work practices, implementation of devices with features and encouragement of injury reporting are keys to safe environment for HCWs. Characteristics of devices with safety features include the following-

- The device is needleless.
- The safety feature is an integral part of the device.
- The device preferably works passively (i.e., it requires no activation by the user). If user activation is necessary, the safety feature can be engaged with a single-handed technique and allows the HCWs hands to remain behind the exposed sharp.
- The user can easily tell whether the safety feature is activated.
- The safety feature cannot be deactivated and remains protective through disposal.
- The device performs reliably.
- The device is easy to use and practical.
- The device is safe and effective for patient care.

Although each of these characteristics is desirable, some are not feasible, applicable or available for certain health care situations. For example, needles will always be necessary where alternatives for skin penetration are not available. Each device must be considered on its own merit and ultimately on its ability to reduce workplace injuries.

Continued education and effective training can be addressed in various ways starting with fostering collaborations with medical, dental, and nursing schools in educating students about sharps injury prevention and improving post-exposure management. Induction programmes in

hospitals should be held once a month for all new recruits and an infection prevention awareness week should be held frequently where needle stick injuries and interventions to prevent these are adequately discussed. The concept of universal precautions (UP) should be explained to all HCWs and steps are taken to enforce them. Appropriate disposal of sharps and avoidance of recapping or bending should form an essential component of this training.

Specific organizational issues may have an impact on sharps injury rates. Nurses who work in units with low nurse-to-patient ratios are more likely to report the presence of sharps injury risk factors and sustain sharps injuries. As a corollary to this, personnel in hospitals with good infection control practices in place, high professional-to-patient staffing ratios are more likely to follow safer sharps handling practices. Further, HCWs are more likely to adhere to Universal Precautions when they perceive a strong institutional commitment to safety, and detect fewer job hindrances in complying with UP.

Employers should implement the following programme elements in their work practice (65)-

- Analyze needle stick and other sharps-related injuries in the work-place to identify hazards and injury trends
- Set priorities and strategies for prevention by examining local and national information about risk factors of NSIs and successful intervention efforts
- Ensure that HCWs are properly trained in the safe use and disposal of needles
- Modify work practices that pose a NSI hazard to make them safer
- Promote safety awareness in the work environment
- Establish procedures for and encourage the reporting and timely follow up of all needle stick and other sharps-related injuries
- Evaluate the effectiveness of prevention efforts and provide feedback on performance

HCWs themselves should take the following steps to protect themselves and their fellow HCWs from NSIs-

- Avoid the use of needles where safe and effective alternatives are available
- Help their employer select and evaluate devices with safety features
- Use devices with safety features provided by the employer
- Avoid recapping needles
- Plan for safe handling and disposal before beginning any procedure using needles
- Disposal of used needles promptly in appropriate sharps disposal containers
- Report all needle stick and other sharps-related injuries promptly to ensure that they receive appropriate follow up care
- Tell their employer about hazards from needles that they observe in their work environment
- Participate in blood borne pathogen training and follow recommended infection prevention practices, including hepatitis B vaccination

The current Federal Standard for addressing NSIs among HCWs is the OSHA Blood Borne Pathogens Standard (56) which has been in effect since 1992. The Standard applies to all occupational exposures to blood or other potentially infectious materials. Notable elements of this standard require the following-

- A written exposure control plan designed to eliminate or minimize HCW exposure to blood borne pathogens
- Compliance with universal precautions (an infection control principle that treats all human blood and other potentially infectious materials as infectious)
- Engineering controls and work practices to eliminate or minimize exposure
- Personal protective equipment (if engineering controls and work practices do not eliminate occupational exposures)

- Prohibition of bending, recapping, or removing contaminated needles and other sharps unless such an act is required by a specific procedure or has no feasible alternative
- Prohibition of shearing or breaking contaminated needles (OSHA defines contaminated as the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface)
- Free hepatitis B vaccinations offered to HCWs with occupational exposure to blood borne pathogens
- HCWs training in appropriate engineering controls and work practices
- Post-exposure evaluation and follow up, including post-exposure prophylaxis when appropriate

In conclusion, NSIs are an important and continuing cause of exposure to serious and fatal diseases among HCWs. Greater collaborative efforts by all stakeholders are needed to prevent NSIs and the tragic consequences that can result. Such efforts are best accomplished through a comprehensive programme that addresses institutional, behavioral, and device-related factors that contribute to the occurrence of NSIs in HCWs. Critical to this effort are the elimination of needle-bearing devices where safe and effective alternatives are available and the development, evaluation, and use of needle devices with safety features. Safety features should be evaluated to ensure that they work effectively and reliably, the device is acceptable to the HCW and it does not adversely affect patient care.

2.32 Sharps Injury Surveillance

Sometimes the HCWs place patient needs before their personal safety. They are less likely to perform a safety measure they perceive to interfere with patient care or to require added steps. Therefore employers must address both the hazards that contribute to NSIs and the institutional barriers and attitudes that affect safe work practices. Procedures for and encouraging the reporting and timely follow up of all needle stick and other sharps-related injuries should be established. Reporting of NSI is essential to ensure that all HCWs receive

appropriate post-exposure medical management and provide a record for assessing needle stick hazards in the work environment. Effectiveness of prevention efforts be studied and feedback obtained on its performance. Employers need to ensure that HCWs are adopting the recommended prevention strategies and that the changes they make have the desired effect. Installation of the software EPINet (Exposure Prevention Information Network) to help further in improving efficiency in tracking and analyzing NSIs is needed to be installed (41).

The HCWs should be provided with a forum to assess their perceptions, evaluate compliance, and identify problems.

Sharps injury surveillance can be improved by standardizing the collection / analysis of data with improvised ways of reporting exposures and applying root-cause analysis for better understanding of long-standing problems as well as linking data collection for dissemination of study results.

Thus we can put together an evidence that the investment into HCWs safety will pay dividends in terms of minimizing the treatment cost. This will also definitely trigger similar initiatives in hospitals across the country.

Lastly, exposure to blood borne pathogens is a harsh reality that one has to comprehend and be committed to prevent. Clearly, transmission of these potentially infectious pathogens can be minimized by adopting effective precautionary measures. As NSIs are the commonest source of occupational exposures to blood and body fluids, we need imaginative thinking, diligent commitment, efficient advocacy, innovative funding and more efficient implementation to handle them.

3. RATIONALE

- 3.1 The vulnerability of HCWs to the simple procedures followed at work place such as wounds cut by NSIs, that accidentally puncture the skin especially for the people who work with hypodermic syringes is very high. Poor needle disposal practices, recapping of used needles and resultant injuries put HCWs at high risk of blood borne infections like HIV, hepatitis B and C. Nurses, ward boys, housekeeping staff and those working in the surgical departments are at the highest risk of getting NSIs and are, as a result, most vulnerable to acquiring blood-borne infections. Unfortunately, HCWs safety has rarely been considered as a high priority by hospitals mostly run commercially.
- 3.2 There are more than a million HCWs in the country including medicos & paramedical workers potentially susceptible to risk of human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV) infection through occupational exposure to blood & bloody body fluids. Of the 36 million HCWs in the world, 3 million receive needle stick exposure to blood borne pathogens every year, 3 million of those are exposed to Hepatitis B virus, 0.9 million are exposed to Hepatitis C virus, around 0.2 million are exposed to the HIV virus and 90% of these infections occur in developing countries(77).
- 3.3 The study conducted by doctors at the Safdarjung Hospital, New Delhi (54) published in Indian Journal of Medical Research in March, 2010 has shown that 60% of HCWs are not aware of precautionary options available to them in hospitals and 75% nursing students did not seek help when exposed to NSIs. The most common clinical activity to cause the NSI was blood withdrawal (55%), followed by suturing (20.8%) and vaccination (11.7%). The study has also highlighted the menace caused by the practice of recapping needles after use. About 66.8% HCWs

responded positively to recapping needles after use. Only 11.4% HCWs admitted to have bent the needles before discarding.

- 3.4 Two year prospective study (5) of needle stick and sharp injuries in 1400 bed tertiary care referral hospital in South India where more than 1000 HCWs are at risk of getting infection revealed that out of the 78 reported cases (49 medical doctors, 20 dental doctors, six nursing sisters and three laboratory technicians), 60 had NSIs (including hollow bore intravenous needle and solid surgical suture needle), There were 15 cases of sharp cut from scalpel or dental instruments and three cases with blood splash on eyes. Among these 78 cases, 43 HCWs got exposure from known serologically tested HIV, HBV and HCV negative patients, 15 got exposure from HIV sero-positive patients and two HCWs were exposed to HBsAg positive patients. A total of 18 HCWs got occupational exposure from OPD patients and the sero-status of those patients was unknown.
- 3.5 These infections also face the great risk of being transmitted to other hospitalized patients through the medium of infected HCWs. This has serious consequences among immuno-compromised individuals.
- 3.6 The high percentage of HCWs with NSIs is primarily because of a high rate of ignorance and also due to lack of regulation of occupational health and safety to foster a safe working environment.
- 3.7 While there is no India-specific data on NSIs, experts say that the situation could be even more alarming. Industry estimates indicate that more than 1.7 billion syringes are sold in the country annually and about 5 billion injections administered, sometimes by inadequately trained staff (41). Also there is underreporting of needle stick injuries which is often less than 50%.
- 3.8 Because the risk of being infected is highest in the lower strata of the HCWs hierarchy, most hospitals do not consider prevention of NSIs important. While countries such as Hong Kong, China, Australia and the

Philippines are undertaking massive work on this front, Indian hospitals are just waking up to the challenges of not putting such a mechanism in place. In the USA, it is mandatory for such prevention and safety mechanisms to be present.

- 3.9 In India, it is needed to conduct surveys to estimate the occupationally acquired infections by a large group of HCWs ranging from ward assistants to the clinical specialists. They are highly vulnerable to getting infected and also in transmitting the same to other HCW's and to patients. NSIs form a significant part of the mode of transmission. The present Study with this rationale in view has chosen sample of HCWs from District and Sub-district hospitals from all 8 circles in the State of Maharashtra to estimate the percentage of infections which may have been acquired at their work place.
- 3.10 Training workshops on the importance of following the safety precautions at workplace and also reporting them appropriately once they occur so that required measures could be taken are needed to be held for HCWs. Awareness creation as well as functioning Hospital Infection Control Committee for laying down and following interventional strategies are required.

4. AIMS AND OBJECTIVES

- 1) To determine Hepatitis B (HBs Ag) prevalence in HCWs in surgical, medical, dental departments and laboratories, in Public Health Hospitals in Maharashtra.
- 2) To determine Hepatitis C (HBC IgM) prevalence in HCWs in surgical, medical, dental departments and laboratories, in Public Health Hospitals in Maharashtra.
- 3) To assess anti-HBs level in HBV vaccinated HCWs in surgical, medical, dental departments and laboratories, in Public Health Hospitals in Maharashtra.
- 4) To study the influence of factors like age and sex in the vaccinated HCWs
- 5) To increase awareness to create a safe working environment in the hospitals amongst HCWs

5. MATERIALS AND METHODS

This study was carried out in 11 Civil Hospitals and Sub-district Hospitals covering 8 circles of the State of Maharashtra among HCWs working in Laboratories, Surgical, Medical and Dental departments. The study population consisted of 2994 HCWs out of which 473 volunteered and actively participated. The study population of HCWs included Ward Helpers, Ward Attendants, Laboratory Technicians, Nursing Staff (Operation Theatre/ Wards/Labour Room), Interns, Medical Officers and Senior Clinicians working as Specialists.

5.1. Study Population

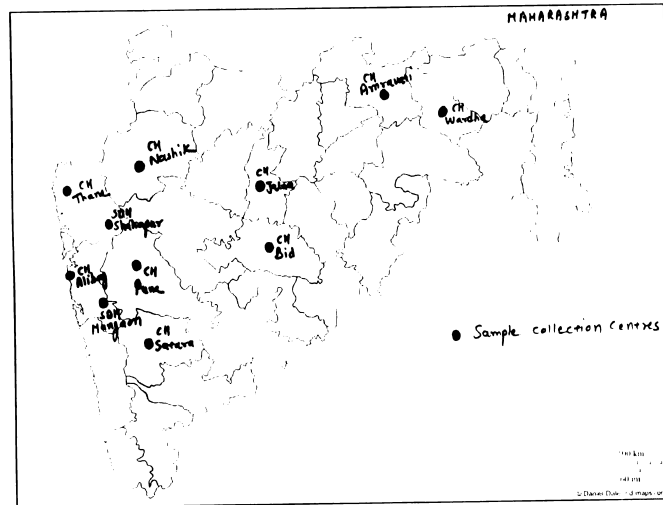
For the study, I travelled all over the State of Maharashtra covering 8 circles of the state from 10th May, 2010 to 10th July, 2010. Total number of 2994 HCWs working in the District / Sub-district Hospitals (DH/SDHs) were contacted of which 473 HCWs volunteered for this study.

Table 3: Circle-wise number of participants

Circle Number	Name of Circle	Civil Hospital (CH)/Sub-District Hospitals (SDH)	Date of visit	Sample Numbers	CH/SDH-wise number of samples	Total number of Circle-wise samples
1.	Thane	- CH, Thane - SDH, Shahapur - CH, Alibaug - SDH, Mangaon	10/05/10 11/05/10 11/05/10 11/05/10	1-20 21-29 30-63 64-78	20 09 34 15	78
2.	Pune	CH, Pune	12/05/10	79-119	41	41
3.	Kolhapur	CH, Satara	28/05/10	120-184	64	64
4.	Nashik	CH, Nashik	29/05/10	185-252	67	67
5.	Aurangabad	CH, Jalna and MCH, Jalna	18/06/10	253-292	39	39
6.	Latur	CH, Beed	19/06/10	293-349	57	57
7.	Nagpur	CH, Vardha	09/07/10	350-413	64	64
8.	Akola	CH, Amravati	10/07/10	414-473	60	60

TOTAL- 473

Figure 5: Sample Collection Centers



In each Hospital, a presentation was given to medical and paramedical workers on the study proposal and details related to it. Individual level counseling and interviews were held with those who came forward to be participants. Information Sheet as at Appendix I was provided to all. Informed consent (forms in bilingual- English and Marathi) (Appendix II) was taken followed by filling up of a questionnaire (data on age, sex, education, training, years in health care profession, job category, direct contact with blood/sputum, injuries, post exposure prophylaxis, vaccination etc.) (Appendix III) by all participants. Five ml blood was then collected using aseptic precautions in the plain vacutainer sterile tube. The tube was labelled and a serial number allotted against each HCW. After collection and serum separation, the sera were reached at Test Laboratory at Haffkine Institute within 24 hours. The samples were then preserved at -20⁰ C. The materials used in this process include BD

vaccutainers/sterile plain tubes for blood collection, needles and holders, disposable gloves and 70% isopropyl alcohol swabs.

The sample collection was done taking all universal safety precautions.

5.2 Clinical Protocol

Permission to carry out the study was obtained from the Institutional Ethics Committee at Haffkine Institute, Mumbai. The study population consisted of 437 HCWs (229 were HBV vaccinated and 208 unvaccinated) out of 473 collected samples (36 samples could not be used due to hemolysis). The HCWs were counselled and informed that they would be tested for HBs Ag, Anti HBs, HBc IgM and Liver Profile as per the need. All HCWs gave consent on the Consent Form for all tests.

