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# Knowledge And Acceptance Of Hepatitis B Vaccine

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## Abstract

Importance of the problem: The potential for Hepatitis B Virus (HBV) transmission in the occupational setting is greater than for human immunodeficiency virus (HIV). The center for disease control (CDC) estimates that 18,000 healthcare workers whose jobs involve exposure to blood became infected with HBV each year. As a result, 250 people will die of fulminate hepatitis, cirrhosis, or liver cancer.

Objective: To determine the effects of perceived threat and knowledge level about hepatitis B Virus on the motivation to accept hepatitis B vaccine.

Design: Cross sectional study in design, based on the elements of the health belief model framework. The independent variables (perceived barriers, perceived susceptibility and perceived severity) were analyzed to determine their direct and indirect effects on the outcome (receiving hepatitis B vaccine).

Subjects: 260 healthcare workers in Miami-Dade County.

Results: 260 (80%) of the healthcare workers responded. 84.6% (n = 220) of the staff have had the hepatitis B vaccine. Whereas, 15.4% (n = 40) didn't have the vaccine. The majority of healthcare workers who had not been vaccinated are concerned about side effects of the vaccine. No significant relationship was found between perceived severity and acceptance of HB vaccine. However, there was a significant relationship between perceived susceptibility, knowledge and acceptance of the HB vaccine.

Conclusions: The percentage of healthcare workers in this study who have had the HB vaccine is considerably higher than that reported in the literature for all healthcare workers. The variable of perceived severity was not a predictor of hepatitis B vaccine acceptance; the variables of perceived susceptibility and knowledge level were predictors of HB vaccine acceptance.

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### CHAPTER 1 - INTRODUCTION

#### BACKGROUND AND IMPORTANCE OF THE PROBLEM

A fairly common systemic disease, viral hepatitis is marked by hepatic cell destruction, necrosis, and autolysis, leading to anorexia, jaundice, and hepatomegaly (Smith, 2000, p. 453). Hepatitis is defined simply as injury to hepatic cells and infiltration of inflammatory cells into the liver; it is not an uncommon manifestation of a variety of systemic infectious processes. In such instances, histopathologic changes are minimal and liver involvement is usually clinically silent, and thus there is little confusion with viral hepatitis (Beare, 1991, p.487; Beeson, 1979, p. 1657; Kolats, 1994, p. 168; Wilkins, 1978, p. 153).

Hepatitis B, acute inflammatory disease of the liver or a form of viral hepatitis caused by the hepatitis B virus (HBV) (Beare, 1991, p. 486). Acute viral hepatitis is a generalized infection with emphasis on inflammation of the liver. The clinical picture of the infection varies in its presentation from a symptomatic or subclinical infection, mild gastrointestinal symptoms and the anicteric form of the disease, acute illness with jaundice, severe prolonged jaundice to acute fulminate hepatitis (Bryan, 1995, p.1114; Weatherall, 1987, p. 339).

There is now compelling evidence of an etiological association between hepatitis B virus and hepatocellular carcinoma, one of the ten most common malignant tumors worldwide (Kawai, 2000, p. 1287; Bryan, 1995, p. 1114; Thomas, 1974, p. 67).

In the past, been called catarrhal jaundice, nonspirochetal infectious jaundice and infectious hepatitis (Goldman, 2000, p. 877; Rakel, 2000, p. 567). It probably is by means a new disease but only for the past twenty or twenty five years has it been properly differentiated from Weil's disease and yellow fever (Rakel, 2000, p. 568).

Hepatitis is an inflammatory state of the liver that may be caused by exposure to toxic chemicals, by autoimmune disease, or by infection (Gladwin, 1996, p. 54; Beeson, 1979, p. 1655). The viral infection most commonly associated with hepatic inflammation includes hepatitis A, B, C, D, and E (Dienstag, 1998, p. 1723). A virus similar in structure to hepatitis C has been designated hepatitis G, but information about this virus and its effects on the liver is limited (Goldman, 2000, p. 878). In 1994 hepatitis F was identified as a cause of fulminate liver failure. This was later found to be a variant subspecies of another virus. Therefore,

the F is now omitted in the hepatitis alphabet (Dienstag, 1998, p. 1725; Dolin, 1999, p. 99). The general term viral hepatitis refers to infections caused by at least six different viruses, hepatitis A (infectious or epidemic hepatitis), hepatitis B (serum hepatitis), hepatitis C (non-A, non-B), and hepatitis D virus (the delta agent). Non-A, non-B hepatitis, which appears to be caused by more than one virus, and an epidemic form of non-A hepatitis. Indeed, viral hepatitis has emerged as a major public health problem occurring endemically in all parts of the world (Lemon, 1995, p. 1485; Michael, 1999, p. 14; Thomas, 1974, p. 68; Thorn, 1977, p. 875; Weatherall, 1987, p. 340).

Epidemic jaundice was described by Hippocrates in the 5<sup>th</sup> century B.C., the first recorded cases of serum hepatitis, hepatitis B, are thought to be those that followed the administration of smallpox vaccine containing human lymph to shipyard workers in Germany in 1883. In the early and middle parts of this century, serum hepatitis was repeatedly observed following the use of contaminated needles and syringes. The role of blood as a vehicle for virus transmission was further emphasized in 1943, when Beeson described jaundice among seven recipients of blood transfusions (Atkinson, 1995, p. 19; Diasio, 1996, p. 1294; Beeson, 1979, p. 1980). Throughout the early part of the 20<sup>th</sup> century, clusters of cases were reported in venereal disease clinic and diabetic clinic in which reuse of contaminated needles and/or syringes had occurred.

In 1965, medical researcher Baruch Blumberg identified a specific antigen in the serum of an Australian Aborigine who had received numerous blood transfusions. This "Australia Antigen" was later found to be associated with hepatitis B, its discovery led to rapid advancement in the knowledge of hepatitis B virus. This antigen has now been renamed the hepatitis B surface antigen (HBsAg). This virus as well as the typical serological response pattern of the host, has been extensively studied (Margolis, 1997, p. 387). Australia Antigen, later called hepatitis B surface antigen (HBsAg), was first described in 1965, and Dane Particle was identified in 1970. Identification of serologic markers for hepatitis B virus infection followed, which helped clarify the natural history of the disease (Atkinson, 1995, p. 23).

The development of immunologic techniques in the 1960's and 1970's further clarified the nature of hepatitis and made precise diagnosis possible, the development of immunoassay after the discovery of Australia Antigen (HBsAg) made possible the detection of persons who were antibody positive (Beere, 1991, p. 488; Johns,

1980, p. 256; Last, 1987, p. 198). Study of this virus has been handicapped in that no susceptible experimental animal has been found. Because of this, much of the study has had to be carried out on human volunteers (Beere, 1991, p. 487; WHO, 2001, p. 4; Miller, 1978, p. 211). In the mid 1960's epidemiologists discovered that HBV could be detected in blood by the use of a reactant present in the blood of patients who had received large numbers of transfusions (Arien, 1991, p. 79). Some transfusion units had contained HBV, and the patients had developed antibodies, which could be used to detect the virus in other people's blood. By a strange irony, the blood of people who had already been exposed to the virus and had developed antibodies against it could be used to detect the virus present in donor's blood and prevent its use to infect others (Tyler, 1995, p. 1314; Wallach, 1992, p. 567).

In a relatively short time, sensitive methods were developed to screen donor blood and detect symptomatic carriers of HBV, prior to this discovery, hepatitis following transfusions was very common, particularly with the introduction in the 1950's of surgical procedures such as open heart surgery and kidney transplantation that required large amounts of blood. In some hospitals where these heroic surgical procedures were performed, as many as 50 percent of the patients became infected, and many of them became seriously ill (Arien, 1991, p. 86). Therefore, as soon as it was realized that hepatitis screening would considerably decrease the frequency of post-transfusion hepatitis, many blood banks established testing as a routine procedure, and it soon became a requirement for all hospitals and blood banks (Henderson, 1992, p. 1). The incidence of post-transfusion hepatitis due to HBV has decreased dramatically. Viruses are the cause of some of the earliest disease processes recorded in the medical literature. Though the natural history of viral diseases such as polio, measles, and smallpox had been described for millennia, the first viruses were not identified until the beginning of the 20<sup>th</sup> century. The knowledge of specific viruses, viral life cycle, and viral/host interaction increased dramatically over the next 50 years, leading to the development of vaccines. More recent techniques such as electron microscopy, electrophoresis, x-ray crystallography, and polymerase chain reaction have permitted in-depth studies of viral structure and more precise identification of viruses causing specific diseases (Tyler, 1995, p. 1327).

Classification of viruses has changed as knowledge of them has increased. Initially, viruses were primarily classified by

size, method of transmission, or organ affected in the disease process. More recently, viruses have been classified by the type of nucleic acid in the viral core, the nucleic acid's method of replication, the presence or absence of an envelope, and the symmetry of the viral capsid (protein coat) (Atkinson, 1995, p. 19). The nucleic acid in the viral core can be RNA or DNA and can be either single stranded or double stranded. These nucleic acid strands can be circular or linear. Viruses replicate nucleic acid in one of five different methods. Discussion of these complex methods of replication is beyond the scope of this study, but the method by which a virus replicates contributes to its classification. In the majority of viruses, the nucleic acid is covered with a protein coat called a capsid. Most capsids are either shaped as a helical spiral or as an icosahedral sphere. Some viruses are surrounded by a lipid envelope, an outer layer beyond the capsid. Using this classification system, poliovirus is classified as a single stranded RNA virus with an icosahedral capsid and no lipid envelope. Similarly, the herpes simplex virus is classified as a double stranded DNA virus with an icosahedral capsid and lipid envelope. Viruses are unable to replicate outside the host. Therefore, in order to survive and reproduce, the virus must interact with the host's cells. The first step of this process is attachment, which occurs when proteins on the surface of the virus attach to receptors on the surface of the host cell. Once attachment has been accomplished, the virus penetrates the cell membrane. Within the cell, the virus undergoes a process of "uncoating" as the capsid is removed. After removal of the capsid, replication of the nucleic acid takes place. Next, the nucleic acid of the new viral particles is coated with a capsid. Finally, the new virus leaves the host cell, either through budding or through rupture of the host cell. Viruses can be transmitted through inhalation of respiratory droplets, via direct introduction into the gastrointestinal, genitourinary, respiratory tract, or percutaneously. The virus may cause a localized infection at the area of entrance or may travel through the blood stream, lymphatic, or nerve pathways to the target organ or organs. In response to viral invasion, non-specific defense mechanisms and a specific immune response are activated. Because viruses are intracellular invaders, phagocytosis, the inflammatory response, and antigen/antibody reactions not result in destruction of viral particles but also may injure or destroy host cells.

Viral hepatitis can be classified by mode of transmission, by the type of virus, and by chronicity. Hepatitis A and E are both transmitted by fecal-oral route while hepatitis B, C, D, and G are considered bloodborne pathogens. Hepatitis B is a

DNA, while hepatitis C, D, E, and G are RNA viruses. Hepatitis A and E cause acute illness; hepatitis B, C, and D can have both acute and chronic manifestations. Hepatitis G has not yet been demonstrated to cause acute disease, but may be implicated in chronic disease. The hepatitis viruses represent different families of viruses: Hepatitis A is a member of the Picornavirus family; Hepatitis B is a Hepadnavirus; Hepatitis C and G are both Flaviviruses; Hepatitis D is sometimes classified as Hepadnavirus and sometimes as a Satellite virus; and Hepatitis E is the family Calicivirus (Lemon, 1995, p. 1478). The commonality in these viruses is their ability to cause inflammation of the liver. The differences in the individual viruses account for the tremendous variation in outcome of infection, chronicity of the disease, and the ease with which tests to diagnose the virus and vaccine to prevent the virus to develop.

Documents from ancient China describe a contagious jaundice in which the victims experienced symptoms consistent with Hepatitis A and E. In the fifth century BC, epidemics of jaundice occurred in Greece and Rome. Outbreaks of jaundice associated with unsanitary conditions during wartime were reported in Europe during the 17<sup>th</sup>, 18<sup>th</sup>, and 19<sup>th</sup> centuries. Analysis of outbreaks of hepatitis during World War II supported the theory that some forms of jaundice resulted from unsanitary conditions while others seemed to be related to a shared percutaneous source of infection (contaminated needle or vaccine). Therefore, hepatitis was classified into two categories: infectious hepatitis and serum hepatitis (Kawai, 2000, p. 1296; Schulman, 1992, p. 341). Hepatitis A virus (HAV) was initially identified when viewed in an electron microscope in 1973. Since that time the virus and the body's response to the virus has been extensively studied. By law, diagnosed cases of HAV must be reported to the local health authorities, who in turn report the incidence to the Center for Disease Control.

Many persons who contract HAV, however, do not have clinical symptoms. Therefore, the Central for Disease Control (CDC) must estimate the actual incidence of HAV infection based upon CDC reports and projections. For the ten-year period 1984 to 1994, the CDC estimates that 125,000 to 200,000 cases occurred within United States each year. The World Health Organization estimates the annual worldwide incidence to be 1.5 million per year (WHO, 2001, p. 3). As indicated above, hepatitis A is transmitted via the fecal-oral route, most commonly from contaminated water or food. After the virus ingested, it is transported from the gut

to the liver, where it invades the hepatocytes. The virus uses the hepatocytes for viral replication. The virus is released into the bloodstream and is excreted in the stool. The cellular immune system responds with infiltration of the liver by lymphocytes and cytokines. These lymphocytes are toxic to HAV infected liver cells, thus producing the inflammatory damage to the liver. IgM antibody against HAV is produced, followed by IgG antibody. Levels of IgM antibody decrease to undetectable levels over time, but IgG antibody remains.

Signs and symptoms of hepatitis A can vary from sub-clinical disease to fulminate infection. In symptomatic patients, evidence of infection appears 15 to 50 days after ingestion of the organism. Clinical evidence of the disease include nausea, vomiting, headache, fever, chills, abdominal discomfort, hepatomegaly, and right upper quadrant tenderness. For most patients, symptoms are mild and subside in three to seven days. Others will have more significant disease and will progress to an icteric phase (jaundice). For these patients, recovery typically occurs after about three weeks. Fulminate infection occurs in less than one percent of the cases. Some of these patients may have such severe damage that they require liver transplant. Fatalities from hepatitis A are rare. There is no known chronic carrier state (Tierney, 2000, p. 358). Treatment of HAV is supportive and directed at maintaining adequate nutrition and controlling symptoms. Ingestion of alcohol and/or hepatotoxic medications is avoided. For patients with fulminate hepatic failure resulting from HAV, corticosteroids are sometimes used. However, clinical research has not demonstrated improved outcomes in patients receiving corticosteroids when compared to those who did not receive steroid treatment (Kawai, 2000, p. 1287). As with any other disease, prevention is the most effective strategy. Hepatitis A vaccine is available and is recommended for anyone traveling abroad as well as for health care providers and food handlers in areas in which the endemic rate of HAV is high. Persons in other-risk categories, including homosexual or bisexual men, sewage workers, animal handlers, and individuals with chronic liver disease, should also receive the vaccine (Dienstag, 1998, p. 1723). Individuals receiving the vaccine is protected after approximately two weeks. A booster dose is recommended 6 to 12 months after the initial dose. Lifetime immunity is expected in those who received both doses (Dienstag, 1998, p. 1724).

Sanitation strategies are also important in controlling HAV. If in water, the virus is inactivated by boiling the water for

five minutes. HAV is also killed by most household grade disinfectants and all hospital grade disinfectants.

Like Hepatitis A, Hepatitis E virus (HEV) is spread through the fecal-oral route, and like HAV, HEV was also first identified via electron microscope examination of stool of infected patients. HEV has been associated with outbreaks in India, Burma, Pakistan, Russia, China, Northern and Central Africa, Peru, and Mexico. Outbreaks are usually associated with a contaminated water supply. No outbreaks have occurred in the United States or Western Europe, though individual cases have been identified in persons who have recently traveled to areas in which the virus is endemic (Tierney, 2000, p. 357).

HEV most often affects young adults. The incubation period is two to nine weeks, with an average of six weeks. Signs and symptoms are similar to HAV, but with a higher incidence of jaundice, which can be prolonged. The disease is self-limited in the majority of patients. The fatality rate in acute HEV is between 1% and 2% except in pregnant women. During outbreaks, the fatality rate of HEV among pregnant women in their third trimester has reached as high as 26% (Schulman, 1992, p. 342; Springhouse, 2000, p. 178; Tepper, 1997, p. 1735).

In 1977, a new antigen was detected in patients with Hepatitis B. At first it was thought to be a variant of HBV. By 1980, Hepatitis D (HDV) was determined to be a separate virus, but a virus that was dependent upon the presence of HBV in order to replicate (Robinson, 2000, p.

1652; Peter, 1996, p. 165). Hepatitis D Virus is an RNA virus. The core is distinctively different from other viruses. However, due to a defect in replication, HDV is unable to synthesize a viral coat. It must "borrow" a coat from HBV in order to complete the replication process. Therefore, HDV cannot cause infection independently but instead must exist as a co-infection (acquired at the same time as HBV) or a super-infection (HDV acquired in a patient who is chronically infected with HBV). In the United States, the infection primarily occurs as a co-infection among intravenous drug users. In some areas of the world in which chronic HBV infection is endemic (including Mediterranean areas, the Amazon Basin of South America, China, and Southeast Asia), HDV is more commonly a super-infection (Kawai, 2000, p. 1296; Guyton, 1991, p. 543). Patients co-infected with HBV and HDV tend to have a more severe case of acute hepatitis. The mortality rate in co-infection has been reported to be as high as 20%. Super-infection with

HDV results in rapid progression of cirrhosis, with liver failure occurring in approximately two years, as opposed to 10-15 years with chronic HBV infection alone (Kawai, 2000, p. 1286).

