# Hepatology Society of the Philippines

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# GUIDELINES ON THE EVALUATION OF HEPATITIS B SURFACE ANTIGEN (HBsAg) POSITIVE WORKERS FOR EMPLOYMENT

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#### **Executive Summary**

One out of eight Filipinos is infected with the Hepatitis B virus (HBV). Therefore, chronic hepatitis B is a major public health concern in the Philippines. However, the current practice of screening for hepatitis B surface antigen (HBsAg) as a basis for employment has no evidence except in certain circumstances.

Hepatitis B surface antigen positivity alone has become a basis for discrimination, work restriction and subsequent disqualification from employment in the Philippines. Each year many potential workers are denied employment solely because of misconceptions about the risk of hepatitis B (HBV) transmission, lack of knowledge about the natural history of this disease and the risk of developing complications while at work.

This has prompted the Hepatology Society of the Philippines (HSP) to formulate guidelines to aid physicians involved in the evaluation of Hepatitits B surface antigen

positive workers for employment. The main objectives of these guidelines is to help physicians recognize the implications of the different phases of chronic HBV infection on the risk of transmission in the workplace, eligibility for treatment and the risk of developing complications and to serve as a guide in categorizing the risk of transmission in the workplace based on the type of occupation and the individual's infectivity.

These guidelines are made with the intention to balance the risk of HBV transmission in the workplace and the probability of losing highly skilled workers due to unduly stringent restrictions. These recommendations are meant to be flexible and are not intended to be the only acceptable approach in the evaluation for employment of HBsAg positive workers. Pertinent facts and circumstances surrounding each individual with chronic HBV infection should always be considered. These guidelines are based on current knowledge and will be updated as new data emerge.

#### INTRODUCTION

Chronic hepatitis B (CH B) affects 350 million people worldwide<sup>1</sup> and is more prevalent in Asia, sub-Saharan Africa and the Pacific rim compared to other regions.<sup>2</sup> With a prevalence rate of approximately 6 to 12% <sup>3,4,5</sup> the Philippines is considered hyperendemic for hepatitis B (HBV). Although the reported prevalence of HBV infection among overseas Filipino workers is slightly lower (4.2%),<sup>6</sup> this still translate s to as many as 12,000 potential workers yearly 7 who may be denied employment solely because of misconceptions about the risk of HBV transmission, the lack of knowledge about the natural history of this disease and the risk of developing complications while at work.

Although safe work practices and standard precautions <sup>8</sup> need to be adhered to by individuals with chronic HBV infection (Table 1), they should not be disc riminated upon or treated differently from all other workers. The natural history of chronic HBV infection is variable, and persons with chronic HBV infection need lifelong monitoring to determine if and when intervention is needed.

These guidelines are recommendations on the evaluation of HBsAgpositive workers for employment. Recent advances and new data on the epidemiology, diagnosis and natural history of HBV infection have prompted the Hepatology Society of the Philippines (HSP) to convene a working group to update the previous recommendations drafted in 2005 by the Council on Liver Diseases of the Philippine Society of Gastroentorology. The working group identified key issues and questions which needed to be addre ssed, with particular reference to HBsAgpositive workers. Individuals from various sectors, including

liver disease and infectious disease specialists, clinical epidemiologists and representa tives from the Department of Heal th were invited to a series of meetings wherein issues on epidemiology, natural history and risk of transmission of HBV were presented and discussed. A review of existing guidelines and policies <sup>9,10,11,12,13,14,15</sup> was likewise performed. Based on data and evidence

presented, the members of the working group were asked to revise and update the previous guidelines or propose new recommendations whenever appropriate.

These recommendations are meant to be flexible and are not intended to be the only acceptable approach in the evaluation for employment of HBsAg positive workers. Pertinent facts and circumstances surrounding each individual with chronic HBV infection should always be considered.

The main objective of these guidelines is to aid physicians involved in the evaluation of HBsAgpositive workers for employment. It aims to 1) help physicians recognize the implications of the different phases of chronic HBV infection on the risk of transmis sion in the workplace, eligibility for treatment and the risk of developing complications and 2) to serve as a guide in categorizing the risk of HBV transmission in the workplace according to the type of occupation and the individual's infectivity.

These guidelines are based on current knowledge and will be updated as new data emerge.