5.3 Criteria for Acceptance of Samples

All HCWs falling in the designated high risk group, between the age 18-60 years and willing to give consent for blood collection and testing were selected. Specific limits were set for each group so that there was adequate representation from each group. Unvaccinated HCWs were selected to see if they have been exposed to infection (anti-HBc) and developed protective antibodies subsequently (anti-HBs).

5.4 Criteria for Rejection of Samples

Grossly haemolysed or lipaemic samples as well as samples containing particulate matter were rejected. Controlled studies have shown that assay performance is not affected by potentially interfering substances or anticoagulants (EDTA, Heparin), bilirubinaemia (up to 20mg/dl bilirubin) or haemolysis (>500mg/dl haemoglobin).

5.5 Preparation of Specimen

The aliquoted deep frozen (-20⁰ C) samples were allowed to stand for 15 minutes and mix-thawed well before testing. Performance was not affected by samples which had undergone up to four freeze thaw cycles.

5.6 Qualitative estimation of HBsAg, (Diasorin, Italy) (28)

This was done by ELISA Diasorin, Italy. It is based on the principle of Sandwich ELISA.

5.6.1 Principle of the Assay

The presence of HBsAg allows the enzyme tracer to bind to the solid phase. The enzyme activity is therefore proportional to the HBsAg concentration present in samples or controls. Enzyme activity is measured by adding a colourless chromogen/substrate solution. The enzyme action on chromogen/substrate produces a colour which is measured with a photometer.

5.6.2 Scheme of Qualitative HBs Ag Assay

- 1) Well (A) was left empty for the Blank.
- 2) 100 µL of negative controls, positive controls and samples were added into their respective wells.
- 3) A cardboard sealer was applied in order to prevent evaporation.
- 4) Plate was incubated for one hour at 37° in a thermostatically-controlled humid chamber.
- 5) The liquid was aspirated and each well rinsed five times with a volume of wash buffer ranging from 0.30 to 0.37 ml. After washing the plate was inverted on to blotting paper to remove excess liquid from the wells.
- 6) 100 µL enzyme tracer solution was added into all wells except for the blank well.
- 7) Plate was incubated for one hour at 37°C in a thermostatically-controlled humid chamber.

- 8) 100 μ L chromogen/substrate solution was added into all wells and plate was incubated for 30 min at room temperature away from direct or intense light.
- 9) 100 μ L blocking reagent was added into all wells in the same order and at the same rate as for the chromogen/substrate.
- 10) Absorbance values were read with a photometer at 450/630 nm within one hour.

5.6.3 Run Validation Criteria

The following criteria were used to validate quality control. Calibrator absorbance was evaluated and calculated for each plate.

- The absorbance of blank was to be between 0.000 and 0.150.
- The absorbance of negative control was to be greater than -0.010 and less than 0.050.
- The difference between the positive control absorbance and the negative control absorbance value was to be greater than or equal to 0.500.
- If these criteria were not met, the run was concluded to be invalid and was to be repeated.

5.6.4 Calculation of Results

The reading photometer was blanked with a blank. The absorbance at 450/630 nm was recorded for each specimen.

The cut-off value was determined by adding 0.030 to the mean absorbance of the negative control value (NC).

The difference between positive and negative control was to be greater than 0.500

5.6.5 Interpretation of Results

The presence or absence of HBsAg was determined by comparing the absorbance value of samples to that of the cut-off value. The sample with absorbance value above the cut off value was considered reactive for HBsAg. The sample with absorbance value below the cut off value was considered non-reactive.

5.7 Qualitative/Quantitative estimation of Anti- HBs (29)

This was done by ELISA Diasorin, Italy. It is based on the principle of Sandwich ELISA.

5.7.1 Principle of the Assay

The method for quantitative/qualitative determination was a direct, non-competitive, Sandwich Assay based on immunoenzymatic ELISA technique (enzyme linked immunosorbant assay).

The samples to be analyzed were incubated in wells of a micro plate that were coated with highly purified HBsAg. If the sample contained anti-HBs it would bind specifically to the HBsAg in the well. After washing to remove residual sample, HBsAg conjugate to peroxidase was added which would bind to the antigen-antibody incubation complex formed during the first incubation. After the second incubation and washing, an enzyme substrate containing a chromogen was added.

This solution developed a blue color if it contained anti-HBs. The blue color changes to yellow after blocking the reaction with sulfuric acid. The intensity of color is proportional to the concentration of anti-HBs present in the test specimens. The concentration of antibodies in the sample was calculated by interpolation from a calibration curve.

5.7.2 Sample Dilution

Samples whose anti-HBs levels were expected to be above 1000 IU/L were diluted 1:10 or 1:100 with negative control before assaying. 20 µL of the specimen and 180 µL of the negative control were put in sterile vials to obtain a 1:10 dilution. 20 µL of the diluted sample were added to 180 µL of the negative control to obtain a 1:100 dilution.

5.7.3 Scheme of Quantitative Anti HBs Assay

- 1) Well (A) was left empty for the blank.
- 2) 100 μ L of the Incubation Buffer was added to all wells (except Blank).
- 3) 100 μ L of negative control was added the well B.
- 4) 100 μ L of the Calibrators 1 to 4(10,100,500 & 1000mIU/ml) were added to the wells C,D,E & F respectively.
- 5) 100 μ L of the samples were added starting from well G in a Serial order.
- 6) Plate was incubated for two hours at 37C.
- 7) Liquid was aspirated repeatedly. Washed with wash buffer. After washing blotted off the inverted micro plate on absorbent tissue to remove excess liquid from the wells.
- 8) 100 μ L working enzyme tracer was dispensed into all well, except for the blank well.
- 9) Incubated for one hour at 37C.
- 10) Liquid was aspirated repeatedly. Washed with wash buffer repeatedly.
After washing blotted off the inverted micro plate on absorbent tissue to remove excess liquid from the wells.
- 11) 100 μ L chromogen/substrate dispensed in to all wells.
- 12) Incubated for 30 mins at room temperature, in the dark.
- 13) 200 μ L blocking reagent dispensed into all wells.
- 14) Absorbance values were read with a photometer at 450/620nm and 405/620nm.

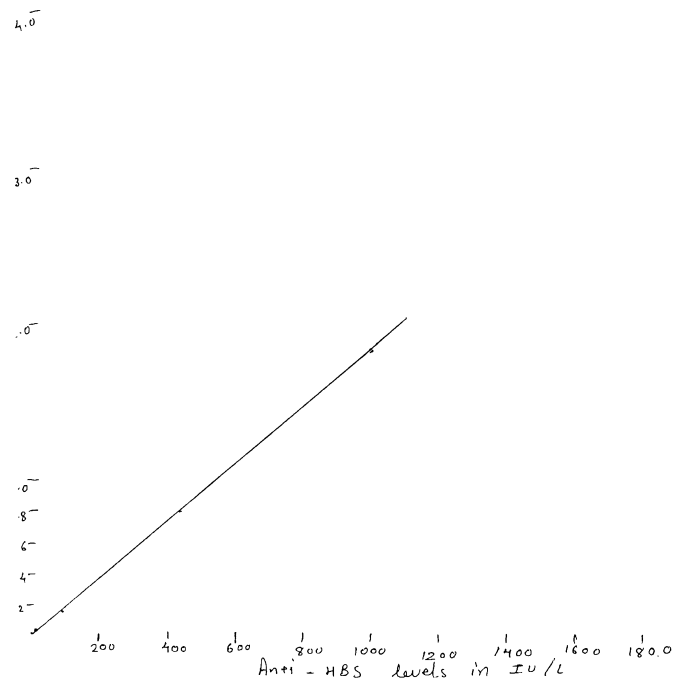


Figure 7 : HBs Ag ELISA Test

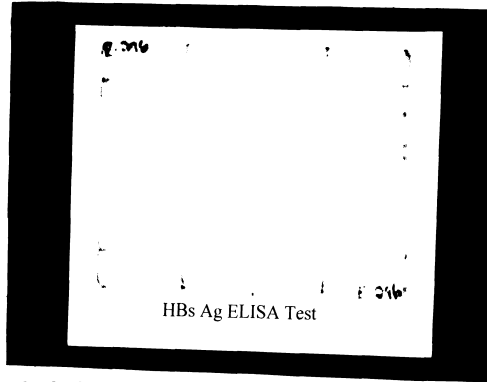
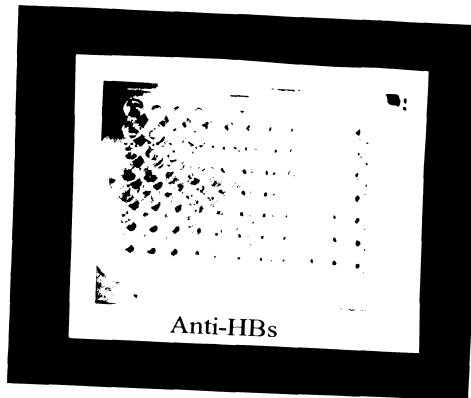


Figure 8 : Anti-HBs ELISA Test



5.7.4 Run Validation Criteria

The following criteria were used to validate quality control. Calibrator absorbance was evaluated and calculated for each plate.

- 1) The absorbance of negative control (0 calibrator) was to be < 100 ($NC < 0.100$).
- 2) The absorbance of calibrator 1 was to range between 0.035 and 0.300
 $0.035 < \text{cal } 1 < 0.300$.
- 3) The ratio of absorbance of calibrator 1 to the absorbance of negative control (0 calibrator) was to be greater than or equal to 2.0; $\text{Cal } 1/NC \geq 2.0$
- 4) The ratio of absorbance of calibrator 4 to the absorbance of calibrator 3 was to be greater than or equal to 1.2; $\text{Cal } 4/\text{Cal } 3 \geq 1.2$.

If these criteria were not met, run was invalid and was to be repeated.

5.7.5 Calculation of Results

As a vertical reading photometer was used, the instrument was blanked with a blank; the absorbance at 450/620nm and 405/620nm was recorded for each specimen. The 620 absorbance value was subtracted from both the 450nm and 405nm absorbance values for all calibrators and samples.

Absorbance values at 450nm that were greater than the photometers linear reading range were to be normalized as equivalent to 450nm by multiplying the k value by the absorbance value at 405nm.

The K value was determined as follows:-

$$K = A_{450-620\text{nm}} / A_{405-620\text{nm}}$$

The equivalent absorbance values at 450nm for the samples with absorbance values at 450-620 that were beyond the linear range of photometer were calculated as follows:-

$$\text{Reading at } 405\text{nm} \times K = \text{Corrected Value at } 450\text{nm}$$

5.8 IgM Anti HBc Estimation (Diasorin, Italy) (30)

5.8.1 Principle of the Assay

The assay is an antibody-capture, non-competitive test based on the use of polystyrene microwells coated with mouse monoclonal antibody to human IgM. An enzyme tracer containing horseradish peroxidase-labelled human antibodies to HBcAg detects any captured IgM anti-HBc via recombinant HBcAg.

5.8.2 Sample Dilution

Samples whose IgM Anti-HBc was to be estimated is diluted to 1:4000. The process is performed by adding 10 μ L sample to 990 μ L sample diluent in first instance by diluting it to 1:100 and then after through mixing adding 10 μ L of the mixed sample to 390 μ L of diluent in the second instance by diluting the sample to 1:4000.

5.8.3 Scheme of Qualitative IgM Anti HBc Assay

- 1) Well (A) was kept as Blank having chromogen/substrate only.
- 2) 100 μ L Calibrator was added to well B, C and D
- 3) 100 μ L Negative control was added to well E.
- 4) 100 μ L Positive control was added to well F.
- 5) 1:4000 Diluted samples added to all other wells starting from well G.
- 6) Plate was incubated for two hours at 37° C.
- 7) The liquid was aspirated and each well rinsed five times with a volume of wash buffer ranging from 0.30 to 0.37 μ L. After washing the plate was inverted on to blotting paper to remove excess liquid from the wells.
- 8) 100 μ L of working enzyme tracer solution was dispensed into all wells except for the blank well.
- 9) Incubated for one hour at 37°C.
- 10) 100 μ L chromogen/substrate solution is dispensed into all wells.
- 11) Incubated for 30 minutes at room temperature.

- 12) 100 μ L stop solution is dispensed into all wells
- 13) Absorbance values were read with a photometer at 450/630 nm.

5.8.4 Run Validation Criteria

The following run validation criteria was used to validate quality control.

Calibrator absorbance was evaluated and calculated for each plate.

- The absorbance of blank was to be ≤ 0.150 .
- The absorbance of calibrator was to range between 0.020 and 0.120.
 $0.020 < Cal < 0.120$.
- The absorbance of negative control was to range between -0.020 and 0.120
 $-0.020 < NC < 0.120$.
- The absorbance of positive control was to range between 0.500 and 2.500.
 $0.500 < PC < 2.500$.
- The difference between the positive control absorbance value and the negative control was to be greater than 0.450, $PC - NC > 0.450$.

If these criteria were not met, run was invalid and was to be repeated.

5.8.5 Calculation of Results

The reading photometer was blanked with a blank. The absorbance at 450/630 nm was recorded for each specimen. The 630 absorbance value was subtracted from the 450 nm absorbance value.

The cut-off value is determined by adding 0.200 to the mean absorbance of the calibrator values after subtraction of the substrate blank. Cut-off value = $Cal + 0.200$.

5.8.6 Interpretation of Results

The presence or absence of IgM anti-HBc was determined by comparing the absorbance value of samples to that of the cut-off value.

The samples with absorbance values above the cut off value were considered reactive for IgM anti-HBc. The samples with absorbance values below the cut off value were considered non-reactive.

5.9 Liver profile(ERBA Kit- IFCC Method, Kinetic)

5.9.1 Serum Glutamic Pyruvic Transaminase (SGPT) (67)

SGPT is found in a variety of tissues but is mainly found in the liver. Increased levels are found in hepatitis, cirrhosis, obstructive jaundice and other hepatic diseases. Slight elevation of the enzymes is also seen in myocardial infarction.

5.9.1.1 Principle

SGPT (ALT) catalyzes the transfer of amino group between L-Alanine and Ketoglutarate to form Pyruvate and Glutamate. The Pyruvate formed reacts with Nicotinamide Adenine Dinucleotide, NADH (reduced form) in the presence of Lactate Dehydrogenase to form NAD. The rate of oxidation of NADH to NAD is measured as a decrease in absorbance which is proportional to the SGPT (ALT) activity in the sample.

Normal Reference Values

- Serum (Male) : upto 40 U/L at 37°C
- Serum (Female) : upto 31 U/L at 37°C

5.9.1.2 Procedure

Substrate Start Assay

0.8 ml enzyme reagent was mixed with 0.1 ml sample in a dry test tube. The mixture was incubated at 37 °C for 1 minute. 0.2 ml starter reagent was added in the mixture. After mixing initial absorbance A was read at 340 nm. The absorbance was repeated after every 1, 2, & 3 minutes. The mean absorbance change was calculated per minute (A/ min).