Prevention of HDV is accomplished through the same means as prevention of hepatitis B. Immunization against hepatitis B is effective prevention of HDV also because if the individual is immune to HBV, he /she cannot become infected with HDV. Avoidance of bloodborne pathogen exposure through observance of standard precautions is primary mechanism of prevention for persons already chronically infected with HBV. After the agents responsible for hepatitis A and hepatitis B were identified and laboratory tests to detect the presence of these agents were available, it became obvious that these two viruses were not the only agents associated with hepatitis. Non-A, Non-B hepatitis became the designation for cases of hepatitis that followed a course indicative of a viral cause, but did not produce laboratory evidence of HAV or HBV. Two separate syndromes of Non-A, Non-B hepatitis were distinguished; one was present in third-world countries and resulted from ingestion of contaminated water (this is now known as HEV), and one related to blood exposures, particularly transfusions. For over ten years attempts to identify the causative agent for chronic post-transfusion Non-A, Non-B hepatitis were unsuccessful. In 1989, a cooperative effort between the CDC and a private clinical laboratory was successful in discovering the virus-specific antigen for Hepatitis C (HCV) (Foster, 2001, p. 7). Since that time, six distinct genotype of HCV have been identified (Tierney, 2000). Hepatitis C virus is the leading cause of end-stage liver disease, and the leading reason for liver transplantation in the United States. Chronic HCV infection has also been associated with membranoproliferative glomerulonephritis, cryoglobulinemia, and B-cell lymphoma. Co-infection of HCV with HIV occurs in 90% of persons who acquired HIV through intravenous drug use (Dolin, 1999, p. 47; CDC, 2000, p. 14). HCV occurs throughout the world, with endemic rates varying widely. The World Health Organization (WHO) estimates that 10% of the population of the Middle East, Africa, and Eastern Europe are positive for HCV. In the United States, 1.8% of the population (approximately 4 million people) carries the virus. The highest incidence of newly acquired HCV infection occurs in persons 20 to 30 and, at this time, shows no pattern of ethnicity. The demographic data for those currently living with HCV is somewhat different from that of new cases. The highest prevalence of persons living with HCV is among

persons 30 to 40, with the rate higher among African American than among Whites and higher among males.

HCV is considered a bloodborne pathogen. The most common source of infection is percutaneous or parenteral exposure through transfusion, use of injectable drugs, and occupational injury of healthcare providers with a contaminated sharp object. The blood supply in the United States has been tested for Hepatitis C since the early 1990s. Therefore, the incidence of HCV transmission from transfusion therapy since 1994 is less than one case per hundred thousand (Bonham, 2000, p. 89). Transmission from mother to infant is uncommon, occurring in less than 5% of pregnancies of HCV positive mothers. Studies of prenatal transmission indicate that HCV transmission does not take place in uterus but instead occurs at the time of delivery. In mothers who are co-infected with both HIV and HCV, the rate of transmission of HCV to the infant is 14% (Baker, 1998, p. 464; Bates, 1995, p. 113).

Transmission of HCV through vaginal intercourse is inefficient, with the transmission rate in long-term mutually monogamous partners who were not using barrier protection reported by various studies as 1% to 21%. HCV is present in menstrual blood; therefore, intercourse during the menstrual period is considered to be higher risk than intercourse when menstrual blood is not present. Studies of transmission among males having sex with males indicates rates of transmission similar to that in heterosexual intercourse, with the highest incidence of infection among those with greater than 50 partners per year (Lemon, 1995, p. 1484; American Health Consultants, 1997, p. 45). Intranasal cocaine use has been associated with HCV transmission, presumably resulting from sharing nasal straws contaminated with blood. Tattooing has been associated with HCV transmission in studies conducted outside the United States (US), but US studies have not demonstrated this association (CDC, 2000, p. 12).

The incubation period for HCV, from exposure to onset of symptoms, is typically six to twelve weeks. HCV antibody is detectable in 80% of cases 15 weeks after exposure and in 97% of cases by six months after exposure. During the acute phase of the illness, 60% to 70% of HCV positive persons will be asymptomatic, approximately 20% of patients will develop mild jaundice, and the remaining persons will have generalized non-specific symptoms such as anorexia, nausea, fatigue, malaise, and abdominal pain (Tierney, 2000, p. 351). After the acute infection, 15% to 20% of patients will demonstrate an absence of HCV RNA in the serum and

normalization of liver enzymes, indicating resolution of the infection. In those persons in whom HCV RNA remains detectable, indicating continued presence of the virus, 30% to 40% will maintain normal ALT levels and will show no evidence of chronic liver disease. The remaining 60% to 70% of chronically infected patients will have fluctuating ALT levels; some will develop progressive liver disease. On rare occasions, a patient will demonstrate positive HCV RNA without the presence of HCV antibody. Therefore, in patient who exhibits chronic hepatitis without cause, assessment of HCV RNA may be indicated (Peter, 1996, p. 157; Marx, 2000, p. 8). Chronic HCV infection usually progresses slowly, with cirrhosis developing in 20% of patients over a period of 20 to 30 years. Persons who ingest alcohol or were over age 40 at the onset of infection have a more rapid progression of cirrhosis. Males have a higher incidence of cirrhosis than females. Because acute HCV infection can be asymptomatic, the first indication of the presence of HCV may be elevated liver enzymes on laboratory tests obtained in conjunction with a routine physical examination. In evaluating the cause of liver enzyme elevation, a hepatitis panel is typically ordered. The only FDA approved tests for HCV infection are tests for HCV antibody (anti-HCV). An enzyme assay (EIA) test is typically performed initially as a screening test. The RIBA (recombinant strip immunoblot assay) is a more specific test for anti-HCV and can be used as a confirmatory test to rule out false positive EIA tests. The presence of anti-HCV does not differentiate between acute, chronic, or resolved HCV infection. Testing for the presence of HCV RNA, while not FDA approved for diagnosis, has become an accepted practice. Qualitative HCV RNA testing determines whether or not Hepatitis C viral particles are present in the blood and can therefore differentiate between resolved and continued infection. Quantitative HCV RNA testing evaluates the amount of hepatitis C virus in the blood and can be used to guide therapy. Two methods have been developed for performing quantitative tests: Polymerase chain reaction (PCR) and branched deoxyribonucleic acid signal amplification (BDNA). Because the two methods are performed using different standards, the results obtained cannot be compared with each other. Therefore, for purpose of monitoring therapy, the same of quantitative test should consistently be used (Sebastian, 2001, p. 23; Shaw, 2000, p. 1324; Sherker, 2000, p. 9; Sherman, 2000, p. 8).

Based upon genetic characteristics, six different genotypes and 90 different of HCV virus have been identified. Because the genotypes respond differently to therapy, genotypic

testing should be performed for persons with chronic progressive HCV infection who are considering anti-viral therapy.

Clinical management of HCV-positive patients varies according to the severity of liver disease. In patients with no overt evidence of liver disease at the time of HCV diagnosis, liver enzymes should be assessed every six to twelve months. Most authorities agree that it is not advisable to treat persons whose ALT levels persistently remain in normal range (CDC, 1997, P. 19). In patients with fluctuating ALT levels, or those whose ALT levels remain elevated, a liver biopsy to assess the degree of liver damage is indicated. If the biopsy indicates portal or bridging fibrosis includes ascites, variceal hemorrhage, or encephalopathy have sustained too much liver damage to benefit from drug therapy; liver transplant should be considered for these patients.

For several years the medication most commonly prescribed for persons with progressing liver damage from HCV has been interferon alfa-2a or alfa-2b, 3 million units administered subcutaneously three times a week, for six to twelve months. With interferon alone, 50% of patients treated demonstrated decreased inflammation and loss of HCV from the serum during therapy. Persons with genotype 1 are less likely to respond to medication therapy than those infected with other genotypes. Once therapy is stopped, 50% to 70% of responders experience a relapse (Foster, 2001, p. 6).

In patients with progressive chronic HCV or chronic HBV infection who does not respond to pharmacotherapy, liver transplant may be indicated. Replacing the liver, however, does not cure the infection. The transplanted liver will also become infected, and immune suppressive agents facilitate the progression of this infection. Nevertheless, chronic viral hepatitis is the most common diagnosis of persons receiving liver transplants. Because hepatitis C is a bloodborne pathogen, prevention of hepatitis C is similar to prevention of hepatitis B. Observing standard precautions is essential. No vaccine is as yet available for prevention of hepatitis C, nor is gamma globulin effective post-exposure (Rosen, 2000, p. 478).

In 1995, a virus similar to the hepatitis C virus was identified and designated hepatitis G. This discovery was confirmed by another laboratory the following year. The virus is transmitted through blood, either through percutaneous injury or through transfusion. Since its

discovery, HGV has been identified in approximately 2% of banked blood (Sherker, 2000, p. 8).

HGV has never been associated with fulminate hepatitis, and the role of this virus in chronic liver disease is questionable. The virus remains detectable in the blood, with documented cases of seropositive blood up to 16 years after initial exposure. Though the presence of the virus persists, it has not been shown to independently cause liver failure. Whether or not the virus accelerated the course of chronic HCV infection is yet to be determined (Marx, 2000, p. 7; American Health Consultants, 1997, p. 29).

Hepatitis B viral infection in man is unique since concentrations of viral-related antigen in the blood may reach 50 mg per ml. Electron microscopic studies of serum have demonstrated typical morphologic appearance of the virus viral-like particles related to hepatitis B infection. Three types of particles have been observed by this technique. The most numerous are the 22 nanometer (nm) particles which appear as spherical, filamentous or tubular forms (200 nm or longer); these are related to the outer surface or coat (HBsAg) of the hepatitis B virus. Less frequently seen in serum are large 42 nm spherical Dane particles, which are believed to represent the intact hepatitis B virus. These large particles characteristically have an outer coat and an inner spherical core measuring approximately 27 nm in diameter (Goldman, 2000, p. 645; Rakel, 2000, p. 432).

HBV is small, double-shelled virus in the class hepadnaviridae. The virus contains numerous antigenic components, including HBsAg, hepatitis B core antigen (HBcAg), and hepatitis B e antigen (HBeAg). The virus contains partially double-stranded DNA, and a DNA-dependent DNA polymerase enzyme. HBV is relatively resilient and, in some instances, has been shown to remain infectious on environmental surfaces for at least a month at room temperature. Several well-defined antigen-antibody systems are associated with HBV infection. HBsAg, formerly called Australia antigen or hepatitis-associated antigen, is an antigenic determinant found on the surface of the virus. It also makes up subviral 22-nm spherical and tubular particles. HBsAg can be identified in serum 30 to 60 days after exposure to HBV and persists for variable periods (Rakel, 2000, p. 428).

During replication, HBV produces HBsAg in great excess. HBcAg is the nucleocapsid protein core of HBV and is distinct from HBsAg and hepatitis B (HBcAg). HBcAg is

not detectable in serum by conventional techniques, but can be detected in liver tissue in persons with acute or chronic HBV infection. HBeAg, a soluble protein, is also contained in the core of HBV. HBeAg is detected in the serum of persons with high virus titers and indicates high infectivity. Antibody to HBsAg (Anti-HBs) develops during convalescence after acute HBV infection or following hepatitis B vaccination. Antibody to HBcAg (Anti-HBc) indicates infection with HBV at an undefined time in the past. IgM class antibody to HBcAg (IgM anti-HBc) indicates recent infection with HBV.

Antibody to HBeAg (Anti-HBe) becomes detectable when HBeAg is lost and is associated with low infectivity of serum (Atkinson, 1995, p. 25). Most HBV infections result from contact with the blood or secretions of HBsAg positive individuals. Abusers may transmit the virus by sharing needles and syringes (Margolis, 1991, p. 88; Tierney, 1994, p. 351). Physicians, dentists, nurses, laboratory personnel, and other health professionals may become infected from contact with blood of HBsAg positive patients (Kawai, 2000, p. 1287).

Contaminated dental instruments or instruments used for ear piercing may also transmit HBV. Since HBV is also present in saliva, vaginal secretions, and seminal fluid, infection may also be spread by close family contacts or sexual contacts (Henley, 1993, p. 739). An HBsAg-positive mother may transmit the virus to her newborn infant, who usually acquires the infection from maternal blood and vaginal secretions at the time of delivery (Robinson, 2000, p. 1671).

Although relatively rare in the United States, hepatitis B is endemic in parts of Asia where hundreds of millions of individuals may be infected. HBV is transmitted horizontally by blood and blood products and sexual transmission. It is also transmitted vertically from mother to infant in the prenatal period which is a major mode of transmission in regions where hepatitis B is endemic. The risk of HBV infection is notably high in promiscuous homosexual men but it is also transmitted sexually from men to women and women to men. Transmission is probably prevented by correct use of condoms. Health care workers and patients receiving hemodialysis are also at increased risk of infection (CDC, 2000, p. 13).

Transmission of hepatitis B virus by the parenteral route is well documented. This is a hazard among recipients of transfused blood, pooled plasma, fibrinogen, factor VIII concentrate, and vaccine contaminated with human serum

(McMahon, 1995, p. 211). Inoculation with minute amounts of infected blood may transmit hepatitis B virus infection, inadequately sterilized syringes, hypodermic needles, and dental and surgical instruments, tattoo needles, and razors have all been implicated in the transmission of infection (McQuillan, 1999, p. 14).

A high frequency of parenteral drug abuse is a major cause for infection in the young adult population. A majority of patients transfused with HBsAg positive blood either develop HBV infection (either anicteric or icteric) or exhibit a rise in the titer of anti-HBs in their serum.

The frequency of post-transfusion hepatitis B infection is significantly decreased when transfused blood is derived from volunteer rather than paid donors and when HBsAg positive blood is discarded (CDC, 1990, p. 25; Bradbury, 1999, p. 655).

Studies on the infants of mothers who suffered from hepatitis B infection during the last trimester of pregnancy or during the immediate post-partum period have shown a high frequency of neonatal infection. Study on the perinatal transmission of hepatitis B infection in a large population of HBsAg positive maternal carriers suggest that the risk of vertical transmission of HBV infection is greatest when the mother has a high titer of HBsAg, is e-antigen positive, and has transmitted hepatitis to previous children. Maternal carriers who were e-antigen negative with anti-e did not transmit hepatitis B. In view of the high incidence of the hepatitis B carrier state in some African and Asian population, vertical transmission may be of considerable epidemiologic importance (Tierney, 2000, p. 357; CDC, 1991, p. 3).

Perinatal transmission from mother to infant at birth is very efficient. If the mother is positive for both HBsAg and HBeAg, 70% to 90% of infants will become infected, and up to 90% of these infected infants will become HBV carriers. An estimated 25% of these carriers will ultimately die of liver failure secondary to chronic active hepatitis, cirrhosis, or primary hepatocellular carcinoma. The risk of perinatal transmission from a woman who is positive for HBsAg only is estimated to be 20%, with 90% of infected infants becoming carriers (Kawai, 2000, p. 1287). The HBV virus is transmitted by parenteral or mucosal exposure to HBsAg-positive body fluids from persons who are carriers or have acute HBV infection. The highest concentrations of virus are in blood and serous fluids; lower titers are found in other fluids, such as saliva and semen. Saliva can be a vehicle of



transmission through bites; however, other types of exposure to saliva, including kissing, are unlikely modes of transmission. There appears to be transmission of HBV via tears, sweat, urine, stool, or droplet nuclei. Direct percutaneous inoculation of HBV by needles during injection drug use is an important mode of transmission. Transmission of HBV may also occur by other percutaneous exposure, including tattooing, ear piercing, and acupuncture, as well as needle-sticks or other injuries from sharp instruments sustained by medical personnel; however, these exposures account for only a small proportion of reported cases in the United States. Breaks in the skin without overt needle puncture, such as fresh cutaneous scratches, abrasions, burns, or other lesions, may also serve as routes for entry (Bonham, 2000, p. 86; CDC, 1992, p. 823).

In United States, the most important route of transmission is by sexual contact, either heterosexual or homosexual, with an infected person. Fecal-oral transmission does not appear to occur. However, transmission among homosexual men occurs possibly via contamination from asymptomatic rectal mucosal lesions at sites of sexual contact. Contamination of mucosal surfaces with infective serum or plasma may occur in mouth pipetting accidents, accidental eye splash, or other direct contact with mucous membranes of the eyes or mouth, such as hand to mouth or hand to eye when contaminated with infective blood serum. Transfer of infective material to skin lesions or mucous membranes via inanimate environmental surfaces may occur by touching surfaces of various types of hospital equipment. Contamination of mucosal surfaces with infective secretions other than serum or plasma could occur with contact involving semen (Briggs, 1994, p. 140).

Hospital personnel, particularly operating room staff, dialysis unit staff, and laboratory technicians, who handle blood, have an increased risk of accidental parenteral exposure to hepatitis B virus. Serologic evidence of previous hepatitis infection was found in 16.8% of health care personnel and in only 8.7% of control group matched for age, sex, and socioeconomic status (Tierney, 2000, p. 340). HBsAg has been detected in mosquitoes and bedbugs collected from West Africa, where there is a high incidence of endemic hepatitis B infection. Although not yet documented, arthropod transmission of hepatitis B virus is possible in tropical areas (Schumacher, 1999, p. 4; Scapa, 1989, p. 402; Sebastian, 2001, p. 23).

Therefore, the outcome of chronic liver disease is often cirrhosis or liver cancer. The clinical course of acute

hepatitis B is indistinguishable from that of other types of acute viral hepatitis (Guyton, 1991, p. 541; Bates, 1995, p. 112). The incubation period ranges from 45 to 160 days (average, 120 days). Clinical signs and symptoms occur more often in adults than in infants or children, who usually have an asymptomatic acute course. However, approximately 50% of adults who have acute infections are asymptomatic. When symptoms occur in acute HBV infection, they may occur in the following patterns. Acute viral hepatitis is commonly a mild disease without jaundice, particularly in those with relative immunity from previous infection, or in infants and children. Infection may be followed by a mild illness without clinical evidence of hepatitis, a rise in viral antibody titer or transiently positive test for HBsAg may be the only evidence of infection. In many subjects exposed to either of the viral agents. There is evidence of hepatitis without jaundice-anicteric hepatitis. Icteric hepatitis is usually a short, uncomplicated illness, but sometimes has a prolonged course. Acute exacerbations may follow complete recovery (Thomas, 1994, p. 56).

The symptoms of an icteric hepatitis are similar to those of many other viral infection, the onset of disease may resemble the prodromal period of icteric hepatitis. The diagnosis is suspected only in epidemic situations, in patients exposed to known patients exposed to known infection, or in those who develop tender enlargement of the liver. A diagnosis is confirmed by liver biopsy. There is often slight hyperbilirubinemia with an increase in urinary urobilinogen and bilirubin (Goldman, 2000, p. 642).

The serum enzyme changes are most helpful in diagnosis, serum transaminase and dehydrogenase levels are elevated, and serum alkaline phosphatase and 5-nucleotidase may be slightly increased. On liver biopsy, the hepatic lesion is indistinguishable from that of icteric hepatitis except for the absence of bile stasis. The preicteric phase of nonspecific constitutional and gastrointestinal symptoms varies in duration from a few days to several weeks. These symptoms may mimic those of other viral infections of the respiratory or gastrointestinal tract (Beare, 1991, p. 487).

Fever is usually most pronounced at the onset, and may be accompanied by a shaking chill; it is unusual, however, for shaking chills to be recurrent, although fever may persist until the early icteric phase. Anorexia, weakness, headache, and myalgia are common symptoms. During this phase, the liver may become enlarged and tender and the urine becomes discolored with bilirubin (Wakefield, 1998, p. 637).