HEPATITIS BV IROLOGY AND SEROLOGY

The hepatitis B virus belongs to the family hepadna virus. The HBV genome is a relaxed, circular partially double stranded DNA of approximately 3200 base pairs.There are four (4) partially overlapping open reading frames encoding the envelope (preS/S), core (precore /core), polymerase, and X proteins. The polymerase protein functions as a reverse transcriptase as well as a DNA polymerase. The X protein is a potent transactivator of oncogenes and may play a role in the development of liver cancer.

The most common serologic tests for hepatitis B are the hepatitis B surface antigen (HBsAg) which denotes the presence or absen ce of infection, antibody to HBsAg (anti-HBs) which when positive signifies protection or immunity from HBV infection, and hepatitis B e antigen (HBeAg), antibody to HBeAg (anti-HBe), antibody to hepatitis B core antigen (antiHBc), HBV DNA, and alanine aminotrans ferase (ALT) which collectively determines the phase of the infection.

<sup>&</sup>lt;sup>1</sup> World Health Organization. Hepatitis B. World Health Organization Fact Sheet 204 (Revised October 2000). 2000: Accessed July 5, 2007 at http://who. int/inffs/en/fact204.html.

<sup>&</sup>lt;sup>2</sup> Lavanchy D. Hepatitis B virus epidemiology, disease burden, treatment, and current and emerging prevention and control measures. J Viral Hepatology 2004; 11:97107.

<sup>&</sup>lt;sup>3</sup> Lansang MA. Epidemiology and control of hepatitis B infection: a perspective from the Philippines, Asia. Gut 1996; 38 Supply 2:S437.

<sup>&</sup>lt;sup>4</sup> Dalmacio LM, Evangelistä KV, Kemp K, Campos JR, Kron MA, Domingo EO, Ramirez BL. Prevalence of hepatitis B virus infection among healthy adults and highrisk groups. Phil J Intern Med 2005; 43:301306.

<sup>&</sup>lt;sup>5</sup> Evangelista KV, Dal macio LMM, Wells J, Kron MA, Ra mirez BL. P revalen ce of hepatitis B virus (HB V) infection among Tagalog s and Mangyans in Orienta I Mindoro, Philippines. Phil J Intern Med 2006; 44:161166.

<sup>&</sup>lt;sup>6</sup> Yanase Y, Ohida T, Kaneita Y, Agdamag DM, Leano PS, Gill CJ. The prevalence of HIV, HBV and HCV among Filipino blood donors and overseas work visa applicants. Bull World Health Organ 2007; 85:1317.

<sup>&</sup>lt;sup>7</sup> Philippine Overseas Employment Agency. Fast stats: OFW deployment JanuaryNovember 2006. Accessed July 5, 2007 at http://www.poea.gov.ph/stats/ faststats.html.

<sup>&</sup>lt;sup>8</sup> Update: universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. MMWR Morb Mortal Wkly Rep 1988;37:37782, 3878.

<sup>&</sup>lt;sup>10</sup> Health Service Circular 2000/020. NHS Executive. Hepatitis B Infected Health Care Workers. 2000.

<sup>&</sup>lt;sup>11</sup> National code of practice for the control of work-related exposure to hepatitis and HIV (bloodborne) viruses [nohsc: 2010(2003)]. 2003: Accessed June 25, 2007 at http://www.ascc.gov.au/ascc/HealthSafet y/DiseaselnjuryIssues/InfectiousDiseases/HivAids/CodeofPracticeforcontrolofworkrelated exposuretohepatitisand HIVbloodborneviruses2ndedition2003.html.

<sup>&</sup>lt;sup>12</sup> Lok AS, McMahon BJ. Chronic hepatitis B. Hepatology 2007; 45:50739.

<sup>&</sup>lt;sup>13</sup> de Franchis R, Hadengue A, Lau G, Lavanchy D, Lok A, McIntyre N, Mele A, Paumgartner G, Pietrangelo A, Rodes J, Rosenberg W, Valla D. EASL International Consensus Conference on Hepatitis B. 1314 September, 2002 Geneva, Switzerland. Consensus statement (long version). J Hepatol 2003; 39 Suppl 1:S325.