Sample Start Assay

1 ml working reagent was incubated at 37°C for 1 minute. 0.1 ml sample was added and mixed. Initial absorbance A was read at 340 nm. The absorbance was repeated after 1, 2 and 3 minutes. The mean absorbance change was calculated per minute (A/ min).

5.9.1.3 Calculation of Results

SGPT (ALAT) activity in U/L 37° C = A/ min. x 1746

5.9.2 Serum Glutamic Oxaloacetic Transminase (SGOT) (66)

SGOT is an enzyme found mainly in heart muscle, liver cells, skeletal muscle and kidneys. Injury to these tissues results in the release of the enzyme in blood. Elevated levels are found in myocardial infarction, cardiac operations, hepatitis, cirrhosis, acute pancreatitis, acute renal diseases, primary muscle diseases. Decreased levels may be found in pregnancy, beri beri and diabetic ketoacidosis.

5.9.2.1 Principle

SGOT (AST) catalyzes the transfer of amino group between L-Aspartate and a Ketoglutarate to form Oxaloacetate and Glutamate. The Oxaloacetate formed reacts with NADH in the presence of Malate Dehydrogenase to form NAD. The rate of oxidation of NADH to NAD is measured as a decrease in

absorbance which is proportional to the SGOT (AST) activity in the sample.

Normal Reference Values

- Serum (male) : upto 37 U/L at 37°C
- Serum (Female) : upto 31 U/L at 37°C

5.9.2.2 Procedure

Substrate Start Assay

0.8 ml enzyme reagent was mixed with 0.1 ml sample in a dry test tube. The mixture was incubated at 37° C for 1 minute. 0.2 ml starter reagent was added in the mixture. After mixing initial absorbance A was read at 340 nm. The absorbance was repeated after every 1, 2, & 3 minutes. The mean absorbance change was calculated per minute (A/ min).

Sample Start Assay

1 ml working reagent was incubated at 37°C for 1 minute. 0.1 ml sample was added and mixed. Initial absorbance A was read at 340 nm. The absorbance was repeated after 1, 2 and 3 minutes. The mean absorbance change was calculated per minute (A/ min).

5.9.2.3 Calculation of Results

SGOT (ASAT) Activity in U/L at 37°C = A/ min. x 1746

5.9.3 Alkaline Phosphatase (ALP) (46)

ALP is present in high concentration in the liver, bone, placenta, intestine and certain tumors. Physiologically elevated serum alkaline phosphatase occurs in pregnant women and in growing children. Increased levels of the enzymes occur in liver diseases, bone diseases (rickets, Paget's disease), Hodgkin's disease or congestive heart failure. Decreased levels occur in hypophosphatasia and malnourished patients.

5.9.3.1 Principle

ALP reacts with 2-amino-2-methyl-1-propanol and p-nitrophenylphosphate in presence of water to form 4-nitrophenol and amino-2-methyl-1-propanol phosphate. The rate of 4-nitrophenol formation is directly proportional to be ALP activity.

Normal reference Values

- Women- 1-12 years- < 500 at 37° C
20-50 years- 42-98 IU/L at 37° C
≥60 years - 53-141 at 37° C
- Men- 1-12 years- < 500 at 37° C
20-50 years- 53-128 IU/L at 37° C
≥60 years - 56-119 IU/L at 37° C

5.9.3.2 Procedure

1000 µL of Reagent is mixed well with 20 µL of the serum and aspirated.

5.9.3.3 Calculation

ALP activity (IU/L)= A/min.X Factor (2764) at 405 nm.

6. OBSERVATION AND RESULTS

6.1 Out of total number of 2994 HCWs working in eleven study sites, a total number of 437 HCWs were studied. Number of males and females were 198 and 239 respectively. **Table 4** shows the sex-wise distribution of in various Specialties. The Nurses constituted the bulk with their number being 156 (33.2%) compared to 70(16.0%) Medical Officers (MOs), 42(10.0%) Laboratory Technicians (LTs)., 38(8.1%) Ward Helpers and 16(4.0%) Clinical Specialists. As per the sex-wise distribution there was a predominance of females at 239 (54.3%) compared to 198 (45.6%) males. There was a preponderance of males in most of the categories except in Nurses where the females dominated, 148 out of a total nursing staff of 156. In the category of Medical Officers and Lab. Tech., there were more males at 57 (79.2%) and 26 (62.0%) out of a total number of 70 and 42 respectively.

Table 4 : Sex-wise distribution of HCWs in various Disciplines

S.No	Departments	Total No. of HCWs	No. of Participants	Sex wise Distribution	
				Male	Female
1	Specialist	287	16	13	3
2	Medical Officer	201	70	57	13
3	Staff Nurse	1058	156	5	148
4	Lab.Tech	53	42	26	17
5	OT, Att.	152	11	7	8
6	Lab. Asstt.	31	12	8	4
7	Intern	94	6	2	4
8	Ward Att.	130	36	20	16
9	Ward Helper	460	38	27	9
10	Sweeper	489	29	17	12
11	Counsellor	20	5	4	1
12	Others	19	16	12	4
Total		2994	437	198	239

6.2 Total number of all Hospital-wise staff of Medicos, Paramedics and HCWs and the number of participants selected under each

category of work at all eleven locations are shown in **Table 5**. Out of total number of 287 Specialists, 16 opted as participants. Against total number of 201 MOs, 20 opted to participate in the study. Out of total 1058 Staff Nurses, 156 volunteered for participation. The number of Lab Technicians and Lab Assistants selected were 42 and 12 out of 53 and 31 numbers respectively. The numbers of OT Attendants were 152 out of which 11 were selected as participants. Against the total number of 130 Ward Attendants and 460 Ward Helpers, 36 and 38 numbers were selected to participate respectively. The number of interns was 94 out of which 6 were selected to participate. Total number of sweepers was 489 out of which 29 were selected to participate. The number of Counsellors was 20 out of which 5 were selected to participate. Other staff consisting of Ophthalmology Technician, Ophthalmology Officer, Pharmacist, Facility Manager, Supervisor, IPHS Coordinator, Data Operator, Telephone Operator, Barber and Servant were in 19 numbers in total out of which 16 were selected to be participants.

Table 5: Details of HCWs at study sites who participated in study

Name of CH/SDH	Specialist (including Dentist)		MO (including Dentists)		Staff nurse (including Matron, PHN etc.)		Lab Tech(including BB Tech & others)		OT Attndt		Lab Asst		Intern	Ward Attendant (including labour room, ophthalmic ward etc.)		Ward Helper (Ward Boy)		Sweeper		Coun cillor		*Others		TOTAL		
	T	P	T	P	T	P	T	P	T	P	T	P		T	P	T	P	T	P	T	P	T	P	T	P	
CH, Thane	31	1	30	6	125	8	3	1	28	-	-	-	-	-	-	56	2	68	2	1	-	-	-	342	20	
SDH, Shapur	4	-	4	1	25	3	3	3	1	-	3	-	8	-	-	-	10	2	3	-	1	-	-	-	62	9
CH, Amravati	29	1	36	10	194	19	9	9	7	3	2	-	22	-	10	8	50	2	68	1	1	-	3	3	431	56
CH,Jalna & M/C Hos., Jalna	18	-	-	6	1	5	4	4	3	-	-	-	7	1	42	2	-	9	44	1	-	1	2	2	121	29
CH, Beed	39	3	31	5	121	9	3	3	27	-	6	4	-	-	3	2	51	3	60	4	3	1	4	2	348	37
CH, Wardha	25	3	9	8	104	18	5	4	14	4	-	-	-	-	5	3	40	5	44	10	2	2	7	7	255	64
CH, Satara	34	-	28	6	133	37	6	3	13	-	3	2	40	3	-	-	33	6	52	4	1	1	2	2	345	64
CH, Nashik	42	3	1	17	171	27	8	3	27	4	7	-	7	-	10	8	64	5	84	1	4	1	1	1	426	68
CH, Pune	31	3	23	5	90	18	8	6	15	-	5	2	-	-	30	5	109	-	30	2	4	-	-	-	345	41
SDH, Mangaon	10	-	13	1	24	2	2	2	3	-	3	3	-	-	10	6	8	1	4	-	2	-	-	-	79	15
CH, Alibaug	24	2	26	5	70	10	2	5	14	-	2	1	10	2	20	2	39	3	32	4	1	-	-	-	240	34
GRAND TOTAL	287	16	201	70	1058	156	53	42	152	11	31	12	94	6	130	36	460	38	489	29	20	5	19	16	2994	437

T- Total Staff, P-Participants

6.3 **Table 6** shows number of HCWs with number of doses of vaccines taken with sex-wise distribution. Total number of 86 males and 106 females

were found to be vaccinated. 19 males out of these 86 males had taken 1 dose, 21 had taken 2 dose, 41 had taken 3 dose and only 5 had taken booster dose. Out of total number of 106 females, 11, 29, 52 and 14 females were found to be vaccinated with 1, 2, 3, and booster dose respectively. Even though total of females were more 239 (54.3%) than 198 males (45.6%) more number of females have opted for booster dose 14 (8.2%) than 5 (1.8%) in males.

Table 6 : HCWs with number of doses of HBV vaccine taken with sex-wise distribution

S.No	Sex	Number of vaccinated HCWs	Doses of Vaccine taken				Total no. of vaccinated HCWs
			1 dose	2 doses	3 doses	Booster dose	
1.	Male	86	19	21	41	5	86
2.	Female	106	11	29	52	14	106
Total		192	30	50	93	19	192

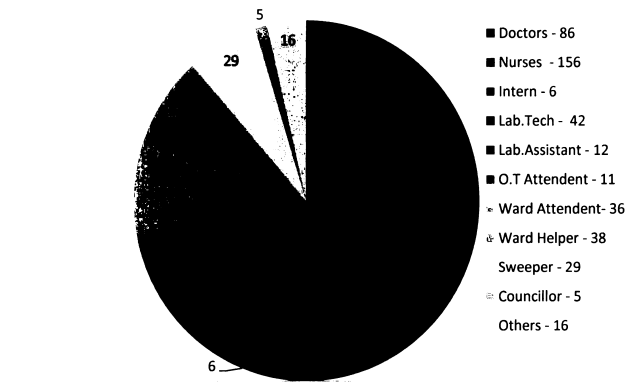
- 6.4 **Table 7** shows sex-wise HCWs with HBs Ag positivity with status of their vaccination and number of doses taken. All 437 samples were tested for the surface antigen (HBsAg), only 11 (0.002%) had tested positive. The number of males were 4 (36%) and 7 females (63.6%). Only 8 (72.7%) of these HCWs who tested positive for HBsAg had been vaccinated. Out of these 11 HCWs 5 (45.4%) had level of antibody 10 and below 10 IU/L. Out of these 5 HCWs 3 (60%) were not vaccinated. Other 2 HCWs, both female had 3 and 1 dose respectively. These 5 HCWs may have had hospital acquired infection or sexually acquired one. Even though HCW histories were taken exact mechanism of this infection can not be known. It could be presumed that they were hospital acquired infections. Vaccine is supposed to have failed to push up the antibody titre in case of 2 vaccinated and in case of other 8 HCWs who had antibody level of more than 10 IU/L. Out of 11 HCWs, 6 (54.5%) were Staff Nurse, 3 (27.2%) lab and Blood Bank Technicians, 1 (9.0%) Medical Officer and 1 (9.0%) was an Attendant.

Table No. 7

Table 7 : Details of HBV sero-positive HCWs with their vaccination status and Anti-HBs level

S.No	Designation	Sex	Vaccination Status	Level of Anti-HBs IU/L
1.	Staff Nurse	Female	Vaccinated-3 doses	55
2	Lab. Tech.	Female	Vaccinated-3 doses	40
3.	Blood Bank Tech.	Male	Vaccinated-2 doses	12
4.	Staff Nurse	Female	Vaccinated-3 doses	10
5.	Lab Tech.	Male	Not Vaccinated	10
6.	Staff Nurse	Female	Not Vaccinated	10
7.	Medical Officer	Male	Vaccinated-3 doses	12
8.	Staff Nurse	Female	Vaccinated-2 doses	10
9.	Nurse	Female	Vaccinated-2 doses	60
10.	Attendant	Male	Not Vaccinated	8
11.	Staff Nurse	Female	Vaccinated-1 dose	10

Figure 9 : showing profession-wise distribution of HCWs (n=437)



6.5 In **Table 8** we have HCWs who have been vaccinated with titre of protective antibodies. The number of vaccinated HCWs were 192 with 86 males and 106 females. There are 3 (18.8%) HCWs (out of 19 HCWs who had booster dose), all females who had booster dose were found

with antibody level ranging from 1-10 IU/L. Of the total number of 93 HCWs who had taken 3 dose only 11 (11.82%) had antibody level ranging from 1-10 IU/L. Out of the total number of 50 HCWs who had taken 2 dose only 8 (16%) had antibody level ranging from 1-10 IU/L. Out of the total number of 30 HCWs who had taken 1 dose only 9 (28.1%) had antibody level ranging from 1-10 IU/L. 63 HCWs had antibody titre in the range of 101-1000 IU/L with 23 males and 40 females. 75 HCWs had antibody titre from 11-100IU/L with breakup of 35 males and 40 females. 23 (10.96%) HCWs out of 192 vaccinated HCWs had Anti-HBs titres in excess of 1000 IU/L. All 4 HCWs who had nil level of protective antibody were non-vaccinated. Out of 4 HCWs, 3 were female Staff Nurse and 1 male Counsellor with ICTC. Total number of non-vaccinated HCWs were 245 with 112 males and 133 females.

Table 8 : Co-relation of Anti-HBs Levels in vaccinated and non-vaccinated HCWs (sex-wise) with number of vaccine dose taken

S. No	Level of Anti-HBs (IU/L) of HCWs	No. of vaccinated male HCWs with no. of vaccine dose					No. of vaccinated female with no. of vaccine dose					Total no. of vaccinated HCWs	Total no. of non-vaccinated HCWs		
		1 D	2 D	3 D	Booster	Total	1 D	2 D	3 D	Booster	Total		Male	Female	Total
1.	Zero	-	-	-	-	-	-	-	-	-	-	-	1	3	4
2.	1-10	4	3	6	-	13	5	5	5	3	18	31	52	71	123
3.	11-100	6	11	15	3	35	3	11	22	4	40	75	42	36	78
4.	101-1000	5	4	13	1	23	3	10	21	6	40	63	14	15	29
5.	>1000	4	3	7	1	15	-	3	4	1	8	23	3	8	11
Total		19	21	41	5	86	11	29	52	14	106	192	112	133	245

6.6 In **Table 9** Injury profile is given. Out of total number of 437 HCWs, 231 (52.8%) had history of injury. Out of these 231 HCWs, 218 (94.3%) had superficial injury and only 13 (5.62%) had deep injury. Maximum number of injuries had occurred during sample collection (30.7%) followed by surgery (29%), cleaning job (16.8%), waste disposal (8.2%) and slide preparation (2.59%). Post Exposure Prophylaxis (PEP) have been taken only by 5 (2.16%) HCWs, out of which 2 are MOs, 1 Lab. Tech, 1 Lab Asstt. and one Blood Bank Attendant. It reflects poor awareness on the importance of PEP. Only 121 (52.3%) HCWs have got vaccination done before injury occurred.