Gastrointestinal symptoms which include anorexia, nausea, and vomiting with right upper abdominal discomfort, usually increase during the early period of increasing jaundice, the liver become more enlarged and tender, and the spleen may be palpable (Beare, 1991, p. 485). Fever usually subsides a few days after the onset of jaundice. Within a few days of hospitalization and bed rest, nausea subsides, and the appetite improves in most patients. Typically, the patient is maximally jaundiced within two weeks, and thereafter clinical jaundice and serum bilirubin levels gradually return to normal within six weeks. Hepatic enlargement may subside with symptomatic improvement, but often persists during the icteric period. Liver enlargement usually persists during the period of jaundice, whereas hepatic tenderness is usually observed early in the acute illness (Goldman, 2000, p. 641; Rosen, 2000, p. 478).

Some patients with otherwise typical acute viral hepatitis may remain icteric with hepatic enlargement and abnormalities of liver function for a period of several months. A liver biopsy is indicated in such patients to confirm a diagnosis of chronic persisting hepatitis, the histological feature of typical viral hepatitis in spite of the prolonged clinical course indicate an excellent prognosis for full recovery (Goldman, 2000, p. 640).

HBV infection is a major cause of acute and chronic hepatitis, cirrhosis, and hepatocellular carcinoma worldwide. Globally, it is estimated that at least 300 million persons clinically die each year from hepatitis B associated with acute and chronic liver disease (Goldman, 2000, p. 639; Francis, 1995, p. 1242; Margolis, 1991, p. 86). The world can be divided into three areas according to the prevalence of chronic HBV infection. Areas where there is a high prevalence (>8% of the general population is hepatitis B surface antigen HBsAg positive) include China, Southeast Asia, most of Africa and the Middle East, most Pacific Islands, some Caribbean Island and the Amazon River Basin. Areas where there is a moderate prevalence (2% to 7% of the general population is HBsAg positive) include most of Central and South America, the Mediterranean, India, Eastern and Southern Europe, the Soviet Union and Japan. Areas where there is a low prevalence (<2% of the general population is HBsAg positive) include most of the United States, Canada, Western Europe, and Australia (Tierney, 2000, p. 351).

Hepatitis has been reportable in the U.S.A. for many years. Hepatitis B became reportable as a distinct entity during the 1970's, after serologic tests to differentiate different types of

hepatitis became widely available (Maynard, 1990, p. 519). Approximately 20,000 cases of hepatitis B are reported annually in the U.S.A.; However, HBV infection is greatly under reported, due primarily to the high proportion of infections that are a non-asymptomatic or non-icteric (Alter, 1990, p. 1219).

More accurate estimates of the magnitude of HBV infection are derived from areas of intensive clinical serologic surveillance for hepatitis. Data from these areas suggest that estimated 200,000-300,000 persons in the United States become infected with HBV each year, and also an estimated one to one and a quarter million persons are chronically infected with it (Atkinson, 1995, p. 22). The estimated incidence of HBV infection rose in the late 1970's through the mid 1980's from approximately 40 cases per 100,000 population in 1970 to the peak of 70 cases per 100,000 population in 1985. Since that time, incidence has gradually decreased to approximately 40 per cases per 100,000 in 1992 (Sherman, 2000, p. 7). Over 80% of acute HBV infections occur among adults. Adolescents account for approximately 8% of infection, and children and perinatal transmissions account for approximately 4% each (Thompson, 1994, p. 56). The most common risk factors for HBV infection in the U.S.A. is sexual contact, either heterosexual (41%) or homosexual (9%), injection drug use accounts for (15%) of cases, 2% of cases occur by household contact with a chronic carrier, and health care workers account for 1% of cases. Approximately 31% of all persons with HBV infection have no known risk factor infection (Atkinson, 1995, p. 23). Although HBV infection is uncommon among adults in the general population (the lifetime risk of infection is <20%), it is highly prevalent in certain groups (Thomas, 1994, p. 59).

Risk of infection varies with occupation, life style, or environment. Generally, the highest risk for HBV infection is associated with lifestyle, occupation, or environments in which contact with blood from infected persons is frequent. In addition, the prevalence of HBV markers for acute or chronic infection increases with increasing number of years of high risk behavior. For instance, an estimated 40% of injection drug users become infected with HBV after one year of drug use, while over 80% are infected after 10 years (Atkinson, 1995, p. 18).

The risk of health care workers contraction HBV infection depends on how often they are exposed to blood or blood products through percutaneous and permucosal exposures. Any healthcare or public safety workers may be at risk for

HBV exposure depending on the tasks performed. If those tasks involve contact with blood or blood contaminated body fluids, then such workers should be vaccinated. Risk is often highest during training periods. Therefore, it is recommended that vaccination be completed during training in schools of Medicine, Dentistry, Nursing, Laboratory, Technology and other allied health professions (Lanphear, 1994, p. 437; Taras, 1994, p. 122; Thomas, 1992, p. 1).

The role of laboratory tests in establishing a diagnosis has gained increasing importance as newer methods of detection and analysis become available. Each of the type of viral hepatitis described in this learning activity has specific tests for the virus and/or the antibody to the virus. The severity of the impact of these viruses upon the liver is measured by less specific tests of general liver function. Patterns of abnormality in liver function tests rather than specific values of a single test permit the clinician to interpret the functional status of the liver. In addition, it is important to note that diseases that are not hepatic in origin can produce abnormalities in liver function tests. These include but are not limited to hemolytic disease as well as congestive heart failure, sepsis, and other disorders that alter liver perfusion.

Though viral hepatitis can occur without the presence of jaundice, jaundice has historically been considered a diagnostic marker for hepatitis. Jaundice results from elevations in the serum bilirubin. The normal level for total serum bilirubin is less or equal 1.6 mg/dl. In order for clinical jaundice to occur, the total serum bilirubin must exceed 2.5 mg/dl. A total serum bilirubin level less than 10 mg/dl is usually found in viral hepatitis; level higher than this are typically indicative of hepatic carcinoma or biliary obstruction (Wallach, 1992, p. 562).

Elevations in the liver enzymes alanine aminotransferase (ALT), formerly known as serum glutamic pyruvic transaminase or SGPT, and aspartate aminotransferase (AST). Formerly called serum glutamicoxaloacetic transaminase or SGOT occur in response to inflammation of the hepatic cells. The source of this inflammation is most often viral hepatitis or chemical injury.

The chemical injury may be due to drug therapy, alcohol ingestion, poisoning with substances such as acetaminophen or carbon tetrachloride. Elevations in ALT and AST are also associated with centrilobular necrosis due to inadequate perfusion in shock states and in cases of biliary obstruction. The normal range for ALT is 5 to 35 units/l ml; the normal range for AST is 5 to 40 units/l ml. Albumin levels are

typically decreased in hepatocellular disease such as hepatitis but are unchanged in uncomplicated obstructive liver disease. Alkaline phosphatase levels remain in normal range in hemolytic disease, are slightly elevated in hepatocellular disease, and are greatly increased in obstructive liver disease (Gladwin, 1995, p. 24).

The diagnosis of HBV infection is generally made on the basis of serology. Virtually all individuals infected with HBV, either acute or chronically, will have detectable serum hepatitis B surface antigen (HBsAg). In acute infection, HBsAg is detectable several weeks after infection and its appearance coincides with the onset of clinical symptoms. HbsAg is also detectable in acute infection which is characterized by a high rate of viral replication. At around the same time, IgM antibodies against core antigen are detectable in serum. Subsequently, IgG antibodies against core are produced. As acute infection resolves, IgG antibodies against core antigen persist and IgM antibodies and HBsAg become undetectable. Subjects who develop an immune response against HBV develop antibodies against HBsAg. Such antibodies are also produced by vaccination.

Most people who have had acute infection that resolves continue to have IgG antibodies against core antigen for life. Some remain immune with antibodies against HBsAg but some lose these antibodies and may be susceptible to future infection (Kawai, 2000, p. 1290). Acutely infected individuals who do not clear HBV continue to have serum HBsAg. In most cases, the chronic infection becomes “non-replicate” and the subjects lose serum HBeAg and develop antibodies against HBeAg. In some cases, “replicate” infection persists along with detectable serum HBeAg. In chronically infected individuals, infection can switch from “non-replicate” to “replicate” and vice-versa. One goal of treatment is to convert patients with chronic hepatitis B from a “replicative” (HBeAg positive) to “non-replicative” (HBeAg negative) state (Foster, 2001, p. 6). HBsAg is the most commonly used test for diagnosing acute HBV infection or detecting carriers. HBsAg can be detected as early as 1-2 weeks and as late as 11-12 weeks after exposure to HBV when sensitive assays are used. The presence of HBsAg indicates that a person is infectious, regardless of whether the infection is acute or chronic (Foster, 2001, p. 6).

Anti-HBc (core antibody) develops in all HBV infections, appears shortly after HBsAg in acute disease, and indicates HBV infection at some undefined time in the past. Anti-HBc only occurs after HBV infection, and does not develop in persons whose immunity to HBV is from vaccine. Anti-HBc

generally persists for life and therefore is not a serologic marker for acute infection (Foster, 2001, p. 6; Dolin, 1999, p. 48). IgM anti-HBc appears in persons with acute disease about the time of illness onset and indicates recent infection with HBV. IgM anti-HBc is generally detectable 4 to 6 months after onset of illness and is the best serologic marker of acute HBV infection. A negative test for IgM anti-HBc together with a positive test for HBsAg in a single blood sample identifies a chronic HBV infection. HBeAg is a useful marker associated strongly with the number of infective HBV particles in the serum and a higher risk of infectivity (Dolin, 1999, p. 49). Anti-HBs (surface antibody) are a protective, neutralizing antibody. The presence of anti-HBs following acute HBV infection generally indicates recovery and immunity from reinfection. Anti-HBs can also be acquired as an immune response to hepatitis B vaccine or passively transferred by administration of HBIG. Using radioimmunoassay (EIA), the manufacturer's recommended positive should be considered an appropriate measure of immunity. The level of anti-HBs may also be expressed in milli-international units/ml. Ten milli-international units/ml are considered to indicate a protective level of immunity (Foster, 2001, p. 7; Dolin, 1999, p. 49).

In individuals suspected of having chronic hepatitis B, the appropriate screening test is for serum HBsAg. Individuals who may have chronic hepatitis B who should be considered for testing include: those with symptoms of chronic liver disease, those with abnormal laboratory tests suggesting liver disease, individuals from countries where HBV infection is endemic, those with risk factors such as intravenous drug use or unprotected promiscuous sex, children of HBV infected parents or household contacts, health care workers, and patients on hemodialysis.

Individuals with chronic hepatitis B are at increased risk for the developments of hepatocellular carcinoma. Although precise recommendations do not exist, it is reasonable for such individuals to undergo periodic screening for cancer. Screening procedures include measurement of serum alpha-fetoprotein (a tumor marker that is elevated in about 85% of individuals with hepato-cellular carcinoma) and ultrasound examination. The optimal frequency of such screening examinations has not been determined (Dolin, 1999, p. 50).

At the present time, alpha-interferon is the only drugs approved in the United States for the treatment of chronic hepatitis B. Treatment is recommended for individuals who have "replicative disease" (HBeAg positive). About 40% of such individuals will lose serum HBeAg after 16 weeks of

treatment with interferon-alpha. Loss of HBeAg is correlated with an improved prognosis. A few treated patients (less than 10%) may even be cured as assessed by the loss of HBsAg (Michael, 1999, p. 432).

Hepatitis B vaccination has been available in the United States since 1981. However, the impact of vaccine on HBV disease has been less than optimal, and the incidence of reported hepatitis B cases is as high now as it was before the vaccine was available (Hanoelman, 1992, p. 265). The apparent lack of impact from the vaccine can be attributed to several factors. First, a large proportion of persons with HBV infection (25% to 35%) deny any risk factors screening approach. Second, the three major risk groups (heterosexuals with contact with infected persons or multiple partners, injection drug users, and homosexually active males) are not reached effectively by targeted programs. Deterrents to immunization of these groups include lack of awareness of the risk of disease and its consequences, lack of public sector programs and vaccine cost. Difficulty in gaining access to these populations is also a problem. Further, there has been limited success in providing vaccine to persons in high-risk groups due to rapid acquisition of infection after beginning high-risk behaviors, low initial vaccine acceptance and low completion rates (Francis, 1995, p. 1243; Waterman, 1994, p. 567).

A comprehensive hepatitis B prevention strategy is now being implemented which includes the following: The risk of health care workers acquired HBV infection depends on the frequency of exposure to blood or blood products and on frequency of needlesticks. These risks vary during the training and working career of each individual but are often highest during the professional training period. For this reason, it is recommended that vaccination be completed during training in schools. The risk of HBV infection for hospital personnel can vary both among hospitals and within hospitals. In developing specific immunization strategies, hospitals should use available published data about the risk of infection and may wish to evaluate their own clinical and institutional experience with hepatitis B. Studies in urban centers have indicated that occupational groups with frequent exposure to blood and/or needles have highest risk of acquiring HBV infection, including (but not limited to) the following groups: medical technologists, operating room staff, phlebotomists and intravenous therapy nurse, surgeons and pathologists, and oncology and dialysis unit staff. Groups shown to be at increased risk in some hospitals include: emergency room staff, nursing personnel, and staff

physicians (Margolis, 1997, p. 88). Other healthcare workers based outside hospitals that have frequent contact with blood or blood products are also at increased risk of acquiring HBV infection. These (but are not limited to): dental professionals (dentists, oral surgeon, and dental hygienists), laboratory and blood bank technicians, dialysis center staff, emergency medical technicians, and morticians.

Susceptible clients and staff who work closely with clients of institutions for the mentally retarded should be vaccinated. Risks for staff are comparable to those for healthcare personnel in other high-risk environment. However, the risk in institutional environments is associated, not only with blood exposure, but also with bites and contact with skin lesions and other infective secretions. Susceptible clients and staff who live or work in smaller (group) residential settings with known HBV carriers should also receive hepatitis B vaccine (Lemon, 1995, p. 1481).

Numerous studies have established the high risk of HBV transmission in hemodialysis units. Although recent data have shown not only a decrease in the rate of HBV infection in hemodialysis units but also a lower vaccine efficacy in these patients, vaccination is recommended for susceptible patients. Environmental control measure and regular serologic screening (based on immune status) of patients should be maintained (Lemon, 1995, p. 1485).

Susceptible homosexually active men should be vaccinated regardless of their ages or duration of their homosexual practices. It is important to vaccinate persons as soon as possible after their homosexual activity begins. Homosexually active women are not at increased risk of sexually transmitted HBV infection.

All users of illicit injectable drugs who are susceptible to HBV should be vaccinated as early as possible after their drug use begins. Patients with clotting disorders who receive clotting factor concentrates have an elevated risk of acquiring HBV infection. Vaccination is recommended for these persons and should be initiated at the time their specific clotting disorder is identified. Screening is recommended for patients who have already received multiple infusions of these products.

Household contacts of HBV carriers are at high risk of acquiring HBV infection. Sexual contacts appear to be at greatest risk. When HBV carriers are identified through routine screening of donated blood, diagnostic testing in hospitals, prenatal screening, screening of refugees, or other

screening programs, they should be notified of their status and their susceptible household contacts vaccinated. Families accepting orphans or unaccompanied minors from countries of high HBV endemic should have the child screened for HBsAg, and if positive, family members should be vaccinated.

Persons in casual contact with carriers at schools, offices, etc., are at minimal risk of acquiring HBV infection, and vaccine is not routinely recommended for them. However, classroom contacts of deinstitutionalized mentally retarded HBV carriers who behave aggressively or have special medical problems that increase the risk of exposure to their blood or serous secretions may be at risk. In such situations, vaccine may be offered to classroom contacts. Some American populations, such as Alaskan Eskimos, native Pacific Islanders, and immigrants and some refugees from areas with highly endemic disease (particularly eastern Asia and sub-Saharan Africa) have high HBV infection rates. Depending on specific epidemiologic and public health considerations, more extensive vaccination programs should be considered.

The prison environment may provide a favorable setting for the transmission of HBV because of the frequent use of illicit injectable drugs and homosexual practices. Moreover, it provides an access point for vaccination of parenteral drug abusers. Prison officials should consider undertaking screening and vaccination programs directed at those who abuse drugs before or while in prison.

Heterosexually active persons with multiple sexual partners are at increased risk of acquiring HBV infection; risk increases with increasing sexual activity. Vaccination should be considered for persons who present for treatment of sexually transmitted disease and who have histories of sexual activity with multiple partners. Vaccination should be considered for persons who plan to reside more than six months in areas with high levels of endemic HBV and who will have close contact with the local population. Vaccination should also be considered for short-term travelers who are likely to have contact with blood from or sexual contact with residents of areas with high levels of endemic disease. Hepatitis B vaccination of travelers ideally should begin six months before travel in order to complete the full vaccine series; however, a partial series will offer some protection against HBV infection.

A plasma derived vaccine was licensed in the U.S.A. in 1981. It was produced from HBsAg particles purified from

the plasma of human carriers. The vaccine was safe and effective, but was not well accepted, possibly because of unbiased fears of transmission of the live HBV and other bloodborne pathogens. This vaccine was removed from U.S.A. market in 1992 (Damme, 1995, p. 27; Waterman, 1994, p. 568). Recombinant vaccine is produced by inserting a plasmid containing the gene for HBsAg, which is harvested and purified. The recombinant vaccine contains over 95% HBsAg protein (5 to 40 meg/ml); yeast-derived proteins may constitute up to 5% of the final product, but no yeast DNA is detectable in the vaccine (Waterman, 1994, p. 568; Wright, 1993, p. 1340).