<sup>&</sup>lt;sup>14</sup> Liaw YF, Leung N, Guan R, Lau GK, Merican I, McCaughan G, Gane E, Kao JH, Omata M, Asian-Pacific consensus statement on the management of chronic hepatitis B: a 2005 update. Liver Int 2005;25:47289.

<sup>&</sup>lt;sup>15</sup> Gunson RN, Shouval D, Roggendorf M, Zaaijer H, Nicholas H, Holzmann H, de Schryver A, Reynders D, Connell J, Gerlich WH, Marinho RT, Tsantoulas D, Rigopoulou E, Rosenheim M, Valla D, Puro V, Struwe J, Tedder R, Aitken C, Alter M, Schalm SW, Carman WF. Hepatitis B virus (HBV) and hepatitis C virus (HCV) infections in health care workers (HCWs): guidelines for prevention of transmission of HBV and HCV from HCW to patients. J Clin Virol 2003; 27:21330.

# Evaluation of HBsAg(+) Workers (HSP)

## Table 1. Recommendations for Application of Standard Precautions

Standard Precautions are based on the principle that all blood, body fluids, secretions, excretions except sweat, non intact skin and mucous membranes may contain transmissible infectious agents such as hepatitis B. Standard precautions include infection prevention practices that must be observed in all patients, regardless of age, sex, economic background and so on and regardless of suspected or confirmed infection, in any setting in which the health care is delivered.

The 2007 US Centers for Disease Control recommendations for standard precautions include: hand hygiene; use of gloves, gown, mask, eye protection or eye shield, depending on the anticipated exposure; and safe injection practices. It also covers the proper handling and disinfection of environment and equipment which may be contaminated with body fluids.

Standard precautions are important not only to prevent infections from patients to health care workers, but to protect as well patients from getting infections from infected healthcare workers such as those who may have hepatitis B or from equipment used in other patients who may have the infection.

The important addition in the latest 2007 guidelines compared to its previous versions is the inclusion of safe injection practices to the components of Standard Precautions. This is an important new addition particularly in areas like the Philippines where the practice of reusing needles and multiple use of the same needle to give intravenous medications from multidose vials must be reviewed and improved.

The application of Standard Precautions is summarized in Table below:

COMPONENT	RECOMMENDATIONS
Hand hygiene	Practice hand hygiene with soap and water, alcohol or alcohol based handrub after touch- ing blood, body fluids, secretions, excretions, contaminated items; after removing gloves, and at all times between patient contact

Personal protective equipment (PPE)

Gloves	Use gloves whenever there is possibility of touching blood, body fluids, secretions, excre- tions, contaminated items; when anticipating touching mucous membranes and nonintact skin
Gown	Use gown during procedures and patientcare activities when contact of clothing or areas of exposed skin with blood, bodyfluids, secretions and excretions is anticipated.
Mask, eye protection or face shield	Use masks, and eye protection during procedures likely to generate splashes or sprays of blood, body fluids, secretions, especially suctioning and endotracheal intubation (goggles) or face shield
Soiled patient care equipment	Handle in a manner to prevent transfer of organisms to others
Environmental Control	Develop procedures for routine care, cleaning and disinfection of environmental surfaces especially frequently touched surfaces in the patient-care areas
Textile and laundry	Handle in a manner to prevent transfer of organisms to others
Injection practices	Use only aseptic technique when preparing and administering parenteral medications. Use sterile, singleuse, disposable needle and syringe for each injection. When possible, singledose vials is preferred over multipledose vials.
Needles and other sharps	Do not recap, bend, break or handle used needles. If recapping has to be done, use the one-handed scoop technique, Place used sharps only in puncture-resistant containers.
Patient resuscitation	Use mouthpiece, resuscitation bag, other ventilation devices to prevent contact with mouth and oral secretions
Cough etiquette	Instruct coughing patients to cover mouth and nose whenever sneezing, coughing; wear surgical mask if tolerated

Reference: Siegel JD, Rinehart E, Jackson M, Chairello L and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions Preventing Transmission of Infectious Agents in the Healthcare Settings June 2007 http://www.cdc.gov/ ncidod/ dhqp/pdf/isolation2007.pdf

#### MODES OF TRANSMISSION

HBV is transmitted by perinatal (mother to infant), percutaneous, mucous membrane and sexual exposure to infectious blood and open cuts that contain blood.<sup>16</sup> HBV DNA has been detected in a wide variety of body fluids such as blood, tears, urine, saliva, breast milk, seven and vaginal fluid. HBV can survive outside the body for up to seven (7) days and HBeAgpo sitive individuals can shed large guantities of viral particles on environmental surfaces, although there have been no reports of transmission from fomites. The presence of HBeAg in serum directly correlates with higher titers of HBV DNA. However, HBV strains that have mutations in the precore or basal core promoter regions of the viral genome, which eliminates and decreases the express ion of the HBeAg, respectively, have also been associated with high viral loads and perinatal and percutaneous <sup>17</sup> viral transmission.