Table 9 : Injury profile of HCWs

Type of Injury		Injuries occurred during							Post-exposure prophylaxis taken by				
Deep	13	Sample Collecti on	Slide Prepar ation	Waste Dispos al	Cleanin g	Surgery	Other s	Tota l	MOs	Lab Tech.	Lab Asstt.	BB Atten .	Tota l
Superf icial	218	71	6	19	39	67	29	231	2	1	1	1	5
Total no. of HCWs	231												

6.7 **Table 10** gives Infection awareness of HCWs. Out of total number of 437 HCWs, 413 (94.5%) were aware of infection hazards. Only 24 (5.49%) HCWs did not have any awareness of infection hazards. Maximum number of 265 HCWs have learnt about infection hazards from Training/Seminars (64.1%), 102 (24.6%) from seniors and 70 (16.9%) HCWs have learnt it themselves. After learning about injury hazards, all 437 HCWs admitted that their attitude changed towards injury hazards and their incidence of injuries were reduced.

Table 10 : Infection Awareness of HCWs

HCWs with awareness of infection hazards		Mode of learning about infection hazards			
Yes	No	Trg./Seminars	From Seniors	Self	Total
413	24	65	102	70	437

Total HCWs-437

6.8 **HBc IgM Test**

All 437 samples were tested for HBc IgM and all tested negative.

6.9 Profile of HBV Sero-positive HCWs

All eleven HBV sero-positive HCWs were followed up clinically and their Liver Function profile was studied. They all were asymptomatic and their liver enzymes SGPT, SGOT and Alkaline Phosphatase were found to be within normal limits.

7. DISCUSSION

- 7.1 This study was planned to understand the awareness level of HCWs working in public health sector, in relation to occupational risk related to health care associated infections in the state of Maharashtra. It was also planned to study the status of Hepatitis B vaccination and response to it. Total 2994 HCWs working in various District Hospitals and Sub-district Hospitals in the state of Maharashtra were planned to study, out of which 473 HCWs volunteered and responded to the questionnaire. However, the number of samples studied were 437. The gender distribution of the 437 HCWs consists of 198 Males and 239 female HCWs. It is very significant to note in this study that wide spectrum of HCWs participated. All categories of HCWs such as Specialist Clinicians, Nurses, Lab Techs., and Attendants etc. participated in it. Regarding awareness of various risk factors leading to injuries and transmission of infections, it was observed that 94.5% HCWs were aware of the infection risk. This is due to the IEC activities undertaken by the Public Health Department of the state under various programs. However, it is also desirable to have positive change in attitude and continued preventive practices. Most of these HCWs were aware of the risk of NSIs as a measure cause of parental transmitted infections.
- 7.2 A NSI is a upper cutaneous piercing wound caused by needle point and possibly, also by other sharp instruments or objects. This situation is faced by the HCWs handling these sharp objects in medical setting. These are avoidable occupational hazards faced by medical and paramedical community. This is a serious concern because of the risk involved in transmitting blood borne diseases such as Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV). Despite their seriousness as a medical event, NSIs are neglected and go unreported but as they have been recognized as an occupational hazard, their prevention has become a subject of regulation in an effort to reduce and eliminate these

preventable incidents. Because the risk of being infected is highest in the lower strata of the HCWs hierarchy, most hospitals do not consider prevention of NSIs as an important task. While countries such as Hong Kong, China, Australia and the Philippines are undertaking massive work on this front, Indian hospitals are just waking up to the challenges of putting such a mechanism in place. In the US, it is mandatory for such prevention and safety mechanism to be present. The ideal way would be to rein in hospitals who do not want to invest in the safety of their HCWs is to bring in legislation that penalizes non-compliance. India is in need of a regulatory agency to control workplace safety like Occupational Safety and Health Administration (OSHA) or the National Institute for Occupational Safety and Health (NIOSH) in the United States. The regulatory mechanism along with strengthening training of HCWs and finding technological solutions to minimize these injuries would help in reducing these incidents.

7.3 Sharp-tip suture needles are the leading source of percutaneous injuries to surgical personnel, causing 51% to 77% of these incidents (65). Sharp-tip suture needles not only injure surgical staff, but also present a risk to patients from potential exposure to injured staff's blood. Suture needle injuries can occur when surgical personnel-

- Load or reposition the needle into the needle holder;
- Pass the needle hand-to-hand between team members;
- Sew toward the surgeon or assistant while the surgeon or assistant holds back other tissue;
- Tie the tissue with the needle still attached;
- Leave the needle on the operative field;
- Place needles in an over-filled sharps container;
- Place needles in a poorly located sharps container

Suture needle injuries frequently occur during suturing of muscle and fascia. In 2005, the American College of Surgeons (ACS) issued a statement supporting universal adoption of blunt-tip suture needles for

suturing fascia and encouraging further investigation of their appropriate use in other surgical applications. The ACS stated that “all published studies to date have demonstrated that the use of blunt suture needles can substantially reduce or eliminate NSIs from surgical needles.”(65).

- 7.4 According to a WHO study, the annual estimated proportions of HCWs exposed to blood-borne pathogens globally were 5.9% for HBV, 2.6% for HCV and 0.5% for HIV corresponding to about 16,000 HCV infections and 66,000 HBV infections in HCWs worldwide (59).
- 7.5 The sample size used in numerous published international and national studies on protective antibodies against HBV varied ranging from 65 to 300 (1,67,70,90). There are few such reported studies from India. A study on evaluation on protective antibodies in Hepatitis B vaccinated HCWs was carried out by Dr. Majid Khan at Sir J. J. Hospital, Mumbai in May, 2009. In his study, 235 HCWs were studied, of which 181 HCWs had been vaccinated while 54 did not receive the vaccine (48). Dr. Majid in his study has reported that 85.52% HCWs were fully protected having Anti-HBS protective antibody titre more than 10 mIU/ml. Similar results in terms of percentages of HCWs not having protective antibodies were reported by Rao et al (61) who had shown the rate to be 10.5% while Alcyone (1) had 18.5%, Goldberg (33) 14% and Saffar (64) 13% respectively. All HCWs who did not have protective antibodies were advised to get vaccinated.
- 7.6 A four-year continuous surveillance study was undertaken at a tertiary care centre in India (52) wherein out of 342 HCWs, 5 HCWs sustained NSIs. PEP was given to HCWs injured from sero-positive sources. If the source was HbsAg positive, HCWs were given a hepatitis B immunization booster. If the HCW was anti HBs negative, both hepatitis B immunoglobulin (HBIG) and hepatitis B vaccine were administered. For HCWs who sustained injuries from HIV positive sources, antiretroviral therapy was started. Follow-up was done after three and six months of exposure. Of 342 injuries, 254 were from known sources and 88 from unknown sources. From known sources, 37 were seropositive; 13 for HIV, 15 for HCV, nine for HBV. Sixty six sharp

injuries were sustained through garbage bags, 43 during IV line administration, 41 during injection administration, 35 during needle recapping, 32 during blood collection, 27 during blood glucose monitoring, 24 from OT instruments, 17 during needle disposal, 16 while using surgical blade, 7 during suturing and 34 from miscellaneous sources. No case of seroconversion was found to have taken place, so far, as a result of NSIs at the Center.

7.7 A study (54) was carried out to determine the occurrence of NSIs among various categories of HCWs and the causal factors, the circumstances under which these occur and to, explore the possibilities of measures to prevent these through improvements in knowledge, attitude and practice. The study group consisted of 428 HCWs of various categories at a tertiary care hospital in New Delhi, and was carried out with the help of an anonymous, self-reporting questionnaire structured specifically to identify predictive factors associated with NSIs. The commonest clinical activity to cause the NSI was blood withdrawal (55%), followed by suturing (20.3%) and vaccination (11.7%). The practice of recapping needles after use was still prevalent among HCWs (66.3%). Some HCWs also revealed that they bent the needles before discarding (11.4%). It was alarming to note that only 40 per cent of the HCWs knew about the availability of PEP services in the hospital and 75 per cent of exposed nursing students did not seek PEP. This study showed a high occurrence of NSI in HCWs with a high rate of ignorance and apathy as the present study. This again emphasizes upon the need of appropriate education and other interventional strategies by the hospital infection control committee for HCWs.

7.8 A study (68) was undertaken in United States to determine the incidence of NSIs in medical school and to examine the behaviors associated with reporting injuries to an occupational health office as medical students have underdeveloped surgical skills and are at high risk of NSIs. Medical school graduates enrolled in a surgery residency at 17 medical centers

were surveyed regarding needle stick injuries that they sustained during medical school. The survey asked about the circumstances and cause of injury and post injury reporting. Of 699 respondents, 415 (59%) reported having sustained a NSI as a medical student; the median number of injuries per injured respondent was 2. It was observed that NSIs and underreporting of these injuries are common among medical students and place them at risk for hepatitis and human immunodeficiency virus. Strategies aimed at improving reporting systems and creating a culture of reporting is required to be implemented by medical centers.

- 7.9 In the present study in Maharashtra, out of total number of 437 HCWs 231 (52.8%) had history of injury. Out of these 231 HCWs, 218 (94.3%) had superficial injury and only 13 (5.62%) had deep injury. Maximum number of injuries have occurred during sample collection (30.7%) followed by surgery (29%), cleaning job (16.8%), waste disposal (8.2%) and slide preparation (2.59%). PEP have been taken only by 5 (2.16%) HCWs, out of which 2 are MOs, 1 is Lab. Tech., 1 Lab Asstt. and one Blood Bank Attendant. It reflects poor awareness on the importance of PEP. Only 121 (52.3%) HCWs have got vaccination done before injury occurred.
- 7.10 A cross-sectional study was undertaken in a tertiary care hospital in Delhi in March, 2008 involving 322 HCWs of the hospital, consisting of 64 senior residents, 47 junior residents, 74 interns, 52 nursing staff, 42 nursing students, and 43 laboratory technicians with the objective to study prevalence and response to needle stick injuries among HCWs (60). A large percentage (79.5%) of HCWs reported having had one or more NSIs in their career. The average number of NSIs ever was found to be 3.85 per HCW (range 0-20). 72 (22.4%) reported having received a NSI within the last month. More than half (50.4%) ascribed fatigue as a cause of their injury. Most of the injuries (34.0%) occurred during recapping. In response to their most recent NSI, 60.9% washed the site of injury with water and soap while 38 (14.8%) did nothing. Only 20 (7.8%) of the HCWs took PEP against HIV/AIDS after their injury. The

maximum NSI within last 1 month was reported among three groups- senior residents (26.6%), lab technicians (25.6%), and nursing students (25.0%). The occurrence of NSI was found to be quite common. Avoidable practices like recapping of needles were contributing to the injuries. Prevention of NSI is an integral part of prevention programs in the work place and training of HCWs regarding safety practices indispensably needs to be an ongoing activity at a hospital.

- 7.11 Another study was carried out to study NSIs in a tertiary care centre in Mumbai (52). A six-year (1998–2003) ongoing surveillance of NSIs was done wherein out of the 380 HCWs who reported NSIs, 45% were nurses, 33% participants were attendants, 11% were doctors and 11% were technicians. On source analysis, 23, 15 and 12 were positive for Hepatitis B surface antigen (HBsAg), human immunodeficiency virus (HIV) and hepatitis C virus (HCV), respectively. Analysis of the source of injuries revealed that known sources accounted for 254 injuries, and unknown sources from garbage bags and operation theatre instruments accounted for 126 injuries. Most NSIs occurred during intravenous line insertion (N=112) followed by blood collection (N=69), surgical blade injury (N=36) and recapping needles (N=36). Immediate PEP for HCWs who sustained injuries with hepatitis-B-virus-positive patients included booster hepatitis B immunization for those positive for anti HBs. A full course of immunization with hepatitis B immunoglobulin was given to those who were anti HBs negative. All staff who sustained injury with HIV were given immediate antiretroviral therapy (AZT 600 mg/day) for six weeks. Subsequent six-month follow-up showed zero seroconversion.
- 7.12 A review of 1-year (July 2006-June 2007) of ongoing surveillance of NSIs in a 2234 bed tertiary care hospital in Tamil Nadu (40) that serves as the teaching hospital for Colleges of Medicine and Nursing in India showed that out of the total number of 296 HCWs reporting NSIs there were 85 (27.4%) nurses, 28 (9.1%) nursing interns, 46 (20.6%) cleaning

staff, 65 (20.6%) doctors, 48 (14.2%) medical interns and 24 (8.1%) technicians. Among the staff who had NSIs, 147 (49.7%) had a work experience of less than 1 year. The devices responsible for NSIs were mainly hollow bore needles (77.7%). In 73 (24.6%) of the NSIs, the patient source was unknown. Recapping of needles caused 25 (8.5%) and other improper disposal of the sharps resulted in 55 (18.6%) of the NSIs. Immediate post-exposure prophylaxis for HCWs who reported injuries was provided. Subsequent 6-month follow-up for human immunodeficiency virus showed zero seroconversion. Improved education, prevention and reporting strategies and emphasis on appropriate disposal are needed to increase occupational safety for HCWs. The study hospital had maintained a NSI register since 1993 and protocols for management and follow-up of NSIs had been established. As soon as a HCW sustains a NSI, he/she is to induce bleeding from the wound and wash with soap and water and to report to the Staff Student Health Services duty doctor immediately. The duty doctor collects information regarding the index patient/source and completes a proforma, which has details of (i) the source, including diagnosis, hepatitis B surface antigen (HBsAg), HIV and HCV antibody status before and after the NSI. If these have not been tested earlier, the investigations are sent and followed-up within 6 hours (ii) HCW position and work experience, previous history of NSIs or blood transfusions (iii) vaccination status, including anti-HBs titer, HIV, HBsAg, anti-HCV antibody and (iv) details of the incident, time of incident, time of reporting, place of incident, description of the incident, type of first aid given and whether universal precautions were followed by the HCW.

- 7.13 In the present study, total number of 86 males and 106 females were found to be vaccinated. 19 males out of these 86 males had taken 1 dose, 21 had taken 2 dose, 41 had taken 3 dose and only 5 had taken booster dose. Out of total number of 106 females, 11, 29, 52 and 14 females were found to be vaccinated with 1, 2, 3, and booster dose respectively. Even though total of females were more 239 (54.3%) than

198 males (45.6%) more number of females have opted for booster dose 14 (8.2%) than 5 (1.8%) in males.