HBV infection cannot result from use of the recombinant vaccine, since no potentially infectious viral DNA or complete viral particles are produced in the recombinant system. Vaccine HBsAg, is absorbed to aluminum hydroxide, and thimerosal is added as a preservative (Damme, 1995, p. 27). After three intramuscular doses of hepatitis B vaccine, over 90% of healthy adults and over 95% of infants, children and adolescents (from birth to 19 years of age) develop adequate antibody responses. The vaccine is 80% to 100% effective in preventing infection of clinical hepatitis in those who receive the complete course of vaccine. Large vaccine doses (2 to 4 times the normal adult dose) or an increased number of doses are required to induce protective antibody in high proportion of hemodialysis patients and also may be necessary in other immunocompromised persons (Kew, 1995, p. 1065; Wright, 1993, p. 1342). The recommended dosage of vaccine utilized may differ depending on the age of the recipient, certain exposure circumstances, and type of vaccine. Hemodialysis patients should receive a 40 meg/ml dose in a series of three or four doses. One of the vaccines (Recomb-Beeves H) has a special dialysis patient formulation that certain 40 meg (Kew, 1995, p. 1067). The deltoid muscle is the recommended site for hepatitis B vaccination in adults and children, while the anterolateral thigh is recommended for infants and neonates. Immunogenicity of vaccine in

### CHAPTER 2 - LITERATURE REVIEW

More than 8 million healthcare workers in the United States work in hospitals and other health care settings. Precise national data are not available on the annual number of needlestick and other percutaneous injuries among health care workers (Schumacher, 1999, p. 5). However, estimates indicate that 600,000 to 800,000 injuries occur annually (CDC, 1997, p. 19). About half of these injuries go unreported. Further data from the EPINet system suggests

that at an average hospital, workers incur approximately 30 needlestick injuries per 100 beds per year (Roush, 1999, p. 165). The potential for hepatitis B virus (HBV) transmission in the occupational setting is greater than for human immunodeficiency virus (HIV). According to the Center for Disease Control (CDC) 1990, the seroconversion rate for healthcare workers with exposure to HIV is less than 1%, for those exposed to HBV, between 6% and 30%. In United States, as many as one million people are carriers of HBV. Not all know they are carriers, so this information may not be reported when they are hospitalized. Fulminate hepatitis, which develops in 1% to 2% of reported hepatitis B cases, is fatal in 85% of cases (CDC, 1990, p. 25).

The CDC (1990) estimates that 1,800 healthcare workers whose jobs entail exposure to blood become infected with HBV each year. As a result, 250 people will die of fulminate hepatitis, cirrhosis or liver cancer. In occupational settings, HBV is transmitted by percutaneous inoculation or contact of an open wound, non-intact skin, or mucous membranes which blood, blood contaminated, body fluids or concentrated virus. Blood is the single most important source of HBV in the workplace setting. Needle sticks and cuts with other sharp objects are high risk exposure, as well as blood splashes into non-intact skin or into the eyes or mouth. Protective measures should focus on HBV vaccination and preventing exposures to blood or contaminated body fluids (Bodenheimer, 1986, p. 253; CDC, 1990, p. 24).

The risk of acquiring HBV infection following infection with a needle contaminated by an HBV carrier varies from 6% to 30% far in excess of the risk (less than 0.3%) of acquiring HIV under similar circumstances (CDC, 1992, p. 823; CDC, 1991, p. 3; Kane, 1989, p. 115).

Most reported needle stick injuries involve nursing staff; but laboratory staff, physicians, housekeepers, and other healthcare workers are also injured. Some of these injuries expose workers to bloodborne pathogens that cause infection. The most important of these pathogens are HBV, HCV, and HIV. Infections with each of these pathogens are potentially life threatening and preventable (McQuillan, 1999, p. 16). The risk of infection varies depending on the pathogen. HBV infections among healthcare workers has declined dramatically over the last ten years, due to widespread immunization of healthcare workers with hepatitis B vaccine, and other measures required by the 1991 OSHA Bloodborne Pathogen Standard (29CFR 1910. 1030) (Betel, 1999, p. 4). Any Healthcare Worker (HCW) who

performs tasks involving contact with blood, blood-contaminated body fluids, other body fluids, or sharps should be vaccinated. Hepatitis B vaccine should always be administered by the intramuscular route in the deltoid muscle with a needle 1-1.5 inches long. Among health-care professionals, risks for percutaneous and permucosal exposures to blood vary during the training and working career of each person but are often highest during the professional training period. Therefore, vaccination should be completed during training in schools of medicine, dentistry, nursing, laboratory technology, and other allied health professions, before trainees have contact with blood. In addition, the OSHA Federal Standard requires employers to offer hepatitis B vaccine free of charges to employees who are occupationally exposed to blood or other potentially infectious materials (Roush, 1999, p. 166). Prevacination serologic screening for previous infection is not indicated for persons being vaccinated because of occupational risk unless the hospital or healthcare organization considers screening cost-effective. Postexposure prophylaxis with hepatitis B immune globulin (HBIG) (passive immunization) and/or vaccine (active immunization) should be used when indicated. Needlestick or other percutaneous exposures of unvaccinated persons should lead to initiation of the hepatitis B vaccine series. Postexposure prophylaxis should be considered for any percutaneous, ocular, or mucous membrane exposure to blood in the workplace and is determined by the HBsAg status of the source and the vaccination and vaccine-response status of the exposed person.

Research indicates that hollow-bore needle account for nearly 60% of all percutaneous injuries (NaSH-CDC National Surveillance System for Hospital Health Care Workers, Data from 1995-1999). Hollow-borne needles are the devices most often associated with the transmission of bloodborne infections. The reason is that the blood remaining inside the bore of the needle after use contains a large volume of virus than the relatively small amount left on the outside of a solid core needle or sharp object. The activities where most sharp injuries occur include; disposal of needles, including collection and disposal of material used during patient care procedures; administering injections; drawing blood; recapping needles and handling trash and dirty linens. The pattern of sharps injuries shows 20% occurring before or during use. Up to 70% occur after the needle has been used, but before disposal, and 10% occur during or after disposal. The most frequent exposures occur in jobs classified as nurses (50%), physicians (13%), nursing

assistants (5%), and housekeepers/laundry workers (5%). These numbers may be under-reported for nurses by as much as 53%, and physicians by as much as 95%. Two-thirds of needle stick injuries occur in patient rooms, operating rooms, emergency rooms, and critical care units (Mahoney, 1996, p. 1115).

The impact of HBV on the morbidity and mortality of health care workers overshadows that of HIV, and 200 or more yearly deaths of health care workers because of HBV infection are described as “tragic and almost entirely preventable less” (Rapoza, 1989, p. 119).

Since it became available in 1982, hepatitis B vaccine has been a powerful weapon in the fight against this major occupational hazard for health care workers (Handelman, 1992, p. 263; Mundt, 1992, p. 568). In 1989, approximately 12,000 health care workers developed hepatitis B infections, and approximately 200 of these workers died from the disease or its consequences. Despite the availability of a safe, effective vaccine, acceptance of hepatitis B vaccine remains low while rate of hepatitis B disease continues to climb (CDC, 1992, p. 824). Even with the Occupational Safety and Health Administration (OSHA, 1910.1030) standard (U.S. Department of Labor, 1991, p.179) that employers must provide free HBV immunization to all employees at risk of contracting HBV; only 20% to 30% of health care workers have completed the series of injections (CDC, 1992, p. 825).

The CDC (1990) recommended that any healthcare worker who performs tasks involving contact with blood or blood contaminated fluids should be vaccinated (p. 826).

Occupational hepatitis B remains a threat to healthcare workers worldwide, even with availability of an effective vaccine (Helcl, 2000, p. 5). Despite limited resources for public health, the Czech Republic instituted a mandatory vaccination program for healthcare workers in 1983.

Despite giving vaccine intradermally from 1983 to 1989 and intramuscularly as half dose from 1990 to 1995, rates of occupational hepatitis B decreased dramatically, from 177 cases per 100,000 workers in 1982 (before program initiated) to 17 cases per 100,000 in 1995.

Healthcare workers are five to ten times more likely than the general population to be hepatitis B carriers (Helcl, 2000, p. 5). Also, hepatitis B in the United States is primarily a disease of young adults, with about 75% of cases occurring in people age 15 to 39 (Kane, 1989, p. 115). The majority of

hospital healthcare workers are within this range. Occupational and employee health nurses have the knowledge and skill to educate healthcare workers about HBV and the importance of vaccination.

Bodenheimer (1986) reports a vaccination acceptance rate of 27% to 58% (p. 254); while the CDC (1990) reports only 45% of high risk personnel have been vaccinated (p. 23). Although intensive care unit nurses have one of the highest risks of exposure to hepatitis B, Spence (1990) reports that only 42% of high risk nurses accepted vaccine in a study of an 800 beds, inner city hospital which employed 4,000 healthcare workers (p. 130).

New cases of hepatitis B in the United States population continue to rise. Between 1978 and 1985 the incidence rose 50% despite the development of the vaccine in 1982 (Spence, 1990, p. 129). CDC (1987) reports that 10% of the new hepatitis B cases occur in healthcare workers, and as many as 30% of healthcare workers have positive serologic markers indicating past exposure to hepatitis B virus (p. 353). Goldstein (2002), conducted a study from 1982-1998, enhanced sentinel surveillance for acute hepatitis B was conducted in four counties in the United States to determine trends in disease incidence and risk factors for infection. During this period, the reported incidence of acute hepatitis B declined by 76.1% from 13.8 cases per 100,000 in 1987 to 3.3 cases per 100,000 in 1998 (p. 713).

Hepatitis B vaccine has a strong record of safety and efficacy, with no major problems reported in the literature since its introduction. According to the studies required for licensure of the vaccine, over 95% of young adults (age 20 to 39) developed protective antibodies following administration of the vaccine (Goldstien, 2002, p. 214). These successfully vaccinated employees are expected to be completely protected from hepatitis B infection (Valenti, 1986, p. 74). Adverse reactions to the vaccine, excluding local injection site soreness and malaise, were reported in less than 1% of recipients (Handelman, 1992, p. 269).

In recent years, concerns have been raised that vaccination against hepatitis B virus might increase risk for developing a variety of diseases, including multiple sclerosis. The concerns related to multiple sclerosis (MS) were raised by report from France of a possible increase in autoimmune diseases, including MS, after hepatitis B vaccination (National Academy of Sciences' Institute of Medicine, 2002). These reports were reviewed but could not be confirmed by any follow-up scientific study, and the World

Health Organization and the Institute of Medicine had concluded that there was no association between hepatitis B vaccine and MS. In addition, two separate reports indicated no association between vaccination and the risk of developing MS or MS relapses. However, some public concern has remained. The current, more comprehensive analysis and report relating to MS is part of the National Academy of Sciences' Institute of Medicine's Immunization Safety Project, which was requested by the Center for Disease Control and the National Institute of Health to study a variety of immunization safety concerns. The Immunization Safety Review Committee comprises 15 members, including experts in pediatrics, neurology, immunology, internal medicine, infectious diseases, genetics, epidemiology, statistics, nursing, ethics and public health, chosen for knowledge and lack of bias or association with vaccine manufacturers. The Immunization Safety Review Committee examined the relationship between hepatitis B vaccine and diseases of the nervous system such as multiple sclerosis, reviewing an extensive collection of published, peer-reviewed scientific and medical literature investigating the association of these diseases with the vaccine. They concluded that epidemiological studies (studies of vaccine-exposed and disease populations and control groups and their vaccination status) reject the idea that the vaccine causes the onset or relapse of MS in adults. They also reviewed biological evidence relating hepatitis B vaccine with MS and concluded such evidence was weak, indirect and did not support a link. While the conclusions related to MS in adults were solid, the committee found that data relating to other demyelinating neurological diseases was lacking, and a firm conclusion could not be made for these conditions. Such conditions include optic neuritis (inflammation of the optic nerve) and other isolated demyelinating events, and Guillain-Barre Syndrome (a disorder affecting peripheral nerves beyond the brain and the spinal cord). The committee recommended continued surveillance of vaccinated individuals, especially among those born after 1991, when the vaccine became routinely used in infants.

Still many healthcare workers are not fully aware of the seriousness of HBV infection or the risk of becoming a chronic carrier should they experience occupational exposure. Chronic carriers are at high risk for chronic persistent hepatitis, chronic active hepatitis, cirrhosis, or primary hepatocellular carcinoma (Kane, 1989, p. 125).

Since its inception in 1982, the U.S. hepatitis B vaccination



effort has faced several challenges. In 1980s, concern was expressed about the possible risk for human immunodeficiency virus (HIV) transmission by the original plasma-derived vaccine; however, no transmission of any microbial agent was demonstrated, and the safety of the vaccine was reaffirmed (CDC, 1984, p. 68). Plasma-derived hepatitis B vaccines are no longer used in the United States, but their use continues safely in other countries.

The vaccines currently available in the United States are produced by recombinant DNA technology. Suggestions that hepatitis B vaccination could result in demyelinating diseases such as multiple sclerosis in adolescents led the French authorities to suspend routine school-based vaccination temporarily in October 1998, despite contrary recommendations by the World Health Organization (WHO) and Viral Hepatitis Prevention Board (VHPB). The factual basis for the allegations was reviewed at a specially convened meeting of the VHPB in Geneva in late September 1998, immediately before the action by the French government. Reports of the main conclusions of this meeting subsequently appeared in leading journals (Halsey, 1999, p. 23; Hall, Kane, Roure, et al., 1999, p. 2475) in which it was stated that there was no basis for concluding that there was a link between the vaccine and any demyelinating diseases, including sclerosis.

The conclusion was reached after considering three main possibilities, the association between vaccination and disease could be a coincidence, the vaccine could have acted as a trigger for disease expression and there might be a true causal relationship. Coincidence emerged as the favored hypothesis to explain observations of central nervous system diseases in subjects shortly (2-3 months) after hepatitis B vaccination. Supporting this is data from routine reporting systems in the US, Italy and Canada, as well as manufacturers' pharmacovigilance system, although these data are derived from passive reporting, which may be insensitive. Three published North American studies and three more recent, unpublished studies failed to uncover evidence for an association between vaccination and neurological adverse events. Moreover, the age and sex distribution of MS cases reported through spontaneous reporting systems matched those cases that preceded the use of the vaccine. Arguments against the other two hypotheses include the distinctly different geographical distributions of naturally occurring hepatitis B infection and multiple sclerosis, and the lack of any plausible biological evidence for a causal link. Epidemiological data on an association

between the two are equivocal. The consensus of the expert group was, therefore, that there was no reason to suspect a link between vaccination and multiple sclerosis, or other demyelinating diseases. However, this advice did not dissuade the French government from ordering a temporary suspension of the immunization program (although vaccination of infants was not interrupted, and vaccination of adolescents was subsequently resumed through primary care physicians rather than in a school context). Other factors than strictly objective considerations are likely to have played a dominant role in this decision, such as; the actions of the media representatives and special interest groups in creating public pressure to halt vaccination, and the sensitization of both the public and regulatory authorities by the previous crisis in France over the transmission of HIV through contaminated blood. Another recent potential threat to perceptions of the safety of hepatitis B vaccines arose in the United States in 1999. This analysis was presented at a private FDA meeting on 22 June 1999, where it was recognized that some infants could be exposed, as a result of vaccination (not exclusively with hepatitis B vaccine), to cumulative mercury levels that exceeded one of the three existing federal guidelines on exposure to methyl mercury. Although thimerosal does not contain methylmercury and there were no reports of any harm caused by the level of mercury exposure due to vaccination, it was deemed appropriate that recommendations of hepatitis B vaccination at birth of infants of HBsAg-negative mothers be amended, until such time as thimerosal-free vaccines became available. A joint PHS-AAP statement issued on July 7, 1999 noted that the first dose of hepatitis B vaccine could be postponed from birth until 2-6 months of age, if desired (unlike the other vaccinations normally given at birth). A subsequent "supplemental guideline" from the AAP took a stronger line, stating that: "if thimerosal-free vaccine is not available, hepatitis B virus vaccination should be initiated at 6 months of age."

This was followed by a more detailed set of guidelines from the CDC, recommending that if vaccination were delayed, it should be started at 2 months of age. These announcements, which were made at a time when the hepatitis B vaccination program was under intense public scrutiny in Congress, had the potential to raise safety concerns in the minds of both public and physicians. However, although a survey carried out in August 1999 of 977 birthing hospitals (representing about 30% of the birthing cohort nation-wide) showed that approximately 55% of hospitals that were aware of the PHS-AAP statement and that had a policy of vaccinating all

children against hepatitis B at birth had stopped vaccinating some or all infants within one month of the issuance of the statement. Despite this fact, there was no widespread public alarm or sensationalized media coverage of this issue. At the end of August 1999, the FDA licensed a thimerosal-free hepatitis B vaccine, which was distributed from the middle of September onwards. This vaccine was initially in short supply and was given by priority to newborns and infants or less than 6 months of age. Although this episode did not give rise to general disquiet about the possible safety of hepatitis B (and other) vaccines a later survey has shown that while thimerosal-free vaccine had become widely available, hospitals were slow to switch back to a policy of vaccinating at birth. This may result in increased perinatal and early childhood HBV transmission, as there is evidence that completion of a full series of hepatitis B vaccine is substantially lower when vaccination is begun more than one month after birth. Hepatitis B vaccine has a strong record of safety and efficacy, with no major problems reported in the literature since its introduction. According to the studies required for licensure of the vaccine, over 95% of young adults (age 20 to 39) developed protective antibodies following administration of the vaccine. These successfully vaccinated employees are expected to be completely protected from hepatitis B infection. Adverse reactions to the vaccine, excluding local injection site soreness and malaise, where reported is less than 1% of recipients (Handelman, 1992, p. 269).

Since the hepatitis B vaccine became available, research indicates less than optimal acceptance rates by healthcare workers. Fulton (1986) reported that actual acceptance of HBV vaccine after participants attended a seminar on the subject was 27% (p. 1339). Chako (1986) found a range of acceptance from 2.6% to 58.3% in six hospital surveyed (p. 34), while the CDC survey (1987) of hospitals with HB vaccine programs showed less than 45% of high risk personnel had been vaccinated by 1987 (p. 358). With the introduction of the synthetic HB vaccine in 1987, acceptance among health care workers at risk increased, but still averages fewer than 50% (CDC, 1991, P. 3). Spence (1990) reported a 41% vaccine acceptance rate in high risk nursing personnel in a 1988 survey (P. 130), while Scapa (1989) found only 24% of the registered nurses who worked in high risk areas had been vaccinated, others estimate that only 30% to 40% of high risk health care workers have been vaccinated (p. 423).

McKenzie (1992) reported that a recent Gallup Poll

commissioned by Smith Kline Beecham, which manufactures an HBV vaccine, showed a decreased level of knowledge among healthcare workers about the means of transmission and prevention of hepatitis B (p. 517). The survey included 1,000 people, 100 of them working in health related professions; physicians, nurses, nursing assistants, dentists and emergency medical technicians. The survey reported that 66% of health care workers felt they knew little or nothing about the disease compared with 83% of the general population. Only 52% of the healthcare workers knew about hepatitis B vaccine, while 31% of the general population knew a vaccine existed. The survey revealed a need for educating healthcare workers about hepatitis B transmission and prevention.