Percutaneous exposures that have resulted in HBV transmission include the use of contaminated equipment for therapeutic injections and dental procedures, illicit or injection drug use, transfusion of blood or blood products, and needlestick or other injuries from sharp instruments sustained by medical and dental personnel. Outbreaks of hepatitis B have also been associa ted with tattooing and acupuncture. Perinatal and sexual transmission of HBV usually results from exposure of mucous membranes to infectious blood or serum derived body fluids. Although HBV DNA has been quantified in saliva<sup>18</sup> and transmission reported in people bitten<sup>19</sup> or spit at in the eye 20 by HBsAgpositive carriers, transmis sion has not been demonstrated in susceptible persons orally exposed (e.g. kissing) to HBV DNA-positive saliva.

#### NATURAL HISTORY OF HEPATITIS B INFECTION

Acute infection with HBV produces clinically apparent disease only in a minority of cases. The rate of evolution into chronic infection depends on the age of the individual when infected. P erina tal infection from an infected mother is almost always asymptomatic or without symptoms, and evolves to chronic infection in 90% of cases. The risk of perinatal infection is approximately 90% in babies born to HBeAgnogative mothers and 10% in babies born to BBeAgnegative mothers and is related to the maternal serum HBV DNA level, where a level below 2 million IU/mI is not likely to transmit infection.<sup>17</sup> In about 5% of babies born to HBeAgnegative mothers, acute symptomatic or

fulminant hepatitis develops within the first 3-4 months of life.  $^{\mbox{\tiny 21}}$ 

Infection acquired in early childhood (1-5 years), presumably from open cuts, scratches and wounds, is in general asymptomatic and evolves to chronic infections in 2530% of cases . In contrast, approximately 30% of infection in adults present as icteric hepatitis and 0.10.5% develop fulminant hepatitis. Infection resolves with the development of antiHBs in >95% of adults and is more common in adults who develop acute icteric hepatitis B. <sup>22</sup>

Acute HBV infection leads to one of these three outcomes:

- \* Fulminant hepatitis
- \* Recovery from acute infection with disappearance of HBsAg
- \* Chronic Hepatitis B infection

Chronic HBV infection is characterized by the persistence of serum HBsAg for at least six (6) months. In adultacquired infection, it is important to recognize that it may occasionally take a few months for some individuals to clear HBsAg, but HBsAg should generally be undetectable 1 year after acute HBV infection.<sup>23</sup> In perinatallyacquired infection, the rate of HBsA g clearan ce ranges from 0.12% per year although a recent study from Taiwan suggests that as much as 25% will have HBsAg clearance if followed for 20 years.<sup>24</sup>

Since HBV is not directly cytopathic, the level of liver necroinflammation is dependent on the activity of the immune system. During the initial phase of chronic HBV infection, serum HBV DNA levels are high, HBeAg is present, and the immune system is not activated against HBV, as evidenced by normal ALT levels and minimal or absent necroinflammation on liver biopsy. The majority of carriers (70-80%) eventually loses HBeAg and develops antiHBe. In most individuals who have undergone seroconversion from HBeAg to antiHBe, levels of HBV DNA decrease below 2,000 IU/mL, ALT normalize and necroinflammation decreases. However, in some cases, liver disease persists or relapses after a period of inactivity. Most of these patients have mutations in the core promoter and precore regions of the viral genome. The different serological patterns and phases of chronic HBV infection are highly dependent on how the balance swings between immune system control and viral activity. Table 2 defines the diagnostic criteria and terms used in chronic hepatitis B infection.