- 7.14 All 437 samples were tested for the surface antigen (HBsAg), only 11 (0.002%) had tested positive. The number of males were 4 (36%) and 7 females (63.6%). Only 8 (72.7%) of these HCWs who tested positive for HBsAg had been vaccinated. Out of these 11 HCWs, 5 (45.4%) had level of antibody 10 and below 10 IU/L. Out of these 5 HCWs, 3 (60%) were not vaccinated. Other 2 HCWs, both female had 3 and 1 dose respectively. These 5 HCWs may have had hospital acquired infection or sexually acquired one. Even though HCW histories were taken, exact mechanism of this infection can not be known. It could be presumed that they were hospital acquired infections. Vaccine is supposed to have failed to push up the antibody titer in case of 2 vaccinated and in case of other 8 HCWs who had antibody level of more than 10 IU/L. Out of 11 HCWs, 6 (54.5%) were Staff Nurse, 3 (27.2%) Lab and Blood Bank Technicians, 1 (9.0%) Medical Officer and 1 (9.0%) was an Attendant.
- 7.15 The number of vaccinated HCWs was 192 with 86 males and 106 females. There are 3 (18.8%) HCWs (out of 19 HCWs who had booster dose), all females who had booster dose were found with antibody level ranging from 1-10 IU/L. Of the total number of 93 HCWs who had taken 3 dose only 11 (11.82%) had antibody level ranging from 1-10 IU/L. Out of the total number of 50 HCWs who had taken 2 dose only 8 (16%) had antibody level ranging from 1-10 IU/L. Out of the total number of 30 HCWs who had taken 1 dose only 9 (28.1%) had antibody level ranging from 1-10 IU/L. 63 HCWs had antibody titer in the range of 101-1000 IU/L with 23 males and 40 females. 75 HCWs had antibody titer from 11-100 IU/L with breakup of 35 males and 40 females. 23 (10.96%) HCWs out of 192 vaccinated HCWs had Anti-HBs titers in excess of 1000 IU/L. All 4 HCWs who had nil level of protective antibody were non-vaccinated. Out of 4 HCWs 3 were female Staff Nurse and 1 male counsellor with ICTC. Total number of non-vaccinated HCWs was 245 with 112 males and 133 females.

7.16 In India, it is not known exactly how many occupation related injuries occur each year, and as data is scarce, it is not possible to estimate an annual incidence. Estimates from the USA indicate that 600,000-800,000 such injuries occur annually and approximately half of these go unreported (8). Data from the EPINET system suggest that in an average hospital, HCWs incur approximately 27 NSIs / 100 beds / year (8). Gross under-reporting of NSI should not lead health care administrators to underestimate the problem. Although the risk may be low, the psychological trauma as well as legal implications that follow such injuries can be considerable. Additionally, financial implications include initial first aid treatment, post-exposure prophylactic drugs, hepatitis B immunoglobulin, cost of baseline investigations and the inevitable cost of treating a disease once transmitted. At a tertiary care hospital in Mumbai, approximately Rs 9000/- HCW / episode of needle stick injury are incurred as short term cost (8). Long term costs such as anxiety, personal impact, adverse effect on work performance and potential litigation have not been factored in. Although the risk may be low, the psychological trauma as well as legal implications that follow such injuries can be considerable. Most reported NSIs involve nursing staff; laboratory staff, physicians, housekeepers, etc. Other than the risk of getting infected, the emotional impact of a NSI can be severe and long lasting, even when a serious infection is not transmitted. This impact is particularly severe when the injury involves exposure to HIV. In one study of 20 HCWs with an HIV exposure, 11 reported acute severe distress, 7 had persistent moderate distress, and 6 quit their jobs as a result of the exposure (35). Other stress reactions requiring counseling have also been reported. Knowing the infection status of the source patient can accentuate the HCWs stress. In addition to the exposed HCW, colleagues and family members may suffer emotionally. Because NSIs are often under reported, health care institutions should not interpret low reporting rate as low injury rate. Injuries recorded through standard occupational reporting system may underestimate the true injury rate. NSIs have significant indirect consequences in health care

delivery especially so in the developing countries, where already the qualified work force is limited in comparison to the disease burden in the population.

- 7.17 HCWs have increased chance of acquiring blood borne pathogens through occupational exposure in developing countries due to a combination of increased risk and fewer safety precautions (44). As loss of HCWs can seriously undermine developing health systems, it is important that risks are minimized. A literature search was conducted to investigate the risk of transmission of three pathogens: human immunodeficiency virus, hepatitis B and hepatitis C viruses; and to identify factors that influenced the risk with reference to developing countries. There are many difficulties faced by developing countries in minimizing the risk of occupational exposure. These injuries not only potentiate health consequences but also cause emotional distress in HCWs which results in missed workdays and directly affects the health care services and resources (60). Between 1985 and June 1999, cumulative totals of 55 "documented" cases and 136 "possible" cases of occupational HIV transmission to U.S. HCWs were reported to the CDC. Percutaneous injury (e.g., needle stick) was associated with 49 (89%) of the documented transmissions. Of these, 44 involved hollow-bore needles most of which were used for blood collection or insertion of an IV catheter. In 1995, an estimated 800 HCWs became infected with HBV. This figure represented a 95% decline from the 17,000 new infections estimated in 1983. The decline was largely due to the widespread immunization of HCWs with the hepatitis B vaccine and the use of universal precautions and other measures required by the Occupational Safety and Health Administration (OSHA) blood borne pathogens standard (73). About one-third to one-half of persons with acute HBV infection develop symptoms of hepatitis such as jaundice, fever, nausea, and abdominal pain. Most acute infections resolve, but 5% to 10% of patients develop chronic infection with HBV that carries an estimated 20% lifetime risk of dying from cirrhosis and 6% risk of dying from liver cancer. HCWs also clearly have an increased occupational

risk for HCV infection. Of the total acute HCV infections that have occurred annually 2% to 4% have been in HCWs exposed to blood in the workplace. HCV infection often occurs with no symptoms or only mild symptoms. But unlike HBV, chronic infection develops in 75% to 85% of patients, with active liver disease developing in 70%. Of the patients with active liver disease, 10% to 20% develop cirrhosis and 1% to 5% develop liver cancer.

- 7.18 Analysis of percutaneous injury surveillance data from 87 hospitals in the United States was undertaken from 1993 through 2006, comparing injury rates in surgical and nonsurgical settings before and after passage of the Needle stick Safety and Prevention Act, 2000 (39). Devices and circumstances associated with injuries among surgical team members were identified. Of 31,324 total sharps injuries, 7,186 were to surgical personnel. After the legislation, injury rates in nonsurgical settings dropped to 31.6%, but increased to 6.5% in surgical settings. Most injuries were caused by suture needles (43.4%), scalpel blades (17%), and syringes (12%). Three-quarters of injuries occurred during use or passing of devices. Surgeons and residents were most often original users of the injury-causing devices. Nurses and surgical technicians were typically injured by devices originally used by others. It thus showed that despite legislation and advances in sharps safety technology, surgical injuries continued to increase during the period that nonsurgical injuries decreased significantly. Hospitals therefore should comply with requirements for adoption of safer surgical technologies and promote policies and practices shown to substantially reduce blood exposure to surgeons, their coworkers, and patients. Although decisions affecting the safety of the surgical team lie primarily in the surgeon's hands, there are also roles for administrators, educators, and policy makers.
- 7.19 A study was done in Syria (79) to determine the hepatitis B vaccination status, to assess the number of vaccinations administered, and to estimate the annual incidence of NSIs among HCWs in Aleppo

University Hospital. A cross-sectional design with a survey questionnaire was used for exploring details of NSIs during 2008, hepatitis B vaccination status, and HBV infection among a random stratified sample of HCWs in three tertiary hospitals in Aleppo (n = 321). Two hundred and forty-six (76.6%) HCWs had sustained at least one NSI during 2008. Nine (2.8%) had HBV chronic infection and 75 HCWs (23.4%) were never vaccinated. Anesthesiology technicians had the greatest exposure risk when compared to office workers and nurses. HCWs under 25 and between the age of 25 and 35 years were at increased risk of NSI when compared to HCWs older than 45 years respectively. This study as the present study repeated the importance of precautions and protection from NSIs in preventing infection of HCWs. It stresses upon the fact that education on the transmission of blood-borne infections, vaccination, and post-exposure prophylaxis requires mandatory implementation and strict monitoring.

- 7.20 HCWs in nine hospitals in Fujian (16) were surveyed between December 2005 and February 2006 regarding the occurrence of Sharp Object Injuries (SOIs). Survey results indicated that 71.3% of the HCWs had sustained SOIs during the past year. The rates of SOIs among surgeons, nurses, anesthesiologists, and clinical laboratory workers were 68.7%, 76.9%, 88.1%, and 40.2%, respectively. Approximately 50% of the SOIs occurred while devices were being used. Disposable syringes caused most of the injuries. A lack of protective and safe device, heavy workload and carelessness contributed to SOIs. SOIs can be reduced among HCWs by decreasing unnecessary manipulation, using safety devices, disposing of used objects properly, and reasonably allocating workloads.
- 7.21 To assess the prevalence and attitude towards NSIs by Nigerian gynecological surgeons, a cross-sectional study was conducted at the 40th Annual General Meeting and Scientific Conference of the Society of Gynecology and Obstetrics of Nigeria (SOGON) held in Ibadan, southwest Nigeria from the 23rd to the 26th of November 2005 (25).

Data was collected using a self-administered questionnaire. Sixty-five (90.3%) respondents had experienced NSIs in the workplace. This occurred in the majority of cases (86.2%) during suturing. Only 9.2% of those experiencing a NSI took the correct or appropriate action afterwards. 14 (80%) of those with NSIs did not report the incident to the appropriate office. Only 26 (37.1%) of 70 respondents indicated the presence of a needle-stick policy in their centers. It shows that majority are either unaware or do not take appropriate action after exposure to hazardous body fluids from NSI either through first-aid steps or post-exposure prophylaxis. All health institutions should have a working needle-stick policy in their centers, and HCWs continually educated on it.

- 7.22 A cross sectional study by interviewing all HCWs in six hospitals of Tigray, Ethiopia was undertaken (32). A total of 618 HCWs were interviewed about exposure in the past three months. NSI was reported in 106 HCWs (17.2%), 348 (56.3%) had contact of blood and body fluid to their skin and 154 (24.9%) reported exposure to their mucus membrane. Working in the delivery room (80.4%) and gynecological wards (75%) had higher risk of exposure to the skin. Regarding their knowledge on preventive measures, only 254 (41.1%) of all HCWs said they wash their skin immediately and 318 (51.5%) flash their eyes with clean water or saline if their skin and mucous membrane are exposed. Incorrect method of processing instruments were practiced by high number of HCWs, namely, decontamination by 47.5%, disinfection by 46.5% and sterilization by 41.5% of them. This study emphasized on the fact that HCWs are at a very high risk of exposure to blood and body fluids. Poor efforts are made to prevent infection after exposure. Wrong practice of processing instrument is shown to be high. It was recommended that HCWs should follow and practice all the standard measure to prevent transmission of infection in a clinical setting.

7.23 A study in Japan involved a modified version of the Hospital Safety Climate Scale, which was distributed to a large cross section of nurses in a Japanese teaching hospital (71). Various aspects of safety climate were associated with a reduced NSI risk, such as being involved in health and safety matters, confidence interval and being properly trained in risk control procedures. Nurses working in departments in which health and safety information was readily available were more likely to report any NSI they sustained whereas, nurses working in departments with in its absence were less likely to underreport their NSI. Overall, this study suggested that hospital safety climate has an important influence on NSI injury rates and reporting behavior among Japanese nurses. Given the multifaceted nature of identified risk, a comprehensive approach to infection control is clearly required and one that encompasses preventive strategies in both the cultural and physical domains.

7.24 Above international and national studies stress upon the fact of NSIs acquired by HCWs at their work place and in turn the infections which could be life threatening in a long term. An integrated and comprehensive approach to handle them has still been lacking in most part of the world even though there are stringent Acts passed by some countries. Occupational safety of this critical work force must be ensured by all concerned through education of HCWs as well as strict monitoring and implementation of legal measures.

7.25 Some Good Practices (Appendix IV) to be followed by the HCWs at their work place are as enumerated below-

Good Practices

- 1) To wear sterile gloves, masks and aprons to ensure safety of staff working in the laboratory, ward, labour room and operation theatre
- 2) To utilize needle destroyer or sharp container for disposing off the needles and other sharp instruments like scalpel, broken glassware and plastic pieces

- 3) Hand washing
- 4) Immunization of all staff with maintenance of immunization records
- 5) Proper handling of sharps, use of protective gear while disposing off the waste (puncture proof boxes, rubber gloves for handlers, disinfection before disposal, bags to be securely tied after 3/4th full)
- 6) Avoiding soiling of investigation slips in the laboratory
- 7) Training in handling and management of Biomedical Waste (BMW) (collection, segregation and transportation of BMW)
- 8) Storage of BMW (not beyond 48 hours) before disposal, safe and hygienic disposal of waste
- 9) Avoiding mixing of regular waste with toxic BMW (presenting serious health hazard for staff, patients and visitors)
- 10) Knowing and observing needle stick injury protocol
- 11) Constitution of Hospital Infection Control Committee (HICC)
- 12) Hospital Infection Control guidelines defined and followed
- 13) Periodic health check up of food handlers once every three months and their training on safe practice. They may otherwise act as carriers for various communicable diseases like typhoid
- 14) Making proper use of protective equipment, radiation monitors and personnel monitoring devices in x-ray room
- 15) Informing the licensee and the Radiological Safety Officer of any accident or potentially hazardous situation that arises
- 16) Notification by pregnant female staff working in radiology department in order to alter working conditions, if necessary
- 7.26 Recommendations for employees to prevent NSIs in health care settings have been given by the National Institute for Occupational Safety and Health (NIOSH) (65). A checklist for HCWs Safety has been given by WHO with key elements of universal precautions (77). Universal precautions for prevention of transmission of HIV and other blood borne infections are issued by CDC (10).



8. SUMMARY AND CONCLUSION

- 8.1 In the present study, a total number of 473 study population blood samples were collected from all 8 circles of the State of Maharashtra and studied. Blood samples were collected from Ward Helpers, Laboratory Technicians, Nursing Staff, Resident Doctors, Senior Clinicians and also Interns.
- 8.2 The collected 437 study population was tested for HBs Ag, Anti HBs, HBC IgM and HIV Antigen. HBs Ag test was positive in respect of 11 HCWs. Liver profile (ALT, AST and Alkaline Phosphatase) of these study population was performed. All these HCWs have been recommended to be evaluated clinically with liver profile and repeat HBs Ag.
- 8.3 107 HCWs have been found to have less than blank titer of antibodies when tested for Anti-HBs. This study population was tested for HBc IgM. All of them have been found to be negative.
- Of the 437 HCWs, 192 had been vaccinated against HBs Ag and the remaining 245 HCWs had not been vaccinated for HBs Ag.
 - Among the 192 vaccinated HCWs, 86 were males and 106 females. Among the 192 vaccinated HCWs, 19 had taken booster dose, 93 taken 3 doses, 50 taken 2 doses and 30 HCWs had taken only one dose.
 - Eight of the total 192 vaccinated HCWs tested positive for HBs Ag, out of which 4 had taken 3 doses, 3 taken 2 doses and one taken one dose.
 - Out of the above 8 HCWs, 2 were males and 6 females.
 - All 437 HCWs were tested for HBs Ag, 11 tested positive, showing a positivity of 2.5%. 3 HCWs were not vaccinated and hence require full vaccination.

- All 437 HCWs were tested for Anti HBs, 127 were 10 IU/L and below, 4 out of which had nil Anti-HBs showing a positivity of 30% and 3.0% respectively. 4 HCWs with nti-HBs

needed full vaccination.