In the study done by McKenzie (1992) to employees of large metropolitan hospital, and his survey asked for information about the healthcare workers acceptance of hepatitis B vaccination and knowledge of appropriate follow up after a significant blood exposure occurs (p. 519). According to his results, 45% of employees at risk for contracting HBV have not received the vaccination. Findings related to the methods of follow up used by employees after a blood exposure indicate a lack of knowledge about HBV, and also the results of his survey support the need for further education about the risk of occupationally acquired HBV.

Israsena (1992, p. 1807) study, a free of charge vaccination programs against hepatitis B, was offered to 1,299 hospital personnel of Chulalongkorn University Hospital, found that the initial acceptance rate for vaccination was 65.7%, with 10% non-acceptance and 24.3% undecided. The authors found the highest rates of acceptance were among medical students (75.5%), nursing students (68.8%), newly graduated nurses (63.6%), and the lowest rate acceptance was among physicians (48.2%). The authors found that factors strongly associated with the acceptance of vaccination were nature of work, age of personnel (< or = 40 years), number of years spent in profession (< or = 15 years), knowledge of hepatitis B, confidence in vaccine efficacy and safety, no history of hepatitis B infection and contact with blood or blood product. The authors concluded, different types of fear, as well as lack of knowledge, were the main reasons responsible for 46.2% of all results.

Burden and Whorwell (1991) assessed the uptake of hepatitis B vaccine amongst 100 medical and 100 nursing staff in a teaching hospital with a policy of recommending to those at risk that they should seek immunization from their general practitioners (p. 257). The author found 16% of

nurses and 31% of doctors had completed a course of immunization with confirmation of seroconversion. An additional 9% and 18% respectively had been immunized without post-immunization serology. Ninety-three percent of nurses and 61% of doctors who had not been immunized would like to receive the vaccine. The authors found the commonest reasons for non-immunization amongst nurses were fear of vaccine and lack of advice, and among doctors, apathy and difficulty in obtaining the vaccine. Also the study showed 87% of medical staff and 57% of nurses had a history of needle stick injury. The authors found the low rates of vaccine uptake in their study combined with the high incidence of needle stick injury calls for a reappraisal of present hepatitis B vaccination programs in hospitals. Briggs et al (as cited in Briggs & Thomas, 1994, p. 137) report the results of a confidential survey of healthcare staff in a South London District in which unvaccinated staff, who had been afforded vaccination, identified their reasons for not being vaccinated. These included a number of serious misconceptions about hepatitis B vaccination. Over half of these unvaccinated staff considered someone in their position to be at high risk of hepatitis B infections as a result of their occupation. Furthermore, 33% of the 202 fully vaccinated staff was unaware of the need to consider booster vaccinations in the future. The authors conclude that the level of awareness and understanding about hepatitis vaccination of any group of healthcare staff should not be assumed and emphasize the importance of improving staff education.

Briggs and Thomas (1994) found that the reasons given by staff for non-uptake included fear of side-effects or injections, misconceptions about hepatitis B transmission, the alternative use of homeopathic vaccine, pressure of work, difficulties in arranging vaccination, forgetfulness and inertia (p. 145). Of the 54 unvaccinated staff, 55.6% believed themselves to be at high risk of contracting hepatitis B as a result of their occupation; 33% of 200 fully vaccinated staff was unaware of the use of booster doses of vaccine to maintain long-term immunity. In a system that relies on voluntary vaccination, attitude towards immunization of both healthcare personnel and parents are of prime importance. These may be formed in a variety of ways, some apparently paradoxical. In the course of reporting on an EC-sponsored meeting Spier (1999) remarks: "It is ironic that when people are compelled to be vaccinated they take the view that vaccines are important and comply with the regulations; when the vaccines are not so mandated they are more inclined to refuse vaccination as

it is clearly not important (p. 401)." One of the most important ways in which parents make up their minds about the desirability of vaccinating their infants is through discussion with a physician such as a pediatrician or general practitioner. It is therefore important to understand how doctors, as the first link in the chain, make their own decisions about recommending vaccination.

This issue has been addressed in terms of a formal modeling of decision-making for the case of pediatric vaccine recommendations by Pathman et al. (Pathman et al., 1996, p. 25). This model considers the formation of attitudes as comprised of four sequential steps: Awareness, leading to; agreement, motivating; adoption, reinforced by; adherence over time. The validity of this model was tested through a survey questionnaire sent out in late 1993 which was answered by 1,421 pediatricians and family physicians (49% vs. 51%) in nine US states, which asked for their attitudes to each of four currently recommended infant vaccinations: Haemophilus influenza type b (Hib), measles, hepatitis B and cellular pertussis. Virtually all of the physicians surveyed (98.4%) had heard of the recommendation for universal hepatitis B vaccination. However, only 70.3% agreed with it, with 12.7% being opposed and 17.0% unsure of its appropriateness. Unexpectedly, a higher percentage had implemented the recommendation (77.7%) than agreed with it, which would appear to violate the requirement of the awareness-to-adherence model proposed, in which each step must be passed in turn for compliance with a guideline to be reached.

This anomaly is explained by substantial minority of those who were uncertain about the guideline having nevertheless implemented it. As would be expected from the model, adoption was highest (94.4%) amongst those who agreed with the recommendation, lower (44.2%) amongst those unsure, and lowest (24%) amongst those who were opposed to it. Finally, only 30.1% of those surveyed had taken the last step and adhered to the recommendation in the long term (defined as 90% or more of children under their care having received three hepatitis B vaccine doses before 18 months of age). Family physicians were found by regression analysis to be less likely to attain each of the steps for hepatitis B vaccination than pediatricians. Also, physicians caring for more than 10% of uninsured patients were less likely to agree with and adhere to this guideline. In multivariate analysis it emerged that physicians who relied on their colleagues for vaccine information were more likely to be aware of and/or agree with the hepatitis B guideline than

those who relied on official sources of vaccine information. However, those relying on the CDC for information reported higher adherence rates than others, once they had adopted the recommendation.

The environmental factors that influence a physician's readiness to implement pediatric vaccination recommendations include sociocultural influences, such as previous history of epidemics, local community/school policies regarding vaccination and demands from parents. They also include professional and organizational determinants such as physician characteristics (age and training), practice characteristics (single vs. group, access to medical peers and thought leaders, adoption of formal quality assurance practices, delegation to nurses and aids etc) and practice management policies (which in turn are increasingly influenced by legal, insurance and pay or requirements, as well as state or local regulations).

The information characteristics that influence adoption are also complex and multi-factorial. The degree to which adopting the recommendation will improve care, the complexity of putting it into practice, and the compatibility with existing practices, values and needs are "classical" factors identified with innovation theory, but the various dissemination factors (including the choice of channel and credibility of information source) are less well researched. Perhaps the most important feature of this model of attitude formation is that it allows analysis of a variety of influencing factors (as just discussed) and suggests definite steps that could be taken in order to increase adherence to the guideline (e.g. target efforts towards family physicians, encourage physician-to-physician dialogue). Its disadvantage is that to generate comparable data in other situations requires carrying out large surveys, which is expensive and demanding of resources and organizational effort (Freed, 1998, p. 234). Nevertheless, it offers a conceptual framework that may be useful when considering how to introduce future changes and additions to vaccine guidelines.

Given their importance as "gatekeepers" for vaccination access, physicians' attitudes towards immunization guidelines are especially important. Freed et al (1996) have published further information on this derived from the nine-state study referred to the above (p. 587). Several significant differences were found between the attitudes of pediatricians and family physicians. Pediatricians were found to be more likely than family physicians to claim to know a lot about the universal hepatitis B vaccination recommendation (95% vs. 84%), to agree with the recommendation (83% vs. 57%)

and to have adopted it themselves (90% vs. 64%). Those in solo practice were less likely to have adopted it, and members of the American Academy of Pediatrics (AAP) were more likely to have adopted it than others, although differences were not very large (85% vs. 96% in the first case, and 93% vs. 84% in the second, both differences significant). By contrast, for family physicians, adoption was not significantly more likely amongst those who belonged to the American Academy of Family Physicians (AAFP).

Family physicians were less likely than pediatricians to report that parents knew about the recommendation (20% vs. 37%), or that they requested hepatitis B vaccination (13% vs. 23%), and were more likely to report that parents resisted the recommendation (14% vs. 9%). More of them also reported that parents and office staff objected to the number of injections required in a single office visit (34% and 23% respectively, vs. 22% and 12% for pediatricians).

Perhaps surprisingly, there was little difference between the percentages of family physicians (90%) that had themselves completed hepatitis B vaccination as compared with pediatricians (87%). Those who had done so were more likely (64% vs. 45%) to have adopted the universal infant vaccination recommendation, although no more likely to agree with it.

The picture emerging from this study is of a differentiation between the attitudes of pediatricians and family physicians; with family physicians holding more negative attitudes both towards the recommendations themselves and the way that they believed that parents viewed them. Both showed high levels of awareness, but family physicians were notably more skeptical of the recommendations' correctness and desirability. The study provided no independent measure of the correctness of family physicians' view that the parents they saw were more likely to be negative towards the recommendations than was reported by pediatricians. Another study (Wood, D. 1995, p. 769) carried out a few months earlier in one of the states (California) included in the Freed's survey provided findings that were in good agreement with these results. Responses by 526 pediatricians (all members of the AAP) to a questionnaire about knowledge, attitudes and practices regarding universal infant hepatitis B vaccination showed similar levels of awareness and agreement to those found by Freed et al. Agreement with the recommendations was the single factor most likely to predict their adoption (odd ratio 9.1). Pediatricians who practiced in an HMO setting or had a high proportion of low-income patients were also found to be more likely to

have implemented the recommendations for universal vaccination. By contrast, those who relied on medical journals for their information about immunization were less likely to have done so than pediatricians who received information put out by the CDC or AAP. Readership of the CDC's publication *Morbidity and Mortality Weekly Report* (MMWR) was, however, much more restricted than that of the AAP's newsletter, which was taken by about 50% of respondents. The most frequently cited reasons the study found for not having adopted the recommendation were doubts about the long-term efficacy of the vaccine, concerns about its cost, and reservations about giving infants multiple injections at a single visit. Two years later, Zimmerman and Mielkowski (1998) conducted another attitude survey (of family physicians, pediatricians and general practitioners) that also found pediatricians to be more likely to rate hepatitis B vaccination to be important than general or family practitioners (p. 373).

In the report of an earlier study (into the speed of adoption of DTP-Hib vaccine) Freed et al (1997) identified some of the distinction between pediatricians and family practitioners that may lie behind their differences in attitude (p. 27). They suggested that pediatricians; order vaccine supplies more often than family practitioners, are primary targets of marketing campaigns by vaccine manufacturers, and have a more narrowly focused practice, making them more likely to be "innovators" or early-adopters in vaccination practice.

Obstetricians are another specialty who may play an important role in education (future) parents about the importance of hepatitis B vaccination, and their attitudes were surveyed in 1994 by Zola et al (1997, p. 61). Among obstetric providers in the San Francisco area (65% in private practice), 79% believed that hepatitis B vaccine should be administered to all infants at birth, and 92% held that it was feasible to educate all their pregnant patients about this. However, only 53% actually provided such education to all of their patients, and only 23% provided education about other routine childhood vaccinations. Reasons for implementation falling below aspirations included the absence of suitable educational materials, lack of time, and lack (in some private practices) of a well-developed or standardized system of prenatal education. For neonatal vaccination, attitudes of staff in hospitals are also a key determinant of vaccine uptake. Hurie et al (1995) surveyed 116 hospitals of all sizes, types and locations in Wisconsin in September 1993, to determine the extent to which they had implemented the 1991/92 ACIP/AAP/AAFP

recommendations for universal hepatitis B vaccination, which allow for vaccination immediately after birth, and to discover what factors influenced their practices (p. 63). The study found, paradoxically, that the region of the state with the lowest prevalence rate for hepatitis B cases had the highest proportion of hospitals offering vaccination at birth. It was suggested that this might be because one of the regional medical centers had pioneered universal infant vaccination at an early stage, acting as a model for other hospital in the region, and several of the region's public health departments had made concerted and coordinated efforts to promote universal vaccination, both to doctors and parents. Nevertheless, the most common reason given by hospitals for not having implemented universal vaccination was the perception that it was unnecessary for infants living in low-risk areas.

Physician attitudes may influence not only acceptance/rejection of specific immunization but also whether it is given in a timely and complete fashion. Person et al (1997) found, in a retrospective cohort study of infants registered at early childhood centers in East Sydney that a significant number of infants had had scheduled vaccinations fragmented into two visits, at the suggestion of the general practitioner (p. 735). Thus, only 29% of infants had received their third hepatitis B and DTP vaccine doses at the same visit, as recommended. Such splitting of vaccinations was likely to lead to delayed or even missed doses of vaccine, and it may be hypothesized that it was motivated at least in part by doctors' attitudes towards giving multiple injections on the same occasion. Some evidence supporting this was found by Bartlett et al (1999), also from the Sydney area, who found that parents were more likely than doctors (54% vs. 28%) to favor multiple injections at a single visit, although they were likely to accept a particular regimen if this was recommended by the doctor (p. 523). Further evidence for the importance of physicians' attitudes is provided by an earlier study by Wood, K. (1995) conducted in the area of Rochester, NY where 60% of practicing physicians (70% pediatricians) said that they would be very concerned at giving three injections to an infant (especially under 3 months of age), whereas only 45% of parents would be very concerned at this, if the doctor recommended it (p. 845). Physicians' concerns centered on the painfulness of multiple injections, followed by doubts about the possibility of increased side effects or reduced immunogenicity, and lastly by fears that the experience would impact negatively on the likelihood of patients returning to complete the vaccination series, or fears about the reactions of office staff.

Continuity of care and other organizational factors may also play a part in affecting vaccine coverage. Thus, Wallis and Boxall (1999) reported that only 34% of babies born to hepatitis B positive mothers completed their vaccination schedule if the responsible practitioner changed during the period, as compared with 66% where the same doctor had been involved throughout (p. 1112). Further, Freed et al (1995) have described the likely adverse effects on vaccination coverage expected to follow from government actions to transfer responsibility for infant vaccination away from specially trained public health nurses operating in government-funded neighborhood clinics in Israel to privately financed sick funds who lacked appropriately trained staff (p. 1909). Given the importance of healthcare workers', especially doctors', attitudes for public acceptance of hepatitis B vaccination, it is of interest to know to what extent they adopt recommended practice for themselves and a number of studies have addressed this issue, while attempting also to elucidate the factors that affect their decision-making.

Doebbeling et al (1996) surveyed a stratified random sample of healthcare workers at the University of Iowa hospital in 1992 to see what factors influenced their likelihood of accepting vaccination against hepatitis B (p. 59). At the time of the survey, vaccination of hospital staff was voluntary and it was found that only 54% of those surveyed had completed the three-dose vaccination series, although 70% had received one or more doses. The same figure (54% vaccinated) was found in a 1989 survey of staff at an unnamed (California) university medical center by Murata et al (1993, p. 163). Doebbeling (1996) reported that among those remaining unimmunized, concern about vaccine side-effects, knowledge about the disease and occupational risk, and access to vaccination were the major factors associated with non-uptake (p. 69). Social influence (by peers, supervisors, role models, friends, spouses), conversely, was the main factor associated with vaccine acceptance, although perception of risk and disease knowledge were also important. Murata et al (1993) had earlier shown that younger doctors (either in training or at an early career stage) were more likely to be vaccinated than older ones (p. 167), and this was confirmed for the physicians in Doebbeling's (1996) study (which did not include a significant number of medical students). As part of a more general survey of attitudes towards self-protective precautions amongst nurses and physicians at five St Louis hospitals, Jeffe et al (1997) noted that 85% overall were already effectively vaccinated against hepatitis B (p. 710). In

the case of the doctors, this was almost certainly because they were vaccinated during their time as medical students or house staff.

Reliance on this vaccination during training may, however, engender a false sense of security, Oates et al (1993) pointed out that two years after being vaccinated 38% of students at a UK medical school had failed to request measurement of their antibody levels (in this student series, only 77% had achieved levels of >100 IU/ml) suggesting that many were unaware of the risk of vaccine failure, and 36% believed that the immunity conferred would be life-long (p. 301). Also in the UK, a study of surgeons at a leading London teaching hospital (Smith, 1996) four years later found that only 59% had proven vaccine-induced immunity, despite their frequent exposure to needle-stick injuries (p. 447).

Llewellyn and Harvey (1994) investigated hospital medical staff at three sites in South Wales in 1993 and found a 71% overall uptake of hepatitis B vaccination, although only 27% had completed the full three doses (p. 352). In agreement with other studies, junior doctors were found to have much the highest percentage of completed vaccination, and this figure declined with seniority. It was suggested that this was partly due to the more experienced doctors more frequently having a perception that they were at low risk (even though this perception was incorrect). A somewhat similar misperception of risk was reported in an earlier survey of GPs in Nottinghamshire by Wood (1989) with practice principals much more likely than trainee doctors to respond that they did not feel it worth getting vaccinated (p. 1066). A similar survey at about the same time (Kinnersley, 1990, p. 238) in Lancashire found that the reason "I have just not got round to it" was the most common. Detailed studies of the reasons for non-compliance among other healthcare staff are not abundant. In the UK, Briggs and Thomas (1994) undertook such a survey in 1990 in South London health district, distributing questionnaires to permanent staff in selected "high risk" occupational groups, finding that at that time only 67% were fully vaccinated (p. 144). Of the 18% of the sample who had not received any vaccination, a variety of reasons were given for non-uptake, including "not needed", fears of side-effects or injections, and use of homeopathic 'vaccine'. Of those who were planning to be vaccinated but had not yet started, "pressure of work" was by far the most frequent reason given for not having started, along with "appointment times not convenient" and "uncertain who to arrange vaccination with." By contrast, a survey of dentists practicing in Maryland (Grace, 1991, p.

197) revealed that those who had not been vaccinated most often voiced concerns about vaccine safety, or believed that they were at low risk, or wanted more information before accepting vaccination.

Lin and Ball (1997) surveyed attitudes towards HBV immunization amongst nurses in Taiwan (selected not to be HBsAg carriers). Although this country has a relatively high rate of chronic HBsAg carriage, vaccination rates amongst healthcare workers at high risk of infection (nurses, dental and medical staff) are low, and annual rates of infection of hospital staff are high. Fear of pain from repeated injections, time needed and cost of vaccination and concerns about efficacy of the vaccine were identified as being the major factors influencing nurses' decisions about hepatitis B vaccination (p. 709). The lowest vaccination rate was found amongst the most experienced nurses and the authors suggest that a specific intervention programme targeted at this group is needed in order to improve vaccine uptake.