- Out of total number of 127 HCWs, 31 were vaccinated and remaining 96 were not vaccinated.

- 106 of the total 192 vaccinated HCWs tested positive for core antibody, meaning that they were infected prior to HBs Ag vaccination, leaving a total of 86 'truly' vaccinated HCWs.

- Out of total number of 127 HCWs having 10 and below IU/L anti HBs, 5 HCWs were positive for HBS Ag, showing a positivity of 3.5% , meaning they may have hospital acquired infection or sexually acquired infection. Even though history was taken, we are not aware of the mechanism of infection. It could be presumed that it is hospital acquired infection seeing their professional background which is vulnerable to be infected. They need follow up as they may transmit infection to others.

- All 437 HCWs were tested for HBc IgM , all tested negative, ruling out recent infection.

- 11 HBs Ag positive HCWs were tested for Liver Profile, Alanine Aminotransferase (ALAT); Aspartase Aminotransferase (ASAT); Alkaline Phosphatase . All HCWs had ALAT ASAT and ALP within normal range.

- 8.4 All HCWs who did not have protective antibodies were advised to get vaccinated or revaccinated.
- 8.5 The limitation of the study has been that Total HBc IgM should have been studied instead of only HBc IgM.
- 8.6 The high rates of non-responders and low responders (anti-HBs) highlight the need for post-vaccination serological testing of all HCWs, although the same is not recommended after routine adult vaccination.

- 8.7 It also highlights the importance of educating the HCWs of safety precautions when handling blood and body fluids and the management of 'sharps' injuries.
- 8.8 Under the study, all HCWs who did not have protective antibodies were advised to get vaccinated or revaccinated. The test results along with the recommendations were forwarded to concerned Medical Superintendents of all the Hospitals for necessary action so as to secure the safety of the staff. Based on the observations during the visit of the team as well as considering the safety precautions to be followed by them, a brochure on "Personal Protection in Hospital work-Some Good Practices" was prepared (Appendix X) for distribution among medical and paramedical workers for increasing awareness on the safety precautions to be taken by them at their work place.

9. REFERENCES

1. Alceyon A Machado- Prevalence of Hepatitis B and C among Brazilian Dentists, Chicago Journals – Infection Control & Hospital Epidemiology, Aug 2006; 27:887-888.
2. Alter M J-The changing epidemiology of Hepatitis B in the US for alternative vaccination strategies. JAMA, 1990;263:1218-1222.
3. Anthony E. Fiore, Annemarie Wasley, Beth P. Bell-Prevention of hepatitis A though active or passive immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP), May, 2006; 55 (RR7):1-23.
4. Ashish Mukhopadhyay- Hepatitis C in India, 2008,J. Biosci;33: 65-473.
5. Bairy I, Rao SP, Dey A-Exposure to blood-borne viruses among HCWs in a tertiary care hospital in South India, Journal of postgraduate Medicine, October-December, 2007;53(4):275-276.
6. Banatwal J, et al-Life-long Protection against Hepatitis B: The Role of Vaccine Immunogenicity in Immune Memory, ACCINE.2001;19:877-885.
7. Bryan J P et al-Persistence of antibody to Hepatitis B surface antigen after low dose intradermal HB Immunization and response to a booster dose vaccine 1992; 10:33-38.
8. Camilla Rodrigues-Needle stick injuries & the HCW- The time to act is now, Indian Journal of Med Res,131, March, 2010:384-386.
9. Center for Disease Control and Prevention (CDC)-CDC data and statistics/Feature/World Hepatitis Day, 28th July:1-4, www.cdc.gov/Features/dsHepatitisAwareness,
<http://www.cdc.gov/hepatitis/Statistics/index.htm> (accessed on 25th October, 2011).
10. CDC-Division of Healthcare Quality Promotion (DHQP)-National Center for Preparedness, Detection, and Control of Infectious Diseases, Universal Precautions for Prevention of Transmission of HIV | CDC http://www.cdc.gov/ncidod/dhqp/bp_universal_precautions.html
(Accessed on 09/03/2012).

11. CDC- A Comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in United States: Recommendations of the ACIP. Part 1 immunization of infants, children, adolescents, MMWR; 2005;54(No RR16).
12. CDC- MMWR-Weekly, Recommendations of the Immunization Practices Advisory Committee Prevention of Perinatal Transmission of Hepatitis B Virus: Prenatal Screening of all Pregnant Women for Hepatitis B Surface Antigen, 10/06/1988/ 37(22); 341-6:351.
13. CDC(1991)-Hepatitis B Virus, A Comprehensive Strategy for Elimination of Transmission in the USA- Universal Childhood Vaccination: Recommendations of American Committee on Immunization Practices. Morbidity and Mortality Weekly Report 40:1-25.
14. CDC-Suboptimal response to HB vaccine given by injection into the Buttock. MMWR 1985; 34:105-108.
15. CDC-Updated U.S. Public Health Services Guidelines for Management of Occupational Exposure to Hepatitis B, Hepatitis C and HIV and Recommendations for Post-exposure, Prophylaxis, MMWR 2001;50(No.RR-11).
16. Chen L, Zhang M, Yan Y et al-Sharp object injuries among HCWs in a Chinese province, AAOHN J, 2009; 57(1):13-16.
17. Child Health Division, Department of Family Welfare, Ministry of Health & Family Welfare-Introduction of Hepatitis B Vaccine in the Universal Immunization Programme, Operations Guide for Programme Managers, June, 2002.
18. Chongsrisawat V,Thawornsuk N, Theamboonlers A, Louisirirachanakul S, Poovorawan Y-Hepatitis B virus DNA in unusual serological profiles of Hepatitis B surface antigen-positive sera, Viral Immunol., 2006;19:623-629.
19. Coberly J S, et al- Suboptimal response following intradermal Hepatitis B vaccine in infants. Vaccine 1994; 12:984-987.
20. Colliers Leslie and Oxford John-Oxford Publications-Human Virology, 1997, Eds : 258-262.

21. Cregg J M, Vedvick T S, Rasche W C-Recent advances in expression of foreign genes in pichia pastoris, Biotechnology (NY),1993; 11:905-910.
22. Danni Daniels, Scott Grytdal, Annemarie Wasley-Surveillance for Acute Viral Hepatitis -United States,2007, May 22, 2009 / 58(SS03);1-27.
23. David M Knipe and Peter M Howle-Eds. Field's Virology.2007 5th Ed, Vol 2:2997-3058.
24. D.L Kasper, E Braunhald, A S Fauce, et al-Harrison Principle's of Internal Medicine Vol. 2.16th Ed; 2005:1822-1838.
25. Efetie ER, Salami HA- Prevalence of and attitude towards needle-stick injuries-Nigerian gynaecological surgeons,Niger J Clin Pract, 2009; 12(1):34-36.
26. Eric E S, Margolis H S, Fiore A E, et al-ACIP, A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B virus infection in the USA; Recommendations of ACIP; MMWR:Dec 32, 2005/54(RR16):1-23.
27. Eric E Mast, Cindy M. Weibaum, Anthony E.Fiore, Miriam J. Alter, Beth P. Bell, Lyn Finelli, Lance E. Rodewald, John M. Douglas, Robert S.Janssen, John W Ward- A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus infection in the United States, Recommendations of the Advisory Committee on Immunization practices (ACIP0 Part II: Immunization of Adults, December, 2006; (RR16):1-33.

28. ETI-MAK-4 (N0019), HBsAg ENZYME IMMUNOASSAY KIT-Procedure for qualitative determination of Hepatitis B surface antigen (HBsAg) in human serum or plasma samples, DIASORIN, S. P. A., LOT No. 0370700A.
29. ETI-AB-AUK-3 (P001603)ANTI-HBs ENZYME IMMUNOASSAY KIT-Procedure for qualitative/quantitative determination of antibodies to Hepatitis B surface antigen (anti-HBs) in human serum or plasma samples, DIASORIN, S. p. A., LOT No. 9230570B/1.
30. ETI-CORE-IGMK PLUS (N0138) IgM Anti-HBc ENZYME IMMUNOASSAY KIT-Procedure for qualitative determination of IgM antibodies to Hepatitis B core antigen (IgM anti-HBc) in human serum or plasma samples, DIASORIN, S. p. A., LOT No. 0270282A.
31. Francis L Delmonico- Cadaver Donor Screening for Infectious Agents in Solid organ Transplantation, Oxford Journals of Medicine & Clinical Infectious Diseases;31(3): 781-786.
32. Gessesew A, Kahsu A.-Occupational exposure of Health Workers to blood and body fluids in six hospitals of Tigray region, magnitude and management, Ethiop Med 16 J, 2009; 47(3):213-219.
33. Goldberg R-Anti-body titres to hepatitis B surface antigen among vaccinated emergency physicians, three years experience in a wellness booth, Ann. Emerg. Med. 01 Feb.; 33 (2):156-159.
34. Hadler S C Francis DP, Maynard JE, et al- Long term immunogenicity and efficacy of Hepatitis B vaccine in homosexual men, N Engl J Med 1986; 315:209-14.
35. Henry K, Campbell S-Needlestick/sharps injuries and HIV exposures among HCWs: National estimates based on a survey of USA hospitals. Min. Med 1995; 78:1765-1768.
36. Hepatitis B Facts-Testing and Vaccination, Immunization Action Coalition;651:647-09.
37. Hsu H M, et al-The Hepatitis Control Committee and Hepatitis Steering Committee, Efficacy of a mass Hepatitis B vaccination in Taiwan, JAMA 1988;260:223.

38. Immunization management issues-Appendix A; MWR December 08, 2006/55(RR16); 26-27.
39. Jagger J, Berguer R, Phillips EK, Parker G, Gomaa AE- Increase in sharps injuries in surgical settings versus nonsurgical settings after passage of national needlestick legislation, J Am Coll Surg, 2010; 210(4):496-502.
40. Jayanth ST, Kirupakaran H, Brahmadathan KN, Gnanaraj L, Kang G- Needle stick injuries in a tertiary care hospital. Indian J Med Microbiol 2009; 27(1):44-47.
41. Jeetha D' Silva and Sudha Menon- Pune Hospitals seen as model for health care workers safety, April 3, 2008.
42. Dr. J. N. Sahay, Ms Ridhima Dutta, Ms Nidhi Jain- Quality Management in Public Health Facilities-Traversing gaps, National Health Systems Resource Centre, Ministry of Health & Family Welfare Government of India, November, 2009.
43. Kubba A K, et al- Non-response to Hepatitis B vaccination; A review, Commun. Dis Public Health 2003 June; 6(2):106-112.
44. Lee R.- Occupational transmission of bloodborne diseases to healthcare workers in developing countries: meeting the challenges, J Hosp Infect, 2009; 72(4):285-291.
45. Lin Yang, Barbara Mullan- Reducing Needle Stick Injuries in Healthcare Occupations: An Integrative Review of the Literature, ISRN Nursing, Volume 2011 (2011), Article ID 315432, 1-11.
46. LIQUIXX-M, Alkaline Phosphatase (ALP), IFCC Method, Kinetic.
47. Magolis H S, Coleman P J, Brown R E , et al-Prevention of Hepatitis B Virus Transmission by Immunization: An economic analysis of current recommendation. JAMA . 1995; 264:1201-1208.
48. Dr. Majid J Khan-Evaluation of protective antibodies in HBV vaccinated Health Care Workers: A Dissertation submitted to University of Mumbai for degree of MD (Microbiology), May, 2009:1-91 (Personal communication).

49. Marc Hohman-Universal Precautions for Prevention of Transmission of Bloodborne Pathogens in Health-Care Settings: 1-16, <http://www.articlesbase.com/print/> (Accessed on 09/03/2012).
50. Margolis H S, et al-Hepatitis B: Evolving epidemiology and the implications for control of liver Disease. 1991;11:84-92.
51. Dr. Martha B. Rao-The prevalence of Hepatitis B in India and its prevention with Ayurveda- A revisit, Journal of New Approaches to Medicine and Health, Jan, 2012;19(4):1-5.
52. Mehta A, Rodrigues. C., Singhal T. et al-Interventions to reduce needle-stick injuries at tertiary care centre, Indian J. Med. Microbiol, 2010;2891:17-20.
53. M. G. Ghany-Hepatitis B Epidemiology, Parthenogenesis, Clinical Care Options www.clinicaloptions.com/Hepatology/ (Accessed on 13/04/2012).
54. Muralidhar S, Singh P, Jain R, Malhotra M, Bala M.- Needle stick injuries among HCWs in a tertiary care hospital of India. Indian Journal of Medical Research 2010; 131(March 2010):405-410.
55. Noh K W, Poland G A. Murray J A.- Hepatitis B vaccine non response and celiac disease, American J Gastroentero.2003 Oct; 98(10):2289-92.
56. Occupational Safety and Health Administration (OSHA), United States Department of Labour, www.osha.gov/pls/oshaweb/owadisp.show :13-16.
57. Playford E G, et al-Intradermal Recombinant Hepatitis B vaccine for HCWs who fail to respond to intramuscular vaccine , Infect. Control Hosp. Epid, 2002;23:87-90.
58. Poovorawan Y, et al-Long Term efficacy of Hepatitis B vaccine in infants born to HBe Ag-positive mothers upon failure of post-exposure prophylaxis, Int. J. Infect. Dis. 1998;2:216-20.
59. Pruss Ustun A, Rapit E, Hutin Y- Sharps Injuries Global Burden of diseases from sharps injuries to health care workers. Geneva, WHO 2003; WHO Environmental Burden of Diseases Series No 3 ,<http://www.who.int/quantifyingehimpacts/publications/en/sharps/pdf>.

60. Rahul Sharma, SK Rasania, Anita Verma, and Saudan Singh-Study of Prevalence and Response to Needle Stick Injuries among Health Care Workers in a Tertiary care Hospital in Delhi, India, Indian Journal of Community Medicine, January, 2010;35(1):74-77.
61. Rao T V, Suseela I J, Sathivathy K A-Estimation of Antibodies to HBsAg in Vaccinated Health Care Workers. Ind. Jour. of Micro, 2008; 26 (1):93-94.
62. Robinson W.S-Hepatitis B virus and Hepatitis D virus-Principles and Practice of Infectious Diseases, 4th ed, 1995:1406-1439.
63. Rottinghans S T, Poland G A et al-Hepatitis B DNA Vaccine induces protective antibody responses in human non-responders to conventional vaccination, 2003;21:4604-4608.
64. Saffar M J, Jooyan AR, Mahdavi M R , Khalilian A R-Hepatitis B Vaccination status in Health care Workers. Indian J of Gastroenterology 2005; 24:82-83.
65. Safety and Health Information Bulletin-SHIB Use of Blunt-Tip Suture Needles to decrease Percutaneous Injuries to Surgical personnel- 03-23-2007. DHHS (NIOSH)Publication.No.2008-101(supersedes 2007-132), vufind.org/demo2/Record/1278875 (accessed on 9th March, 2012).
66. SGOT (ASAT) KIT (Mod. IFCC method)-Determination of SGOT (ASAT) activity in serum IFCC methods for the measurement of catalytic concentrations of enzymes, J. Clin. Chem. Clin Biochem. (1986) 24:4977.
67. SGPT (ALAT) KIT (Modified IFCC Method)-Determination of SGPT (ALAT) Activity in Serum IFCC Methods for the measurement of catalytic concentrations of enzymes, J. Clin. Chem. Clin. Biochem. (1986) 24:481.
68. Sharma G K, Gilson M M, Nathan H, Makary M A-Needlestick injuries among medical students: incidence and implications, Academic Medicine 2009; 84(12):1815-1821.