The activities of the mass media (TV and newspapers) and anti-vaccination groups have a major influence in feeding vaccine "scares" that undermine confidence in vaccine safety, and this is not restricted to the case of hepatitis B vaccination. Publication of a report by Wakefield et al (1998) on a possible association between MMR vaccination and the development of chronic bowel disorder and behavioral abnormalities (autism) was also given widespread publicity and has resulted in a significant downturn in vaccine coverage in the UK (p. 637).

Careful qualifications of this type, appropriate in scientific publications, are not always included in the "punchier" reports that appear in the mass media. Hence, an allegation may end up being spread in a stronger form than its original proposes intended given the available data (Bradbury, 199, p. 655).

Linder et al (1999) reporting their suspicion of a possible association between unexplained neonatal fever and hepatitis B vaccination on the first day of life "The increase in the number of cases of unexplained neonatal fever seems to be associated with the introduction of routine hepatitis B vaccination on the first day of life(p. 206). The possibility that an excess number of neonates will undergo unnecessary procedures and treatment to diagnose unexplained fever justifies planning a controlled study to determine whether these preliminary findings point to a significant problem." Those reporting a possible problem with vaccination may not themselves hold negative views about the value of

vaccination in general, but may be seeking to act as "whistle-blower" to prevent future damage to individuals. This is, of course, a manifestation of the second ethical imperative-the "duty of beneficence". Such investigators may also be sensitive to the possibility that their reports may be taken "out of context" and may choose to employ non-sensational language in formulating their arguments.

### CHAPTER 3 - METHODOLOGY FRAMEWORK

The Health Belief Model (HBM) was formulated in the early 1950's by a group of social psychologist at the U.S. Public Health Service in an effort to provide a framework for analyzing why some people who are illness free take actions to avoid illness, while others fail to take such protective actions (Rosenstock, 1988, p. 175).

Although the model evolved gradually in response to very practical programmatic concerns that will be described presently, its basis in psychological theory and provided as an aid to understanding its rationale as well as its strengths and weaknesses (Carmel, 1990, p 74). Many investigations have helped expand and clarify the Health Belief Model and extended it beyond screening behaviors to include all preventive actions, illness behaviors and sick-role behavior.

In general, it is believed that individuals will take action to ward off, to screen for, or to control ill-health condition if they regard themselves as susceptible to the condition, if they believe it to have potentially serious consequences, if they believe that a course of action available to them would be beneficial in reducing either their susceptibility to or the severity of the condition, and if they believe that the anticipated barriers taking the action are out weighed by its benefits (Glans, 1990, p. 220).

It is an appropriate model for this study of motivation to accept HB vaccine, as it was designed to explain or predict health protecting or preventive behavior. It has been applied mainly in situations where the behavior in question is purely voluntary and the individuals studied do not believe themselves to have dysfunctional systems.

The authors of the model suggest that health care providers need to learn that; behavior is motivated, certain beliefs seem central to a client's decision to act; not all persons process these beliefs and motives to equal degrees; and intellectual information, while necessary, is often not sufficient to stimulate needed beliefs (Becker, 1974, p.21; Glans, 1990, p. 215).

### VARIABLES OF HEALTH BELIEF MODEL

**Perceived Susceptibility.** The dimension of perceived susceptibility refers to one's subjective perception of the risk of contracting a health condition. In the case of medically established illness, the dimension has been reformulated to include acceptance of the diagnosis, personal estimates of re-susceptibility and susceptibility to illness in general.

**Perceived Severity.** Feelings concerning the seriousness of contracting an illness or of leaving it untreated include evaluations of both medical and clinical consequences (example: death, disability and pain) and possible social consequences (such as effects of the conditions on work, family life and social relations). Many investigators have found it useful to label the combination of susceptibility and severity as a perceived threat (Carmel, 1990, p. 75).

**Perceived Benefits.** While acceptance of personal susceptibility to a condition also believed to be serious (perceived threat) it is held to produce a force leading to behavior, it does not define the particular course of action that is likely to be taken. This is hypothesized to depend upon beliefs regarding the effectiveness of the various available actions in reducing the disease threat, or the perceived benefits of taking health action. Thus, an individual exhibiting an optimal level of beliefs in susceptibility and severity would not be expected to accept any recommended health action unless that action was perceived as feasible and efficacious.

**Perceived Barriers.** The potential negative aspects of a particular health action, or perceived barriers, may act as impediments to undertaking the recommended behavior. A kind of unconscious, cost-benefit analysis is thought to occur wherein the individual weighs an action's effectiveness against perceptions that it may be expensive, dangerous (having negative side effects or intragenic outcomes), unpleasant (painful, difficult, upsetting), inconvenient, time-consuming and so forth. Thus, the combined levels of susceptibility and severity provided the energy or force the act and the perception of benefits "less barriers" provided a preferred path of action (Glans, 1990, p. 217).

**Readiness to Engage in Health Behavior.** The outcome of a person's perceived susceptibility to a serious health threat and a person's perceived benefits of taking action to reduce the threat.

**Other Variables.** It is believed that diverse demographic, sociopsychological, and structural variables may, in any

given instance, affect the individual's perception and thus indirectly influence health related behavior. Specifically, sociodemographic factors, particularly educational attainment, are believed to have an indirect effect on behavior by influencing the perception of susceptibility, severity, benefits and barriers.

### STUDY DESIGN

This study is cross sectional in design. The value of the independent variables of perceived threat (perceived susceptibility plus perceived severity) and knowledge level were measured to predict the value of the dependent variable, motivation to accept hepatitis B vaccine. The study is based on the elements of the health belief model framework (Becker, 1974, p. 53) and originated specifically for this research to illustrate that the independent variables were analyzed to determine their direct and indirect effects on the outcome.

The outcome this research is "health action taken", as opposed to Becker's "likelihood of action", and is defined as acceptance of the hepatitis B vaccine and, therefore, evidence of positive motivation.

In the Health Belief Model, demographic factors and knowledge level about the disease are modifying factors. They indirectly affect the likelihood of action by influencing perceived susceptibility to and perceived severity of a disease, as well as the perceived benefits of preventive action minus the perceived barriers (Becker, 1974, p. 53). This research measured the indirect and direct effects of demographic factors and knowledge on health actions. Endogenous factors are the equivalent to "individual perceptions" in the HBM. This refers to the individuals' perceptions of their own susceptibility to HBV, and may directly influence the likelihood of action (Becker, 1974, p. 53). However, the variables of "barriers and safety" are depicted as endogenous also. For example, regardless how high an individual's level of knowledge, perceived susceptibility and perceived severity, if the preventive action is considered too risky or if barriers exist, this will block the avenue toward positive health action (motivation).

This study is cross sectional in design, utilizing a self administered survey questionnaire. This study was designed to find frequencies, percentages and relationship of information. It was designed with the goal of finding the sample's knowledge base, acceptance responses, and the relationship between knowledge and acceptance of hepatitis B vaccine among health care workers. The method of data



collection utilized in this study was the Hepatitis B Vaccine Knowledge and Acceptance Questionnaire developed by the writer, (as shown in appendix A).

### **SAMPLE**

The study population was health care workers (hospitals and nursing homes) in Miami Dade County, Florida, USA. A simple random sample was selected by using a procedure that gives every hospital and nursing home in Miami-Dade a known, nonzero and equal chance of being included in the sample. So, before the sample was drawn, every element in the sampling frame the researcher assigned a unique identifying number, and then all numbers placed in a container and mixed together, after that the researcher draw out one hospital and three nursing homes. The following hospitals and nursing homes were included in the lottery process; Avetura Hospital and Medical Center, Baptist Hospital, Bascom Palmer Eye Institute, Cedars Medical Center, Community Health Inc., Coral Gables Hospital, Health South Doctors, Hialeah Hospital, Highland Park Pavilion, Homestead Hospital, Jackson Memorial Hospital, Jackson North Maternity Center, Jackson South community Hospital, Kendall Medical Center, Larkin Community Hospital, Mercy Hospital, Miami Children's Hospital, Miami Heart Institute, Mount Sinai Medical Center, North Shore Medical Center, Palmetto General Hospital, Palms Springs General Hospital, Pan American Hospital, Parkway Regional Medical Center, South Miami Hospital, South Shore Hospital, Southern Winds Hospital, University of Miami Hospital, Vencor Hospital, Veterans Administration Hospital, Westchester General Hospital, Windmoor Healthcare Hospital. Arch Plaza Nursing Home, Berkshire Manor, Brookwood Gardens

Convalescent Center, Claridge House, Coral Gables Convalescent Center Coral Reef Nursing and Rehabilitation, East Ridge Retirement Village, Epworth Village, Fair Haven Center, Florida Club Care Center, Floridean Convalescent Center, Fountainhead Nursing Home, Franco Nursing and Rehab, Gramercy Park Nursing Center, Greynolds Park Manor, Hampton Court Nursing and Rehab, Health South Rehab Center, Heartland Health Care Center of Kendall, Heartland Health Care Center of Miami Lakes, Hebrew Home of Miami Beach, Hebrew Home of North Miami, Heritage Nursing, Hialeah Convalescent Home, Hialeah Shares Nursing and Rehabilitation Center, Homestead Manor and Salem Nursing Home, Human Resources Health Center, I.H.S. at Greenbriar, Jackson Heights Rehabilitation Center, Jackson Plaza, Miami Gardens Care Center, Miami

Jewish Home and Hospital, Miami Shares Nursing and Rehabilitation Center, Mount Sinai-St. Francis Nursing and Rehabilitation Center, New Riviera Health Resort, Nightingale

Gardens, Nursing Center at Mercy, Oceanside Extended Care, Palace at Kendall Nursing and Rehabilitation, Palace Gardens, Palm Garden, Palmetto Health Center, Palmetto Sub-Acute Care Center, Purdue Medical Center, Pinecrest Convalescent Center, Pine Nursing Home, Plaza Nursing Rehabilitation Center, Ponce Plaza Nursing and Rehab, Regents Park at Aventura, Riverside Care Center, St. Anne's Nursing Center, Sun Bridge Care Rehabilitation Center, Susanna Wesley Health Center, The Grand Court North, The Grand Court South,, Treasure Isle Care Center, Villa Maria Nursing and Rehabilitation Center, Victoria Nursing and Rehabilitation, Water Crest Care Center, Waterford Convalescent Center and West Gables Health Care Center.

The following healthcare facilities are included in this study; Larkin Community Hospital, 7031 S.W. 62<sup>nd</sup> Ave. South Miami, Florida; Fair Haven Center, 201 Curtis Parkway, Miami Springs, Florida; Mercy Nursing Home, 3671 S. Miami Ave. Miami, Fl. 33133 ; and Oceanside Extended Care, 550 9<sup>th</sup> St. Miami Beach, Florida. This study was included the health care workers who are currently working at Larkin Community Hospital, Fair Haven Center, Mercy Nursing Home and Oceanside Extended Care. Healthcare workers include; medical doctors, nurses, pharmacists, and lab. tech., and others. The study was conducted on October 23<sup>rd</sup> 2003. The questionnaires were administered by the writer and the department managers in each unit in the healthcare facilities. 260 employees out of the total sample accepted to participate in the study and returned the questionnaires to the writer.

### **DATA COLLECTION INSTRUMENT**

Given the lack of research involving knowledge and acceptance to Hepatitis B Vaccine among health care workers, a relevant tool for data collection was available. After determining what information was needed for this study, a questionnaire was developed, referred to as the Hepatitis B Vaccine Knowledge and Acceptance Questionnaire (Appendix A).

The questionnaire contains 44 multiple choice and open ended questions that measures the extent of knowledge, perceived susceptibility, perceived severity, and also perceived barriers and acceptance of hepatitis B vaccine of those health care workers regarding hepatitis B vaccine.

The demographic information collected includes the health care workers' gender, race, age, education, marital status, income, religion, healthcare facility units and healthcare workers experience. The demographic questions for the sample were placed at the beginning of the questionnaire. The rationale for this placement was to attempt to attain accurate background information. The demographic data was used to assist in developing an accurate description of the characteristics of the sample and in turn, this information will also aid in identifying the sample for potential replication studies.

The questionnaire was designed to elicit the respondent's knowledge and acceptance to hepatitis B vaccine. The study was explained in a cover letter indicated that completion and return of the questionnaire would constitute consent. The questionnaire's validity was tested in one pilot study. This was a test for peer evaluation of the draft questionnaire and for corrections and further revisions. Before the questionnaire was administered to the sample, a pilot study was conducted and tested for inter reliability. The questionnaire was administered to a group of health care workers within the same demographic categories in a similar setting. The progression of questions, amount of clarification needed and time needed to complete the questionnaire was evaluated. In order to help gauge the reliability of the test re-test method was used. The responses to some of the test items were compared between each of the pre-test groups.

### **VARIABLE LIST**

Dependent variable. Acceptance and receiving hepatitis B vaccine.

Independent variable. Barriers (safety and effectiveness); perceived of hepatitis B vaccine. Susceptibility; perceived risk of contracting hepatitis B virus infection. Severity; perceived risk of serious illness after contracting hepatitis B virus infection.

Confounding variable. Demographic; the basic classification variables that characterized an individual. Knowledge; knowledge of hepatitis B virus.

### **PROCEDURE**

A proposal statement, institutional review board for research with human subjects (IRB) submission form, institutional review board for research with human subjects (IRB) research protocol, and institutional review board for research with human subjects (IRB) informed consent for the study were developed and submitted to Dr. Richard David (Dean,

College of Allied Health) and IRB Committee at Nova Southeastern University, 3200 S. University Drive. Fort Lauderdale, Fl. 33328. For approval to use human subjects in research.

After receiving a written approval (via e-mail) from Dr. Davis, the proposal statement was submitted to the owners of the proposed sites. Permission to conduct the study was granted by the Medical Director/Owner of Larkin Community Hospital, and the Owner of Fair Haven Center, Mercy Nursing Home, and Oceanside Extended Care.

On the designated testing day (10/23/03), each health care worker on duty at Larkin Community Hospital, Fair Haven Center, Mercy Nursing Home, and Oceanside Extended Care, was asked if he/she initially agreed to participate in the survey. They were handed the questionnaires and cover letter. The purpose of the study was explained and the healthcare worker was allowed to decline if he/she did not want to participate. To minimize distractions, the questionnaire was then completed in a private room. Written guidelines were given to the administrators of the questionnaire to assure that each healthcare worker received the same directions and information. After the questionnaire was completed, the healthcare workers deposited the questionnaire in a sealed envelop in the collection box to assure anonymity. At the end of the day the collection boxes were emptied by the assistant or investigator and the envelopes were placed in a large manila envelope and labeled with the date and the total number of envelopes. The debriefing process included asking the participants if he/she has any questions regarding hepatitis B virus and hepatitis B vaccine or the questionnaire. All questions were addressed and answered. After the participants completed the questionnaires, the responses were compiled and analyzed.

### **DATA PREPARATION AND ANALYSIS**

Using descriptive statistics, the demographic data was analyzed in terms of frequency distributions, percentages, and cross tabulated with other questionnaire data. The respondents'

knowledge, perceived barriers, perceived susceptibility, perceived severity and acceptance were measured by multiple-choice and open ended survey questionnaire. The questionnaire was coded and scored. The questions were divided into categories of those that measure; demographic, knowledge, barriers (safety and effectiveness), susceptibility, severity, and acceptance. The knowledge questions addressed the health care workers' knowledge, transmission

and complication of hepatitis B virus. There were questions investigating the safety and effectiveness of hepatitis B vaccine (perceived barriers) of the sample to determine whether they consider hepatitis B vaccine effective and safe. There were also questions investigating the perceived susceptibility, perceived severity of the sample to determine whether they believe they are under the perceived threat of hepatitis B virus.

The sensitivity of the questions was considered when determining the order of questions on the questionnaire. The least sensitive questions were placed toward the beginning of the instrument and the more sensitive questions toward the end of the questionnaire.

Using descriptive statistics, the data was analyzed in terms of frequency distribution, percentage and cross tabs utilizing the SPSS computer program. Chi-square significance testing and cross tabulations were used to describe the relationship between the variables of acceptance of hepatitis B vaccine and knowledge, perceived threat or perceived barriers (figure 3.1).

### Figure 1

Figure 3.1: The Organization of Findings.

- I. Demographic characteristic of the sample.
- II. Knowledge of hepatitis B virus and hepatitis B vaccine:
  - A. Mode of transmission.
  - B. Nature of hepatitis B vaccine.
  - C. Possibility of clinical infection.
  - D. Complication.
  - E. Prevention of hepatitis B virus.
- III. Knowledge vs. acceptance of hepatitis B vaccine.
- IV. Perceived threat:
  - A. Perceived susceptibility:
    - 1. Risk of getting hepatitis B.
    - 2. Potential seriousness of hepatitis B infection.
    - 3. Frequent contact with blood and/or body fluid.
    - 4. Needle sticks.
    - 5. Splash blood and/or body fluid.
  - B. Perceived susceptibility vs. acceptance of hepatitis B vaccine.
  - C. Perceived severity:
    - 1. Reported needle sticks.
    - 2. Reported splash and/or body fluid.
  - D. Perceived severity vs. acceptance of hepatitis B vaccine.
- V. Perceived barriers: safety and effectiveness of hepatitis B vaccine:
  - A. Get AIDS from hepatitis B vaccine.
  - B. Side effects of hepatitis B vaccine.
  - C. The effectiveness of hepatitis B vaccine.
- VI. Perceived barriers vs. acceptance of hepatitis B vaccine.
- V. Acceptance of hepatitis B vaccine.

## CHAPTER 4 - RESULTS

### DEMOGRAPHIC CHARACTERISTICS OF THE SAMPLE

The demographic data collected in the questionnaire include: gender, race, age, education, marital status, household income, religion, unit of experience and years of experience. Of the study sample, 96.2% (n=250) of the healthcare workers were women and 3.8% (n=10) were men. 59.6% (n=155) of the respondents were Whites, 21.2% (n=55) were Afro-American, 9.6% (n=100) were Asian, 7.7% (n=20) were Hispanic, and 1.9% (n=5) were Indian American. 9.6% (n=25) were under the age of 30 and 90.4% (n=235) were above the age of 30. Nearly two thirds of the healthcare workers held either a diploma or a bachelor's degree, either AA in nursing or in Lab technology or BSN in nursing or BSc in Lab Technology (36.5% and 34.6% respectively), followed by 5.75% with a master degree in nursing, 5.75% with MD degree, 13.5% LPN and 3.8% assistant nurses. 5.8% (n=15) of the subjects were never married, 51.9%

(n=135) were married, 19.2% (n=50) were separated and 23.1% (n=60) were divorced. 1.9% (n=5) of the respondents had an annual household income of less than \$40,000. 80.8% (n=210) had \$40,000 exactly. 3.8% (n=10) more than 40,000 and 13.5% (n=35) didn't know the annual household income last year. 26.9% (n=70) of the respondents were Protestant, 46.2% (n=120) were Catholic and 26.9% (n=70) were Jewish.

1.78% (n=10) of the respondents were working in the emergency room, 1.53% (n=4) were working in the operation room, 1.15% (n=3) were working in the recovery room, 2.30% (n=6) were working in the ICU. 3.8% (n=10) were working in medical surgical floor, 2.6% (n=7) were working in outpatient clinic, 3% (n=8) were working in pediatric floor, 1.92% (n=5) were working in psychiatric unit, 0.76% (n=2) were working health nurses, 1.92% (n=5) were working in laboratory, and 76% (n=200) were working in nursing homes. 28.8% (n=75) of the respondents had less than three years experience and 81.2% (n=185) had more than three years of experience (See Table 4.1).

In attempting to gain a clear understanding of the data collected, a breakdown of the demographics for cross tabulation analysis was done. Each of the demographic categories were collapsed into two groups and labeled appropriately (See Table 4.2).

Acceptance of the hepatitis B vaccine was not affected by gender, race, marital status, income and religion of the healthcare workers in this research. Nor were relationships found between acceptance of the hepatitis B vaccine and type of the unit or floor.

The statistically significant demographic variables in this research include age and experience of the healthcare workers. Age predicted acceptance of the hepatitis B vaccine. The younger healthcare workers were more likely to have been vaccinated. In the analysis of maximum likelihood estimates, chi-square was 7.89 with probability of 0.16220. Experience in healthcare facilities and acceptance of the hepatitis B vaccine were also correlated (chi-square: 5.354, probability: 0.49924). Healthcare workers who had worked more years in healthcare facilities were more likely to have had the hepatitis B vaccine than those with less experience.

**Figure 2**

Table 4.1: Demographic Characteristics

Frequency Distribution and Percentage			
Demographic	Variables	Frequency	Percent
Gender	Male	10	3.80
	Female	250	96.20
Race	White	155	59.60
	Black	55	21.20
	Asian	25	9.60
	Hispanic	20	7.70
	Indian/American	5	1.90
Age in Years	Less than 20	5	1.90
	20-29	20	7.70
	30-39	100	38.50
	40-49	80	30.80
	50-59	40	15.40
	60 or above	15	5.80
Education	Assistant Nurse	10	3.80
	LPN	35	13.50
	RN with a Nursing Diploma	60	23.10
	Lab Technology with Diploma	35	13.50
	RN with a BSN Degree	90	34.60
	Lab Technology with a BSc	000	000
	RN with a Master Degree	15	5.75
	MD	15	5.75
Marital Status	Never Married	15	5.80
	Married	135	51.90
	Separated	50	19.20
	Divorced	60	23.10

**Figure 3**

Demographic	Variables	Frequency	Percent
Income	Less than 40,000	5	1.90
	More than 40,000	210	80.80
	40,000 exactly	10	3.80
	Don't know	35	13.50
Religion	Protestant	70	26.90
	Catholic	120	46.20
	Jewish	70	26.90
Unit of Experience	Emergency Room	10	1.78
	Operation Room	4	1.53
	Recovery Room	3	1.15
	I C U.	6	2.30
	Medical/Surgical	10	3.80
	Outpatient Clinic	7	2.60
	Pediatric	8	3.00
	Psychiatric	5	1.92
	Health Nurse	2	0.76
Nursing Home	200	76.00	
Experience in years	Less than 2	30	11.50
	2-3	45	17.30
	4-5	75	28.80
	6-7	60	23.10
	8-9	20	7.70
	10-11	5	1.90
	12 or more	25	9.60
Total Sample Size (n) = 260			

Figure 4

Table 4.2: Demographic Breakdown for Cross-Tabulation Analysis

Frequency Distribution and Percentage

Demo-graphic	Variable	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Gender	Male	10	3.8	10	3.8
	Female	250	96.2	260	100.0
Race	Non-White	60	23.07	60	23.07
	White	200	76.93	260	100.00
Age	30/Younger	25	9.6	25	9.6
	30 & Older	235	90.4	260	100.0
Education	Not RN	110	42.3	110	42.3
	RN	150	57.7	260	100.0
Marital Status	Not Married	125	48.07	125	48.07
	Married	135	51.93	260	100.00
Income	< \$40,000	15	5.76	15	5.76
	> \$40,000	245	94.24	260	100.00
Religion	Jewish	70	26.92	70	26.92
	Catholic	190	73.08	260	100.00
Unit of Experience	Unit Floor/Ng	50	19.23	50	19.23
	Home	210	80.77	260	100.00
Years of Experience	< 4 years	75	28.85	75	28.85
	> 4 years	185	71.15	260	100.00

Frequency Missing = 0                      Total Sample Size (n) = 260

**KNOWLEDGE OF HEPATITIS B VIRUS AND HEPATITIS B VACCINE**

The participants were asked questions relating to hepatitis B vaccine and hepatitis B infection, mode of transmission, nature of hepatitis B vaccine, possibility of subclinical infection, complication of hepatitis B virus, and prevention of hepatitis B virus.

Mode of Transmission. The questionnaire included three questions about the mode of transmission of hepatitis B virus, each question included answers beginning with always, usually, sometimes, never and not sure (See Table 4.3).

Figure 5

Table 4.3: Knowledge of Transmission of Hepatitis B Virus

Frequency Distribution and Percentage

Question	Answers	Frequency	Percent	Cumulative Percent
3.1 Hepatitis B can be caught through casual contact:	Always	45	17.3	17.3
	Usually	35	13.5	30.8
	Sometimes	30	11.5	42.3
	Never	130	50.0	92.3
	Not Sure	20	7.7	100.0
3.2 Hepatitis B can be passed from the mother to the baby at birth:	Always	55	21.2	21.2
	Usually	65	25.0	46.2
	Sometimes	110	42.3	88.5
	Never	15	5.8	94.2
	Not Sure	15	5.8	100.0
3.3 It is possible to get hepatitis B from eating shell fish:	Always	15	5.8	5.8
	Usually	20	7.7	13.5
	Sometimes	25	9.6	23.1
	Never	160	61.5	84.6
	Not Sure	40	15.4	100.0

Missing = 0                      Total Sample Size (n) = 260

Nature of hepatitis B vaccine. When I asked the respondents the following question: Is hepatitis B vaccine made from human blood? One fourth (26.9%) of them correctly identified the answer. While, 7.7% answered hepatitis B vaccine is always made from human blood (See Table 4.4).

Figure 6

Table 4.4: Knowledge: Nature of Hepatitis B Vaccine

Frequency Distribution and Percentage

Question	Answers	Frequency	Percent	Cumulative Percent
4.1 Is Hepatitis B vaccine made from human blood?	Always	20	7.7	7.7
	Usually	20	7.7	15.4
	Sometimes	30	11.5	26.9
	Never	155	59.6	86.5
	Not Sure	35	13.5	100.0

Missing = 0                      Total Sample Size (n) = 260

Possibility of clinical infection. When I asked if there are people who are carriers of hepatitis B that are not sick but may pass the disease to others? One fourth (25%) of the respondents correctly identified the answer (See Table 4.5)

Figure 7

Table 4.5: Knowledge: Possibility of Clinical Infection

Frequency Distribution and Percentage

Question	Answers	Frequency	Percent	Cumulative Percent
5.1 Carriers of Hepatitis B may pass the disease to others.	Always	65	25.0	25.0
	Usually	35	13.5	38.5
	Sometimes	90	34.5	73.1
	Never	40	15.4	88.5
	Not Sure	30	11.5	100.0

Missing = 0 Total Sample Size (n) = 260

Complication. When asked if the hepatitis B virus can cause liver cancer? One-tenth (9.6%) of the respondents correctly identified the answer, while 32.7% of the respondents did not know the answer (See Table 4.6).

Figure 8

Table 4.6: Knowledge: Complication of Hepatitis B virus

Frequency Distribution and Percentage

Question	Answers	Frequency	Percent	Cumulative Percent
6.1 Is hepatitis B virus the cause of the liver cancer?	Always	25	9.6	9.6
	Usually	30	11.5	21.2
	Sometimes	95	36.5	57.7
	Never	25	9.6	67.3
	Not Sure	85	32.7	100.0

Missing = 0 Total Sample Size (n) = 260

Prevention of Hepatitis B Virus. When asked if skin without rashes or cuts or open areas will keep you from getting hepatitis B virus, 7.7% of the respondents correctly identified the answer (See Table 4.7).

Figure 9

Table 4.7 : Knowledge: Prevention of Hepatitis B Virus

Frequency Distribution and Percentage

Question	Answers	Frequency	Percent	Cumulative Percent
6.1 Skin without rashes or cuts or open areas will keep you from getting Hepatitis B Virus.	Always	20	7.7	7.7
	Usually	35	13.5	21.2
	Sometimes	100	38.5	59.6
	Never	70	26.9	86.5
	Not Sure	35	13.5	100.0

Missing = 0 Total Sample Size (n) = 260

**KNOWLEDGE VS. ACCEPTANCE OF HEPATITIS B VACCINE**

In attempting to examine the relationship of healthcare workers' knowledge of hepatitis B infection and healthcare

workers' acceptance of hepatitis B vaccine, a cross tabulation comparing responses by variables was performed. The responses to the knowledge and acceptance questions were cross tabulated and many significant results were discovered. Cross tabulations were done using the responses always and never with the acceptance of the hepatitis B vaccine. The responses of always, usually and sometimes were collapsed into one group for cross tabulation. The author found that there was a significant relationship between modes of transmission, complication of hepatitis B virus and acceptance of hepatitis B vaccine. 210 out of 230 subjects who received hepatitis B vaccine correctly identified the answer, while 10 out of 30 subjects who did not receive the vaccine did not identify the answer (See Table 4.8).

Figure 10

Table 4.8 : Knowledge vs. Acceptance of HB Vaccine

Significant cross tabs relating the acceptance of hepatitis B vaccine toward the knowledge of HBV.

Question	Always/Usually/Sometimes			Never/Not Sure	
	Yes	#	%	#	%
8.1 Hepatitis B can be passed from the mother to the baby at birth.	Yes	210	91.3	20	66.7
	No	20	8.7	10	33.3
N = 260 Chi Square = 3.156 (P = 0.0756) Missing = 0					
Question	Always/Usually/Sometimes			Never/Not Sure	
	Yes	#	%	#	%
8.2 The hepatitis B virus can cause liver cancer.	Yes	140	96.6	90	78.3
	No	5	3.4	25	21.7
N = 260 Chi Square = 4.204 (P = 0.0403) Missing = 0					

**PERCEIVED THREAT**

Perceived Susceptibility. The perceived susceptibility of the respondents regarding hepatitis B virus were measured in five areas; risk of getting hepatitis B, potential seriousness of hepatitis B infection, frequent contact with blood and/or body fluids, needle sticks and splash blood and/or body fluid.

Risk of Getting Hepatitis B. The majority (88.5%) of the sample indicated that they consider themselves as very high and somewhat high of risk of getting hepatitis B virus (See Table 4.9.1).

Potential Seriousness of Hepatitis B Infection. Almost three-quarters (73.1%) of the respondents said that they considered themselves for potential seriousness of hepatitis B infection

very serious and serious. Whereas, 25% of the sample considered themselves as a minor and very minor (See Table 4.9.2).

**Frequent Contact with Blood and/or Body Fluid.** 35% of the respondents indicated that they had more than five times per day contact with blood and/or body fluid in their jobs, on the other hand, 55.8% of the respondents said that they have less than five times a day contact with blood and/or body fluid (See Table 4.9.3).

**Needle Sticks.** The majority (52%) of the sample indicated that they acquired more than one time needle sticks in the past, while, 48% of the respondents indicated that they did not have any needle sticks or they were not sure (See Table 4.9.4).

**Splash Blood and/or Body Fluid.** Less than half (46.1%) of the sample indicated that they had at least one time splash blood or body fluid into their mouth, eye, nose, while 53.9% of the sample did not have any splash or they were not sure (See Table 4.9.5).

**Perceived Susceptibility vs. Acceptance of Hepatitis B Vaccine.** In attempting to examine the relationship of perceived susceptibility of healthcare workers to hepatitis B virus and acceptance of hepatitis B vaccine, across tabulation comparing responses by variable was performed. The responses to the perceived susceptibility and acceptance questions were tabulated and many significant results were discovered.

Cross tabulation was done using the respondents “risk” to hepatitis B virus, serious of hepatitis B infection, number of needle sticks that have been acquired in the past, numbers of blood splash in the past year with acceptance of hepatitis B vaccine. The responses of very high risk, some risk and low risk to hepatitis B were collapsed into one group for cross tabulation. The responses of very serious and serious of hepatitis B infection were collapsed into one group for cross tabulation. The responses of 10 or more, 5 or more but less than 10, 2 or more, but less than 5 and less than 2 were collapsed into one group for cross tabulation. The author found in his study that there was a significant relationship between the components of perceived susceptibility (risk of getting hepatitis B, potential seriousness of hepatitis B infection, splash blood and/or body fluid) and acceptance of hepatitis B vaccine among healthcare workers (See Table 4.10).

**Figure 11**  
Table 4.9 : Perceived Susceptibility

Frequency Distribution and Percentage

Question	Response	Frequency	Percent
9.1 Do you consider yourself at risk of getting hepatitis B through your job?	Very high risk	100	38.5
	Somewhat of risk	130	50.0
	Low risk	15	5.8
	No risk	10	3.8
	Not sure	5	1.9
9.2 Potential seriousness of hepatitis B infection for yourself considered.	Very serious	85	32.7
	Serious	105	40.4
	Minor	60	23.1
	Very minor	5	1.9
	Not sure	5	1.9
9.3 I have frequent contact with blood and/or body fluid in my job.	More than 10 times a day	70	26.9
	More than 5, but less than 10	25	9.6
	More than 2, but less than 5	145	55.8
	No contact at all	20	7.7
9.4 To the best of your knowledge how many needle sticks have you acquired in the past.	10 or more	10	3.8
	5 or more, but less than 10	20	7.7
	2 or more, but less than 5	40	15.4
	Less than 2	65	25.0
	None	95	36.5
	Not sure	30	11.5

**Figure 12**

Frequency Distribution and Percentage

Question	Response	Frequency	Percent
9.5 How many times in the past year did you splash blood or body fluid into your mouth, eyes or got blood on unprotected skin with cuts or rashes?	10 or more	15	5.8
	5 or more, but less than 10	5	1.9
	2 or more, but less than 5	15	5.8
	Less than 2	85	32.7
	None	85	32.7
	Not sure	55	21.2

Missing = 0

Total Sample Size (n) = 260

**Figure 13**

Table 4.10: Perceived Susceptibility vs. Acceptance of Hepatitis B Vaccine Cross Tabulation Analysis.

Significant Cross Tabs Relating the Acceptance of HB Vaccine toward the Perceived Susceptibility

Question	Very/Somewhat/Low Risk		No Risk/Not Sure		
	Yes	No	#	%	
10.1 Do you consider yourself at risk of getting HBV through your job?	Yes	225	91.8	5	33.3
	No	20	8.2	10	66.7
N = 260 Chi Square = 9.479 (P = 0.00208) Missing = 0					
Question	Very Serious/Serious		Minor/Not Sure		
	Yes	No	#	%	
10.2 Potential seriousness of HB injection for yourself considered.	Yes	180	94.7	50	71.4
	No	10	5.3	20	28.6
N = 260 Chi Square = 5.445 (P = 0.01962) Missing = 0					
Question	One and More		None/Not Sure		
	Yes	No	#	%	
10.3 How many times in the past year did splash blood or body fluids into your mouth, eyes, nose, or get blood or body fluids on unprotected skin with cuts or rashes?	Yes	90	78.3	140	96.6
	No	25	21.7	5	3.4
N = 260 Chi Square = 4.204 (P = 0.04032) Missing = 0					

**PERCEIVED SEVERITY**

The perceived severity of the respondents regarding hepatitis B virus were measured in two areas; reported needle sticks to employee health office and/or emergency room in the past and reported splash blood or body fluids into the mouth, eyes, nose in the past year to the employee health office or emergency room.

Reported Needle Sticks. 30.8% (n = 80) of the sample indicated that they were reported in the past the entire needle sticks to their employer health office and/or emergency room. Whereas 13.4% (n = 35) of the respondents did not report any needle sticks to the employee health office or emergency room (See Table 4.11.1).

Reported Splash Blood or Body Fluid. 25.0% (n = 65) of the sample indicated that they were reported in the past year all of the splash blood or body fluids to the employee health office and/or emergency room, while only 15.4% (n = 40) of the respondents did not report any of the incidents to the employee health office and/or emergency room (See Table 4.11.2).

**Figure 14**

Table 4.11 : Perceived Severity

Frequency Distribution and Percentage

Question	Response	Frequency	Percent
11.1 How many of the needle sticks in the past were reported to the employee health office or to the ER?	All of them were reported	80	30.8
	Some to few of them were reported	15	5.8
	None of them were reported	35	13.4
	Not Sure	130	50.0
11.2 How many of the splash blood or body fluid into your mouth, eyes and nose in the past year were reported to the employee health office and/or ER?	All of them were reported	65	25.0
	Some to few of them were reported	15	5.8
	None of them were reported	40	15.4
	Not Sure	140	53.8

Missing = 0 Total Sample Size (n) = 260

Perceived Severity vs. Acceptance of Hepatitis B Vaccine. In attempting to examine the relationship of perceived severity to hepatitis B virus and acceptance to hepatitis B vaccine, a cross tabulation comparing responses by variable was performed. The responses to the perceived severity and acceptance vaccine questions were cross tabulated.

Cross tabulation were done using the respondents questioning how many of the needle sticks in the past were reported and how many of the splash blood or body fluid into the mouth, eyes and nose in the past year were reported to the employee health office or emergency room with acceptance of hepatitis B vaccine.

The responses of all, some and few were collapsed into one group. None and not sure were collapsed into one group for cross tabulation. The author did not find any significant relationship between perceived severity and acceptance of hepatitis B vaccine (See Table 4.12).



**Figure 15**

Table 4.12 : Perceived Severity vs. Acceptance of Hepatitis B Vaccine: Cross Tabulation Analysis.

Significant Cross Tabs Relating the Acceptance of HB Vaccine  
Toward the perceived Severity.