69. Shaw F C Jr., Guess H A et al-Effect of anatomic injection site, age and smoking on the immune response to HBV vaccination, 1989;7:425-430.
70. Liiva AE, McMahon BJ, Parkinson AJ, et al-Hepatitis B virus DNA in persons with isolated antibody to hepatitis B core antigen who subsequently received hepatitis B vaccine, Clin Infect Dis. 1998;26:895-897.
71. Smith DR, Mihashi M, Adachi Y. et al-Organizational climate and its relationship with needlestick and sharps injuries among Japanese nurses, Am J Infect Control, 2009; 37(7):545-550.
72. Sunil M. Shah, Shivaram Prasad Singh- Hepatitis B Virus Serology: Use and Interpretation; 39-54, www.hepatitisbannual.org (Accessed on 20/04/2012).
73. Thomas K. Hodous, Linda A. Chiarello, Scott D. Deitchman, Ann N. Do, Anne C. Hamilton, Janice M. Huy, E. Lynn Jenkins, Andrew M. Maxfield, Edward L. Peterson, Raymond C Sinclair, Angela M Weber-Alert Preventing Needlestick Injuries in Health Care Settings, US Department of Health and Human Services, Public Health Service, Center for Disease Control and Prevention, National Institute for Occupational Safety and Health (NIOSH), November, 1999, Publication No. 2000-108:1-16.
74. US Public Health Service-Updated US public health service guidelines for the management of occupational exposures to HBV, HCV, and HIV and recommendations for postexposure prophylaxis, MMWR Recomm Rep., June, 2001;50 (RR11):1-42.
75. Vaccine Insert-Shanvac B; 07/2006: Shanta Biotech's Ltd.
76. Van Damme P, J Banatvala et al- Hepatitis A Booster Vaccination – Is there a need?, The Lancet, 2003;362:1065-7.
77. WHO-Health Care Worker Safety,
www.who.int/injection_safety/toolbox/docs/AM_HCW_Safety.pdf
(Accessed on 09/03/2012).

78. Williams I T, et al-Long term antibody response to Hepatitis B Vaccination beginning at birth to subsequent booster Vaccination, Paed. Infect. Dis.2003;22:157-163.
- 79.Yacoub R, Al AR, Moukeh G, Lahdo A, Mouhammad Y, Nasser M.- Hepatitis B vaccination status and needlestick injuries among Healthcare Workers in Syria, J. Glob Infect Dis., 2010; 2(1):28-34.
- 80..Zanetti A R, et al- Vaccination against Hepatitis B : a Historical Preview, 2007;5:7-12.
- 81.Zuckerman A J.-Hepatitis Viruses, Medical Microbiology, 4th ed.,1996:849-863.

10. Glossary

Abbreviations of Terms used in this study

ACIP	Advisory Committee on Immunization Practices
ALT	alanine aminotransferase
Ant-HBc	antibody to hepatitis B core antigen
Anti-HBe	antibody to hepatitis B e antigen
Anti-HBs	antibody to hepatitis B surface antigen
Anti-HBx	antibody to hepatitis B x antigen
AZT	Azidothymidine (Zidovudine)
BB	Blood Bank
CDC	Centre for Disease Control
ELISA	enzyme linked immunosorbant assay
HBcAg	hepatitis B core antigen
HBeAG	hepatitis B e antigen
HBsAg	hepatitis B surface antigen
HBxAg	hepatitis B x antigen
HBV	hepatitis B virus
HCC	hepatocellular carcinoma
HCV	hepatitis C virus
HCV-Ab	antibody to hepatitis C virus

HCWs	Health Care Workers
HIV	human immunodeficiency virus
IgG	immunoglobulin G
IgM	immunoglobulin M
IgM anti-HBc	IgM antibody subclass of anti-HBc.
IgG anti-HBc	IgG antibody subclass of anti-HBc.
LT	Laboratory Technician
NSI	Needle Stick Injury
OPD	Out patient Department
OT	Operation Theatre
PEP	Post Exposure Prophylaxis

11. APPENDIX

Participant Information Sheet

Project Name

Sero- epidemiological survey of health care workers in Maharashtra

Study Principle

1. To understand the risk factors and risk agents in the work environment of the health care workers catering to the public health services.
2. To estimate latent (HIV), HBV, HCV, HDV etc prevalence in health care workers.
3. To study the effect and protection offered by vaccination if previously taken, if not the consideration of vaccination to be done.
 - For Hepatitis B, no booster dose is required as per 2008 Guidelines of the American Council of Immunization Practice (ACIP).
 - For HIV and Hepatitis C, vaccine is not available
 - HBS-antigen if found +ve, denotes infection and infectious.
 - Presence of Anti-HBS occurs after vaccination or infection and offers protection
 - Anti-HBC develops after infection. Anti – HBC IgM denotes infection which has been acquired recently.
 - Anti-HBS and Anti- HBC indicates the infection which may be acquired in the work place.

Procedure

Collection of 5 ml of blood by vein puncture will be a voluntary procedure informed consent of all participants will be obtained.

Sr. No

Informed Consent

I understand that health care workers are exposed to blood transmitted infections as a professional hazard. They include infections such as Hepatitis B, Hepatitis C, HIV virus etc. Hepatitis B is preventable as vaccine is available. As a result, antibodies to surface antigen given protection.

This study protocol aims to detect protective antibody level against anti-HBS as an antibody against Hepatitis B infection.

I therefore give my consent voluntarily for collection of 5 ml of blood by vein puncture and study various Hepatitis Markers. I understand that it is a completely voluntary study and the participant can withdraw from study at any time.

Signature

Name of Participant

Date-

Address , Contact #

Place-

Before Me

Signature-

Date-

PROFORMA FOR HEPATITIS B SURVEILLANCE

NAME				
DRESS				
Email Address		Sex	Male	Female
MARITAL STATUS	Married	Unmarried	Separated	
PHONE (landline)		PHONE (Mobile)		
Number of sexual partners		Single	Multiple	
HOSPITAL NAME				
DESIGNATION		DEPARTMENT		
EMPLOYMENT HISTORY				
WORKING HOURS/DAY	8 hours	12 hours		
JOB RESPONSIBILITIES				
Examination of patients	physical care	Collection of body fluids	Cleaning and sterilization of instruments	
blood collection	disposing of blood clot	disposing of needles, bottles	preparing blood smears	
performing/assisting surgery	cleaning/disposing OT waste			
HISTORY OF INJURIES				
INJURIES / YEAR				
RECOUNT LAST INJURY				
TYPE OF INJURY	Superficial		Deep	
	needle prick		Glass	
INJURY OCCURRED DURING	sample collection	slide preparation	waste disposal	
	Cleaning	Surgery	others.....	
POST EXPOSURE PROPHYLAXIS	YES	NO	DATE:.....	
SYMPTOMS POST INJURY	Fever	Rash	dark urine	Jaundice
	Anorexia	Nausea	Malaise	
VACCINATIONA DETAILS	DATE OF HEPATITIS B VACCINATION			
	DOSE 1	DOSE 2	DOSE 3	BOOSTER
Did you get vaccinated after the injury?			Yes	No
Have you ever gotten your anti HBsAG antibody titre checked?			Yes	No
Are you aware of the infection hazards of your work?			Yes	No
How did u learn?	self learnt	from senior	training / sen	
Have you changed your attitude to avoid injuries?		Yes	No	
Do you implement universal precautions during work?		Yes	No	
Has the number of sharp injuries reduced		Yes	No	

Sample No. ----

Proforma filled by

Date

Good Practice No. 10

Knowing and observing needle stick injury protocol

Why?

It becomes possible to take immediate action to prevent contracting the infection with first aid & post exposure prophylaxis with drugs for HIV and with vaccine for Hepatitis B.

Good Practice No. 11

Constitution of Hospital Infection Control Committee (HICC)

Why?

The HICC has the responsibility of monitoring the occurrence of hospital infection and recommend corrective action.

Every hospital should have an efficient HICC consisting of a member of a hospital staff preferably:

- Medical microbiologist,
- Epidemiologist or infectious disease physician,
- Personnel from medical and nursing staff,
- Hospital administrator with experience and training in infection control.

Regular meetings are needed along with fixed agenda and proper briefing of the members.



Good Practice No. 12

Hospital Infection Control guidelines defined and followed

Why?

It lowers the risk of an infection during the period of hospitalisation.

It develops surveillance system with a database providing endemic rates of nosocomial infection.

It develops policies and procedures for decreasing the risk of hospital infection.

It facilitates enrolment of medical and paramedical staff in continuing medical education.

Good Practice No. 13

Periodic health check up of food handlers once every three months and their training on safe practice. They may otherwise act as carriers for various communicable diseases like typhoid



Why?

Sending hand and nasal swabs of surgeons and nursing staff to laboratory for examination to stop spread of infection in the hospital. Infections may spread through fomites & inter-personal contacts.

Good Practice No. 14

Making proper use of protective equipment, radiation monitors and personnel monitoring devices in x-ray room

Why?

Over exposure to radiation may result in serious complications like leukaemia in health care workers specially those working in the radiology department. Proper monitoring and timely reporting to monitoring authority like Bhabha Atomic Research Centre (BARC) enhances the staff safety.



Good Practice No. 15

Informing the Licensee and the Radiological Safety Officer of any accident or potentially hazardous situation that arises

Why?

So that corrective and preventive action could be taken.

Good Practice No. 16

Notification by pregnant female staff working in radiology department in order to alter working conditions, if necessary

Why?

For safety of mother as well as of foetus from the hazardous radiation which may cause teratogenic (adverse) effect on the foetus.

Personal Protection in Hospital Work



Some Good Practices

November, 2010

Designed and Developed by
Ms Sushma Taishete under the guidance of
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Good Practice No. 1

To wear sterile gloves, masks and aprons to ensure safety of staff working in the laboratory, ward, labour room and operation theatre

Why?

Sterile gloves, mask and apron protect health care staff from hazards like exposure to blood, saliva, other body fluids and aerosol that may contain infectious pathogens like HIV, Hepatitis B, Hepatitis C and H1N1 (swine flu). Use of sterile gloves also prevents cross infection from patient to patient, hence are critical for patient safety.

- **Gloves** - Use while touching blood, body fluids, secretions, excretions, contaminated items; for touching mucus membranes and non-intact skin.
- **Apron/Gown** - Use during procedures and patient care activities when clothing/ exposed skin is anticipated to come in contact with blood/body fluids, secretions, or excretions.
- **Mask** - Use during patient care activities likely to generate splashes or sprays of blood, body fluids, secretions, or excretions.

Good Practice No. 2

To utilise needle destroyer or sharp container for disposing off the needles and other sharp instruments like scalpel, broken glassware and plastic pieces



Why?

40% of all needle stick injuries occur after use and before disposal, 15 % occur during disposal and 5% during recapping the syringe. Occupational needle-stick injuries account for 40%-65% of Hepatitis B and C infections in healthcare

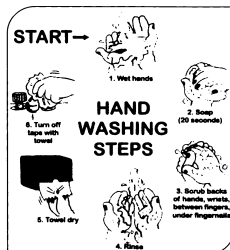
workers. These injuries can be reduced substantially by using needle destroyer or sharp container. It also eliminates the chances of needle reuse. It improves waste disposal by decreasing both the amount of infectious waste and the amount of safety boxes needed for the waste, since safety boxes can pack syringes 20-60% more compactly without the needles.

Good Practice No. 3

Hand washing

Why?

Many studies have shown that the bacteria that cause hospital-



acquired infections are most frequently spread from one patient to another through the hands of healthcare workers. So adherence to proper hand washing practice not only reduces hospital acquired infections but also enhances patient and staff safety.

Good Practice No. 4



Immunisation of all staff and maintenance of immunisation records

Why?

Health Care Workers are vulnerable to getting infected from patients and hospital environment. Immunization ensures their safety from these hazards, instils confidence as well reduces the cost

of treatment that could become a future burden on the hospital facility.

For Human Immuno Deficiency Virus (HIV) and Hepatitis C vaccine is not available

For Hepatitis B:-

Dose schedule (3 doses)- 0,1 & 6 months

Routine booster doses are NOT routinely recommended

Good Practice No. 5

Proper handling of sharps, use of protective gear while disposing off the waste (puncture proof boxes, rubber gloves for handlers, disinfection before disposal, bags to be securely tied after 3/4th full)



Why?

Hospital waste material contains sharps which may accidentally prick the staff and infect them while collecting and disposing off the waste material. Infected material may lead to transmission of pathogens like HIV, Hepatitis B and Hepatitis C.

Good Practice No. 6

Avoiding soiling of investigation slips in the laboratory



Why?

Any pathological and investigation laboratory deals with body fluids. These fluids may possibly be harbouring the pathogens. Soiling of papers (most possibly investigation slips) easily acts as a carrier of infection to holders like ward boys & nurses.

Good Practice No. 7

Training in handling and management of Biomedical Waste (BMW) (collection, segregation and transportation of BMW)

Why?

Wrong handling of BMW increases the incidence of occupational hazards for healthcare workers. Practices of proper segregation and collection of biomedical waste make the hospital a better workplace. Segregation of waste should take place at the point of production as 50% of waste sent for incineration as clinical waste is in fact general waste which leads to unnecessarily high disposal costs.

Non-compliance with BMW Rules, 1998 may invite punitive action.

Good Practice No. 8

Storage of BMW (not beyond 48 hours) before disposal, safe and hygienic disposal of waste

Why?

Non-infected waste becomes infected waste.

Uncovered waste becomes accessible to animals, insects and birds scattering the waste all over.

Unsafe storage of BMW leaves the hospital staff open to needle stick injuries and infections such as Hepatitis B, Hepatitis C and HIV/AIDS.

Good Practice No. 9

Avoiding mixing of regular waste with toxic BMW (presenting a serious health hazard for staff, patients and visitors)



Why?

Mixing of regular waste with toxic BMW infects it, in turn presenting a serious health hazard for staff, patients and visitors. Disposal of such a waste, if not done properly may lead to infectious hazards for hospital as well as nearby community where this waste is dumped as general waste. On the other hand if this waste is treated as biomedical waste it increases the cost of BMW management as general waste is also mixed with infectious waste.

If the mixed waste gets marked as biomedical waste, hospital staff may not take any precaution while handling it and could therefore get infected.

A SYNOPSIS OF THE THESIS
SUBMITTED TO THE UNIVERSITY OF MUMBAI
FOR THE DEGREE OF MASTER OF SCIENCE (BY RESEARCH)
IN THE FACULTY OF MICROBIOLOGY

TITLE OF THE THESIS - SERO-EPIDEMIOLOGICAL SURVEY
OF HEALTH CARE WORKERS IN
MAHARASHTRA

NAME OF THE CANDIDATE - SUSHMA TAISHETE

NAME AND DESIGNATION - DR. ABHAY CHOWDHARY
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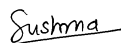
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Introduction

The risk of infection to health workers depends on prevalence of disease in patient population as well as nature and frequency of exposure. Occupational exposure to blood can result from needle stick or other sharp injury, splash of blood or other bodily fluids into the eyes, nose or mouth and blood contact with non-intact, damaged and wounded skin.

The vulnerability of health workers to the simple procedures followed at work place such as wounds cut by needle stick injuries that accidentally puncture the skin especially for the people who work with hypodermic syringes is very high. Poor needle disposal practices, recapping of used ones and injuries put health care workers at high risk of blood borne infections like HIV, hepatitis B and C. Nurses, ward boys, housekeeping staff and those working in the surgical departments are at the highest risk of getting needle-stick injuries and are, as a result, most vulnerable to acquiring blood-borne infections.

Of the 36 million health care workers in the world, 3 million receive needle stick exposure to blood borne pathogens every year, 3 million of those are exposed to Hepatitis B virus, 0.9 million are exposed to Hepatitis C virus, 1, 70,000 are exposed to the HIV virus and 90% of these infections occur in Developing countries.

A 2005 study published in the *American Journal of Industrial Medicine* estimates that overall, 16,000 Hepatitis C, 66,000 Hepatitis B and 1,000 HIV infections may have occurred in the year 2000 worldwide among health care workers due to their occupational exposure to injuries.

The study conducted by doctors at the Safdarjung Hospital, New Delhi published in Indian Journal of Medical Research in March, 2010 has shown that 60% of health care workers are not aware of precautionary options available to

them in hospitals and 75% nursing students did not seek help when exposed to needle injuries. The most common clinical activity to cause the needle stick injury was blood withdrawal (55%), followed by suturing (20.8%) and vaccination (11.7%). The study has also highlighted the menace caused by the practice of recapping needles after use. About 66.8% health care workers responded positively to recapping needles after use. Only 11.4% health care workers admitted to have bent the needles before discarding.

The high percentage of health care workers with needle stick injuries is primarily because of a high rate of ignorance and also due to lack of regulation of occupational health and safety to foster a safe working environment.

Training workshops on the importance of following the safety precautions at workplace and also reporting them appropriately once they occur so that required measures could be taken are needed to be held for health care workers. Awareness creation as well as functioning Hospital Infection Control Committee for laying down and following interventional strategies are required.

While there is no India-specific data on needle-stick injuries, experts say that the situation could be even more alarming. Industry estimates indicate that more than 1.7 billion syringes are sold in the country annually and about 5 billion injections administered, sometimes by inadequately trained staff. Also there is underreporting of needle stick injuries which is often less than 50%.

Because the risk of being infected is highest in the lower strata of the health care workers hierarchy, most hospitals do not consider prevention of needle-stick injuries important. While countries such as Hong Kong, China, Australia and the Philippines are undertaking massive work on this front, Indian hospitals are just waking up to the challenges of not putting such a mechanism in place. In the USA, it is mandatory for such prevention and safety mechanisms to be present.

India is in need of a regulatory agency to control workplace safety like Occupational Safety and Health Administration (OSHA) or the National Institute for Occupational Safety and Health (NIOSH) in the United States.

It is also needed to rein in hospitals who do not want to invest in the safety of their workers is to bring in legislation that penalizes non-compliance.

Review of Literature

Health care workers (HCWs) are at risk of infection with blood-borne viruses in the course of their work. Over 90% of these infections are occurring in low-income countries and most are preventable. A cross-sectional survey amongst HCWs involved in collecting blood samples and administering injections in all wards of the Army hospital¹ has highlighted the urgent need for interventions to enhance the occupational safety of workers. Surprisingly, reasons for not using personal protective equipment (PPE) ranged from busy schedule (37.14%), non use of PPE by co-workers (67.14%), emergencies (91.43%) risk that patients may get offended by PPE use by HCWs (27.14%) to discomfort while using PPE (24.29%).

In a study done by Mehta et al ² accidental exposure from blood/body fluid of patients is a risk to healthcare workers (HCWs). Percutaneous injury is the most common method of exposure to blood-borne pathogens. It was observed that most needle-stick injuries occurred during intravenous line insertion (N=112), followed by blood collection (N=69), surgical blade injury (N=36) and recapping needles (N=36).

Education and sharp disposal methods can reduce needle-stick injuries as documented and reported at a hospital in Vellore, India ³, in 1993. In 1995 large containers for sharps were placed in the centre of each ward, and an education programme instituted. In 1998 smaller containers were introduced into all patient areas, and another education programme used. Following each there was a diminution in needle-stick injuries, but between the two initiatives the number of injuries rose substantially. Even though it does not tell us about the intensity of work in the hospital, nor about other factors that may have affected the number of needle-stick injuries. Introduction of sharps containers probably helped, but it is likely that it was the education programmes that contributed the

most. It highlights the importance of continuing education on precautions to be taken at the work place by the health care workers.

The phenomenon has been observed to be associated also with medical students ⁴. The most common injury was associated was with drawing blood with a needle and syringe, occurring at about 1.5 injuries per student per month, but other injuries also occurred frequently, particularly stitching of wounds and intracatheter manipulations.

In the study conducted in the tertiary care hospital in Delhi ⁵ a large percentage (79.5%) of HCWs reported having had one or more needle stick injury. More than half (50.4%) ascribed fatigue as a cause in their injury. 60.9% washed the site of injury with water and soap while 38 (14.8%) did nothing. Only 20 (7.8%) of the HCWs took post-exposure prophylaxis (PEP) against HIV/AIDS after their injury. It only reinforces the fact that avoidable practices like recapping of needles were contributing to the injuries. Prevention of needle stick injuries is an integral part of prevention programs in the work place, and training of HCWs regarding safety practices indispensably needs to be an ongoing activity at a hospital.

Outside India, needle-stick injuries among health care workers are a recognized health hazard ⁶, with 400,000 needle-sticks occurring annually among the 4 million health care workers in the United States. Nurses have been found to be at high risk of needle-stick injury from syringes and i.v.equipment relative to the other health care workers. Recapping (prohibited by the OSHA Blood-borne Pathogens Standard) continues to be an identified cause of injury. Health care organizations should assess their worksites to identify hazards and select products and strategies to correct the problem. Future research should clarify accurate needle stick injury rates (e.g., establish consistent denominators), address non-hospital setting risks, validate self reported data, and evaluate comprehensive interventions that employ engineering strategies to minimize the risk.

In a review done by Trim et al in University Hospital in Birmingham, UK ⁷ it is seen that exposure to blood-borne pathogens from sharps injuries continues to

pose a significant risk to healthcare workers. Nurses and doctors were most at risk of sharps injuries, frequently from hollow-bore needles. Approaches to reduce this risk have included education and training on the safe handling and disposal of sharp devices, awareness campaigns and legislative action. Introducing needle protective devices should be considered particularly in high-risk areas, after training, education, evaluation and cost–benefit analysis.

Needle-stick injuries frequently occur among healthcare workers, introducing high risk of blood-borne pathogen infection for surgeons, assistants, and nurses. This systematic review by Lin Yang et al ⁸ aims to explore the impact of both educational training and safeguard interventions to reduce needle-stick injuries. This review suggests that both safeguard interventions and educational training programs are effective in reducing the risk of having needle-stick injuries. More studies are needed to evaluate interventions in nonsurgical settings, such as departments of nursing and other hospital units and among other healthcare personnel such as nurses. The current evidence suggests that both safeguard interventions and educational training programs are effective in reducing the risk of having needle-stick injuries. However, there are insufficient studies using a combination of both safeguards and educational interventions in surgical and nonsurgical settings. In future research, evaluations of these two types of interventions in both randomized controlled trials and in studies utilising other designs are needed.

To describe the characteristics of needle-stick injuries occurring to health care workers outside the hospital, a new case report form ⁹ was implemented and analyzed after 12 months. A total of 144 incidents were reported. Of the needle-stick injuries in nursing assistants, 84% involved an insulin needle or pen. Thirty-five percent of all health care workers and 47% of the nursing assistants were not vaccinated against hepatitis B. Hepatitis B vaccination grade in health care workers outside the hospital should be improved, in particular among nursing assistants.

Therefore the study was planned to associate in following standard operating procedures to deal with needle-sick injuries. They will educate workers on the

hazards of needle-sick injuries, on what they can do to protect themselves and what they need to do in case they are so injured.

The infections also face the great risk of being transmitted to other hospitalized patients through the medium of infected health care workers. This has serious consequences among immune-compromized individuals. Systematic selective vaccination of susceptible healthcare workers among hospital personnel would be recommended.

Basic objective is to put together the evidence that the investment into health care workers safety will pay dividends in terms of minimizing treatment costs to them. This, in turn, will trigger similar initiatives in hospitals across the country.

Aims and Objectives of the Study

1. To determine Hepatitis B and C prevalence in health care workers (HBs Ag, Anti HBs, HBC IgM) using Enzyme-linked Immunosorbent Assay (ELISA).
2. To increase awareness of the health care workers on the good practices to be followed on personal protection in hospital work.
3. To develop training modules for repeated on the job training of the health care workers on the occupational hazards of handling blood, body fluids, sputum etc..

Materials and Methods

Context - Various occupationally transmitted infections in health care workers has not been adequately studied in Maharashtra using various diagnostic tests

Objectives - To determine Hepatitis B and C prevalence in health care workers (HBs Ag, Anti HBs, HBC IgM) using Enzyme-linked Immunosorbent Assay (ELISA) to determine agreement between the tests and to compare their correlation with risk factors

Design, Setting, and Participants- A cross-sectional comparison study of 440 health care workers (out of 473 collected samples, 33 samples could not be used due to hemolysis) including specialists, medical officers, nurses, laboratory technicians, ward boys working at district hospitals in Maharashtra (from 8 circles of the state Nashik, Thane, Pune, Kolhapur, Aurangabad, Latur, Nagpur and Akola) was done. The number of Hospital-wise samples collected are-

Name of the Hospital	Number of blood samples tested
Civil Hospital , Thane	20
Sub-district Hospital, Shahapur	09
Civil Hospital, Alibaug	34
Sub-district Hospital, Mangaon	15
Civil Hospital, Pune	41
Civil Hospital, Satara	65
Civil Hospital, Nashik	68
Civil Hospital, Jalna	29
Civil Hospital, Beed	37
Civil Hospital, Wardha	64
Civil Hospital Amravati	58

Each participant was provided with a Participant Information Sheet (a copy attached) Data on age, sex, education, training, years in health care profession, job category, direct contact with blood/sputum, injuries, post exposure prophylaxis, vaccination etc. along with the informed consent (forms in bilingual English and Marathi) was obtained from all the participants (a copy each of Informed Consent Form and Proforma for Hepatitis B Surveillance is attached)

Interventions

The collected blood samples were tested for HBs Ag, Anti HBs and HBC IgM. HBs Ag test is positive in respect of 11 samples. Liver profile (ALT, AST and

Alkaline Phosphatase) of these 11 samples was performed. The concerned Medical Superintendent have been recommended to evaluate these samples clinically with liver profile and repeat HBsAg.

Results

106 Samples have been found to have less than blank titer of antibodies when tested for Anti-HBs. All these samples were tested for HBc IgM. All of them found to be negative.

Based on the observations during the visit of the team as well as considering the safety precautions to be followed by the them, a brochure on "Personal Protection in Hospital work- Some Good Practices" has been prepared as attached.

The test results along with the recommendations have been forwarded to concerned Medical Superintendents of all these Hospitals for necessary action so as to secure the safety of the staff. 50 brochures each were also sent to them for circulation among the hospital staff.

Total number of 25,000 brochures have been provided to the Health Department of the Government of Maharashtra to be distributed in all Sub-divisional Hospitals and District Hospitals in the state among medical and paramedical workers for increasing awareness on the safety precautions to be taken by them at their work place.

Conclusion

Recommendations offered to the Government of Maharashtra

- 1) Based on the finding of the study the workers are needed to be trained repeatedly on- the- job on the occupational hazards of handling blood, bloody body fluids, sputum etc.. Sensitization of the workers on the precautions to be taken on the duty should be highlighted. Sensitization would not only involve loading information on them but to identify the gaps in their knowledge through participatory communication approach and

convincing them on the importance of taking precautions for a safer environment for themselves as well as for their co-workers and patients. Attitudinal change in the health care workers specially those at the bottom rung of the health care delivery is must as they are the crucial transmission agents due to their active handling of body fluids of the patients. Necessity of creation of safe working environment by protecting oneself by using proper gadgets as well as by abiding to cleanliness need to be stressed upon. Training modules need to be developed accordingly for filling up of the knowledge gaps for on- the- job training of these health workers.

- 2) All health care workers should be vaccinated with Hepatitis- B vaccine
- 3) All health care workers should be provided with appropriate PPEs such as gloves, gown, apron, mask etc. Sharp tips of objects such as needles need to be covered with a protective sheath after use.

References

1. Occupational exposure to blood and body fluids amongst health care workers in a teaching hospital of the armed forces by BR Sangwan, Atul Kotwal and A. K. Verma, Medical Journal Armed Forces India , Volume 67, Issue1, Page 21-24, Jan, 2011
2. Needlestick injuries in a tertiary care centre in Mumbai, India by A. Mehta, C. Rodrigues, S. Ghag, P. Bavi, S. Shenai and F. Dastur, Journal of Hospital Infection, 2005, Volume 60, Issue 4, Pages 368-373
3. VS Richard et al. Impact of introduction of sharps containers and of education programmes on the pattern of needle stick injuries in a tertiary care centre in India. Journal of Hospital Infection, Volume 47, Issue 2, Feb, 2001, Pages 163-165.
4. M Varma, G Mehta. Needle stick injuries among medical students. Journal of the Indian Medical Association 2000, Volume 98, Pages 436-438.

5. Study of Prevalence and Response to Needle Stick Injuries among Health Care Workers in a Tertiary Care Hospital in Delhi, India. by Rahul Sharma, Sk Rasania, Anita Verma, Saudan Singh, Indian Journal of Community Medicine, Jan 2010, 35(1), Pages 74-77
6. A review of sharps injuries and preventative strategies by J. C. Trim and T. S. J.Elliott, Department of Clinical Microbiology and Infection Control, University Hospital, Birmingham NHS Trust, Edgbaston, Birmingham, UK, Journal of Hospital Infection, Volume 53, Issue 4, April 2003, Pages 237-242
- 7.Reducing Needle Stick Injuries in Healthcare Occupations: An Integrative Review of the Literature-by Lin Yang and Barbara Mullan, ISRN Nursing, Volume 2011, Article ID 315432, 11 Pages
- 8.Needlestick injury and accidental exposure to blood: The need for improving the hepatitis B vaccination grade among health care workers outside the hospital by Dieuwke Vos, Hanelore M. Gotz and Jan Hendrik Richardus, American Journal of Infection Control, November 2006, Volume 34, Issue 9, Pages 610-612