Question	Reported		Not Reported/Not Sure	
	Yes	No	#	%
12.1 How many needle sticks in the past were reported?	85	10	145	20
	89.5	10.5	87.9	12.1
N = 260 Chi Square = 0.03005 (P = 0.86238) Missing = 0				
Question	Very Serious/Serious		Reported	
	Yes	No	#	%
12.2 How many of splash blood or body fluid in your mouth, eyes and nose in the past year were reported to employee health office or ER?	70	10	160	20
	89.5	10.5	94.1	5.9
N = 260 Chi Square = 0.02093 (P = 0.88496) Missing = 0				

**PERCEIVED BARRIERS: SAFETY AND EFFECTIVENESS OF HEPATITIS B VACCINE**

The safety and effectiveness of hepatitis B vaccine of the respondents were measured in three areas; get AIDS from hepatitis B vaccine, side effects of hepatitis B vaccine and the effective of hepatitis B vaccine.

Get AIDS from hepatitis B vaccine. 73.1% (n = 190) of the respondents answered, it is never to get AIDS from hepatitis B vaccine, while 3.8% (n = 10) of the sample indicated in their answer always possible to get AIDS from hepatitis B vaccine (See Table 4.13.1).

Side effects of hepatitis B vaccine. The majority of the sample (78.8%) indicated that hepatitis B vaccine has two or more side effects; on the other hand 15.4% of the respondents indicated that hepatitis B vaccine has no side effects (See Table 4.13.2).

The effectiveness of hepatitis B vaccine.78.8% of the sample indicated that hepatitis B vaccine usually and always effective in preventing hepatitis B virus. Whereas 3.8% (n = 10) of the sample indicated that hepatitis B vaccine is not effective at all (See Table 4.13.3).

**Figure 16**

Table 4.13 : Perceived Barriers: Safety and Effectiveness of Hepatitis B Vaccine.

Frequency Distribution and Percentage

Question	Response	Frequency	Percent
13.1 Is it possible to get AIDS from the hepatitis B vaccine?	Always	10	3.8
	Usually	10	3.8
	Sometimes	20	7.7
	Never	190	73.1
	Not Sure	30	11.5
13.2 The hepatitis B has side effects.	5 or more	25	9.6
	2 or more, but less than 5	180	69.2
	No side effects	40	15.4
	Not Sure	15	5.8
13.3 Effectiveness of HB vaccine in prevent hepatitis B virus in staff at risk considered.	Always	10	3.8
	Usually	195	75.0
	Sometimes	40	15.4
	Never	10	3.8
	Not Sure	5	1.9

Missing = 0 Total Sample Size (n) = 260

**PERCEIVED BARRIERS: SAFETY AND EFFECTIVENESS OF HEPATITIS B VACCINE VS. ACCEPTANCE OF HEPATITIS B VACCINE**

In attempting to examine the relationship of perceived barriers; safety and effectiveness of hepatitis B vaccine and healthcare workers' acceptance of hepatitis B vaccine, a cross tabulation comparing responses by variable was performed. The responses to the effectiveness and acceptance questions were cross tabulated and many significant results were discovered.

Cross tabulations were done using the respondents always, two or more side effects with the acceptance of hepatitis B vaccine. The responses of always, usually and sometimes were collapsed into one group. Five or more side effects, 2 or more side effects but less than 5 were collapsed into one group for cross tabulation.

The author found that from the results of this study, there were significant relationship between the effectiveness and safety of the hepatitis B vaccine and the acceptance of hepatitis B vaccine (See Table 4.14).

**Figure 17**

Table 4.14: Perceived Barriers: Safety and Effectiveness of Hepatitis B Vaccine vs. Acceptance of Hepatitis B Vaccine.

Significant cross tabs relating the acceptance of HB vaccine toward the safety and effectiveness of hepatitis B vaccine

Question	Always/Usually/Somewhat			Never/Not Sure	
	Yes	#	%	#	%
14.1 Is it possible to get AIDS from HB vaccine?	Yes	35	87.5	195	88.4
	No	5	12.5	25	11.6
N = 260 Chi Square = 0.92929 (P = 0.00856) Missing = 0					
Question	2 or More			No Side Effects/Not Sure	
	Yes	#	%	#	%
14.2. The hepatitis B vaccine has side effects	Yes	190	95.0	40	66.6
	No	10	5.0	20	33.4
N = 260 Chi Square = 7.259 (P = 0.00705) Missing = 0					
Question	Always/Usually/Somewhat			Never/Not Sure	
	Yes	#	%	#	%
14.3 Effectiveness of hepatitis B vaccine in preventing HBV in staff at risk considered.	Yes	225	91.9	5	33.3
	No	20	8.1	10	36.7
N = 260 Chi Square = 9.479 (P = 0.00208) Missing = 0					

**ACCEPTANCE OF HEPATITIS B VACCINE**

86.4% (n = 220) of the healthcare workers in the research sample have had the hepatitis B vaccine, on the other hand, only 15.4% (n = 40) did not have the vaccine (See Table 4.15).

**Figure 18**

Table 4.15 : Hepatitis B vaccine Acceptance

Frequency Distribution and Percentage				
Vaccine	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1. Not Vaccinated	40	15.4	40	14.4
2. Vaccinated	220	84.6	260	100.0
Missing = 0		Total Sample Size (n) = 260		

**CHAPTER 5 - DISCUSSION**

**SUMMARY**

The purpose of this study was to determine the effects of perceived threat and knowledge level about the hepatitis B virus on the motivation to accept hepatitis B vaccine among healthcare workers. This research study about the acceptance of hepatitis B vaccine among healthcare workers in a Miami-Dade Healthcare Facilities. 15.4% of healthcare workers at risk for contracting HBV had not received the vaccine. The

majority of healthcare workers who had not been vaccinated are concerned about side effects of the vaccine. In accordance with the OSHA Bloodborne Pathogens Standards, the employee health department has offered the HBV vaccine to all employees at risk for contracting hepatitis B. The department also provides information about the side effects (Roup, 1993, p. 128).

The overall knowledge of the respondents was surprising in some sections and disappointing in others. The majority of the respondents consistently answered the knowledge questions correctly. The percentage of healthcare workers in this study who have had the hepatitis B vaccine is considerably higher than that reported in the literature for all healthcare workers. The variable of perceived severity was not a predictor of hepatitis B vaccine acceptance; the variables of perceived susceptibility and knowledge level were predictors of hepatitis B vaccine acceptance. Also, a significant relationship was found between age and experience and the acceptance of the hepatitis B vaccine. Most of the literature reviewed for this research showed little effect of knowledge level on vaccine acceptance (Bodenheimer, 1986, p. 252; Fulton, 1986, p. 1339; Scapa, 1989, p. 401).

Mundt (1992) did find that the variables of perceived threat and knowledge level were not predictors of HB vaccine acceptance (p. 568). A significant relationship in Mundt's study was found between experience and perceived susceptibility and acceptance of the HB vaccine.

In studying a swine influenza vaccine program, Larson, et al (1979), found that persons who received the vaccine believed the influenza to be more serious, believed they are more susceptible to influenza, and believed that the vaccine is more efficacious than did persons who were not vaccinated (p. 1207). Rives (1978, p. 533) and Rundall (1979, p. 191) found that people refusing the vaccine believed they were not susceptible to influenza, or that the vaccine is not reliable. Cumming, et al (1979), demonstrated that the influence of the Health Belief Model (HBM) variables on behavior is mediated through behavioral intention (p. 639). Aho (1979) concluded that the findings of HBM variables as primary determinants of vaccine acceptance suggests that many of the beliefs influencing non-participation in a vaccination program are amenable to change with specific reference to beliefs about the effectiveness and safety of inoculation (p. 201). HBM variables have been found to be predictive of the utilization of an HBV vaccination program offered to hospitals

employees (Palmer, 1983, p. 1120). As in my study, those who chose not to be vaccinated tended to believe that the vaccine itself was unsafe, or that their jobs did not make them especially susceptible to HBV infection. These data are consistent with the findings of a retrospective study of Veterans Administration Personnel (Anderson, 1983, p. 207). In a review of the HBM literature, Becker (1975) also reports a similar finding (p. 15). "Evidence indicates that, no matter how concerned the individual is with poliomyelitis, he or she will not accept vaccination if the vaccine's safety is in question. Indeed, doubts about the safety and effectiveness of swine influenza vaccine prompted many individuals to avoid vaccination" (Rives and Mooney, 1978, p. 533). Initial media coverage portrayed lack of unanimous support for this immunization program, largely based on doubts of vaccine safety. This information may have helped formulate health beliefs adverse to vaccine acceptance. My finding of the predictive value of HBM variables in hepatitis B vaccine acceptance may help address the failure to vaccinate a large proportion of healthcare workers at risk of contracting hepatitis B infection. Programs to vaccinate healthcare workers against hepatitis B virus should focus on forming or reforming beliefs about the safety and efficacy of the vaccine. Level of education and knowledge of hepatitis B are determinants of these health beliefs which may be subject for modification.

In this study younger healthcare workers were found more likely to have been vaccinated for HBV and this may be related to the younger healthcare workers' expectations of remaining in medical, paramedical, and nursing as a career for more years than older healthcare workers. In fact, the healthcare workers with more experience in the hospitals and nursing homes were significantly more likely to have been vaccinated. Fear concerning the safety and effectiveness of the HBV vaccine was a major reason for non-acceptance of HB vaccine. Whereas, the acceptance of HB vaccine respondents indicated that hepatitis B vaccine is very safe and effective.

Healthcare workers need to be aware of the greater likelihood that they may be HB carriers compared to the general population, therefore are at risk for occupational exposure to HBV when their position involves giving injections, treating injuries, and performing phlebotomies. Increasing perceived susceptibility can be addressed through the professional literature and educational seminars for healthcare workers.

Further research on the issue of the HB vaccine acceptance

among healthcare workers might focus on subgroups with high acceptance of HB vaccine, as in this study. Variables within the framework of the HBM could be analyzed, particularly perceived susceptibility. Other instruments, such as the locus of control scales, or those which measure psychosocial variables were not measured in this study, might provide insight into reasons for taking the health action of acceptance of the HB vaccine.

Another approach is to research hospitals in which the HB vaccine acceptance rate is high and compare it to those in which the HB vaccine acceptance rate is low. Differences in variables, using the HBM or other frameworks, might provide further insight into the significant variables associated with acceptance of the HB vaccine. Also research is needed to ascertain whether education about HBV infection and vaccination is effective in modifying acceptance of the vaccine. Educational sessions incorporated as part of vaccine programs should ensure that persons who are candidates for vaccination have access to complete and accurate information. However, the proper formation of beliefs regarding the safety and efficacy of vaccine may be the most important factor in determining vaccine acceptance.

The present study did explore and answer the research question. The perceived threat and knowledge level of healthcare workers have related to the acceptance of hepatitis B vaccine.

### LIMITATIONS

The primary limitations of this study are the design of the instrument. The measurement of the perceived barriers toward hepatitis B vaccine needs to be more fully developed. One of the first thoughts during the designing findings mostly perceived threat data. Conceivably all of the questions should have been eliminated. Possibly, selected only three to four areas of perceived threat and more questions on perceived barriers. Another limitation of this study was getting only one small group of volunteers.

### IMPLICATION

In spite of the above mentioned limitations, this study represents the attempts to measure the depth of knowledge and perceived threat held by healthcare workers regarding the hepatitis B virus. This is also the first study to explore the relationship between healthcare workers knowledge of perceived threat and acceptance of hepatitis B vaccine. The findings of the perceived susceptibility relating to risk of getting HBV have opened a new area of study. Overall, the

data did indicate a good knowledge base for the majority. In clinical practice the minority must be remembered. More education about hepatitis B and hepatitis B vaccine is warranted to clear up some of the misconceptions and to promote good health.

The physical and emotional trauma that many healthcare workers dealing with hepatitis B infection and liver cancer could possibly be avoided by assisting them to attain increased knowledge toward how to prevent hepatitis B infection by taking the vaccine.

### CONCLUSION

The findings in this study support recommendations for providing the hepatitis B vaccine to healthcare workers early in their careers. Education programs should focus on increasing healthcare workers' perceived severity to occupational exposure to hepatitis B virus and stress the safety and effectiveness of the synthetic hepatitis B vaccine. Enhancing accessibility may be another effective method for increasing acceptance of the hepatitis B vaccine. Immunization against hepatitis B is an important public health measure that protect healthcare workers against the risk of developing and transmitting a contagious disease that potentially severe long-term consequences. Universal healthcare workers vaccination has been successful in greatly reducing seroprevalence where it has been introduced. There is evidence, however, that unjustified allegations linking the vaccination with the development of chronic neurodegenerative disorders have negatively affected coverage and tended to obscure the real health benefits associated with this vaccine. There is also a risk that some countries, including countries in less developed parts of the world where hepatitis B is endemic, might be dissuaded from taking steps to adopt universal vaccination where they intended to implement this measure. It is the author concerned that widespread (and sometimes inaccurate) reporting of such 'scares' may have a detrimental effect on efforts to eliminate this vaccine-preventable disease and the health burden it imposes on individuals and society.

### APPENDIX A - INSTRUMENT

#### HEPATITIS B VACCINE KNOWLEDGE AND ACCEPTANCE QUESTIONNAIRE.

##### DIRECTIONS:

Please answer the following questions and choose one answer for each question that best expresses your opinion and circle it. Do not sign your name or identify yourself on

this questionnaire. Thank you for your cooperation.

### SECTION A:

What is your gender? Are you... Male Female What is your racial background? Are you... White Black Asian Hispanic American Indian Other (specify)\_\_\_\_\_ Don't Know. What was your age on your last birthday? Less than 20 years 20 to 29 years 30 to 39 years 40 to 49 years 50 to 59 years 60 years or above. What is your level of education? Assistant nurse LPN RN with AA RN with BSN RN with MSN RN with Ph.D M.D. Pharmacist Lab Tech. Other (specify)\_\_\_\_\_ What is your marital status? Never married Married Separated Divorced Widowed Other (specify)\_\_\_\_\_ For 2002, was your total household income from all sources before taxes..... Less than \$40,000 More than \$40,000 \$40,000 exactly Don't know. What is your religious preference? Would you describe yourself as... Protestant Catholic Jewish Something else (specify)\_\_\_\_\_ Which area or unit do you work in? Emergency room Operating room Recovery room I.C.U. Medical surgical Outpatient clinic Pediatric Psychiatric Health nurse Lab. Other (specify)\_\_\_\_\_ How long have you worked in the area mentioned above (question #8)? Less than 2 years 2 to 3 years 4 to 5 years 6 to 7 years 8 to 9 years 10 to 11 years 12 years and more. Section B: Hepatitis B can be caught through casual contact such as hugging and holding hands. Always Usually Sometimes Never Not sure. There are people who are carriers of hepatitis B that are not sick but may pass the disease to others. Always Usually Sometimes Never Not sure The hepatitis B vaccine is made from human blood. Always Usually Sometimes Never Not Sure Hepatitis B can be passed from the mother to the baby at birth. Always Usually Sometimes Never Not sure. It is possible to get hepatitis B from eating shellfish. Always Usually Sometimes Never Not sure Skin without rashes or cuts or open areas will keep you from getting hepatitis B. Always Usually Sometimes Never Not sure. The hepatitis B virus can cause liver cancer. Always Usually Sometimes Never Not sure. Section C: Part I. Is it possible to get AIDS from the hepatitis B vaccine? Always Usually Sometimes Never Not sure. The hepatitis B vaccine has side effects: 5 or more side effects 2 or more side effects, but less than 5 No side effects at all Not sure. Effectiveness of hepatitis B vaccine in preventing hepatitis B virus in staff at risk concerned: Always effective Usually effective Sometimes effective Not at all effective Not sure. Section C: Part II. Do you consider yourself at risk of getting hepatitis B through your job? Very high risk Somewhat of risk Low risk No risk

Not sure. Potential seriousness of hepatitis B infection for yourself considered: Very serious Serious Minor Very minor Not sure. Have frequent contact with blood/or body fluids in my job: More than 10 times per day More than 5 times per day, but less than 10 times More than one time per day, but less than 5 times No contact at all. For the best of your knowledge how many needle sticks have you acquired in the past? 10 or more 5 or more, but less than 10 2 or more, but less than 5 Less than 2 None Not sure. How many times in the past year did you splash blood or body fluids into your mouth, eyes, nose, or get blood or body fluids on unprotected skin with cuts or rashes? 10 or more 5 or more, but less than 10 2 or more, but less than 5 Less than 2 None Not sure. Section C: Part III. Referring to question #23, how many of the needle sticks were reported to the employee health office or to the emergency room? All of them were reported Some to few of them were reported None of them were reported Not sure how many were reported Not applicable. Referring to question #24, how many of the above incidents were reported to the employee health office or to the emergency room? All of them were reported Some to few of them were reported None of them were reported Not sure how many were reported Not applicable. Section D: Please indicate whether you have received the hepatitis B vaccine: Yes No (please skip question #28, and complete section E). If you answered yes to question #27, please specify how many doses did you take? 1st dose only (please complete section F) 1st dose and second dose (please complete section F) 1st dose, 2nd and 3rd dose (thank you, your questionnaire has been completed). Section E: Please complete this section if you have not received any doses of hepatitis B Vaccine. I am not at risk for getting hepatitis B. Yes No Not sure. I do not believe in the hepatitis B vaccine. (please explain in the comment section below) Always Usually Sometimes Never Not sure. I think hepatitis B vaccine cost too much: Always Usually Sometimes Never Not sure. I can never find the time to get the hepatitis B vaccine: Always Usually Sometimes Never Not sure. I forgot to get the hepatitis B vaccine: Yes No Not sure. I have antibodies against hepatitis B and do not need the vaccine: Yes No Not sure. I am/was pregnant or breast feeding: Yes No Not applicable. I had hepatitis B in the past: Yes No Not sure. I am afraid of the side effects of hepatitis B vaccine: Very afraid Usually afraid Somewhat afraid Not very afraid at all Not sure. Is hepatitis B vaccine available free of charge at your facility? Free all of the time Not free at all Sometimes free Not sure. Comments for section E.

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\_\_\_\_\_ Section F: Please complete this section if you have received 1 or 2 doses of the HB vaccine: I have just started the hepatitis B vaccine series, and I am planning to return to the health office for my 2nd or 3rd doses of hepatitis B vaccine. Yes No Not applicable. I was not aware that I need 3 doses of hepatitis B vaccine. Yes No Not applicable. I forgot to get my next dose of hepatitis B vaccine. Yes No Not applicable. I was on vacation or on sick leave when my 2nd or 3rd series was being offered. Yes No Not applicable. I had side effects from the hepatitis B vaccine and decided not to have any more doses. Yes No Not applicable. I have heard negative rumors about the hepatitis B vaccine so I decided not to have any further doses. Yes No Not applicable.

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