<sup>&</sup>lt;sup>16</sup> de Franchis R, Hadengue A, Lau G, Lavanchy D, Lok A, McIntyre N, Mele A, Paumgartner G, Pietrangelo A, Rodes J, Rosenberg W, Valla D. EASL International Consensus Conference on Hepatitis B. 1314 September, 2002 Geneva, Switzerland . Consensus statement (long version). J Hepatol 2003; 39 Suppl 1:S325.

<sup>&</sup>lt;sup>17</sup> Liaw YF, Leung N, Guan R, Lau GK, Merican I, McCaughan G, Gane E, Kao JH, Omata M. Asian-Pacific consensus statement on the management of chronic hepatitis B: a 2005 update. Liver Int 2005; 25:47289.

<sup>&</sup>lt;sup>18</sup> Gunson RN, Shouval D, Roggendorf M, Zaaijer H, Nicholas H, Holzmann H, de Schryver A, Reynders D, Connell J, Gerlich WH, Marinho RT, Tsantoulas D, Rigopoulou E, Rosenheim M, Valla D, Puro V, Struwe J, Tedder R, Aitken C, Alter M, Schalm SW, Carman WF. Hepatitis B virus (HBV) and hepatitis C virus (HCV) infections in health care workers (HCWs): guidelines for prevention of transmission of HBV and HCV from HCW to patients. J Clin Virol 2003; 27:21330.

<sup>&</sup>lt;sup>19</sup> Cancio-Bello TP, de Medina M, Shorey J, Valledor MD, Schiff ER. An institutional outbreak of hepatitis B related to a human biting carrier. J Infect Dis 1982;146:6526.

<sup>&</sup>lt;sup>20</sup> ReissLevy EA, Wilson CM, Hedges MJ, McCaughan G. Acute fulminant hepatitis B following a spit in the eye by a hepatitis B e antigen negative carrier. Med J Aust 1994;160:5245.

 <sup>&</sup>lt;sup>21</sup> Chang MH. Natural history of hepatitis B virus infection in children. J Gastroenterol Hepatol 2000;15 Suppl:E16-9.
 <sup>22</sup> Tassopoulos N, Papaevangelou G, Sjogren M, RoumeliotouKarayannis A, Gerin J, Purcell R. Natural history of acute hepatitis B surface antigenpositive

hepatitis in Greek adults. Gastroenterology 1987;92:18441850.

<sup>&</sup>lt;sup>23</sup> Kumar M, Satapathy S, Monga R, Das K, Hissar S, Pande C, Sharma BC, Sarin SK. A randomized controlled trial of lamivudine to treat acute hepatitis B. Hepatology 2007; 45:97101.

<sup>&</sup>lt;sup>24</sup> Chu CM, Liaw YF. HBsAg seroclearance in asymptomatic carriers of high endemic areas: appreciably high rates during a longterm followup. Hepatology 2007; 45:118792.

# Table 2: Glossary of terms and diagnostic criteria used in chronic HBV infection

# Chronic Hepatitis B

A chronic necroinflammatory disease of the liver caused by persistent infection with HBV and can be subdivided into:

- 1. HBeAg-positive chronic hepatitis B
  - Diagnostic Criteria:
  - a. HBsAg positive >6 months
  - b. HBeAg positive, antiHBe negative
  - c. Serum HBV DNA>20,000 IU/ml or>112,000 copies\*
     d. Persistent or intermittent elevation in ALT levels
  - a. Persistent of intermittent elevation in A
  - e. Liver biopsy showing HAI >4
- HBeAg-negative chronic hepatitis B Diagnostic Criteria:
   a. HBsAg positive >6 months
  - b. HBeAg negative, antiHBe positive
  - c. Serum HBV DNA>2,000 IU/ml or>11,200 copies/ml\*
  - d. Persistent or intermittent elevation in ALT levels
  - e. Liver biopsy showing HAI >4

## Inactive HBsAg Carrier State

Persistent HBV infection of the liver without significant ongoing necroinflammatory disease. Diagnostic Criteria:

- a. HBsAg positive >6 months
- b. HBeAg negative, anti HBe positive
- c. Serum HBV DNA<2.000 IU/ml or <11.200 copies/ml\*
- d. Persistently normal ALT levels
- e. Liver biopsy confirms absence of necroinflammatory disease

# Acute Exacerbation or Flare of Hepatitis B

Intermittent elevations of ALT to more than 10 times Upper Limit of Normal (ULN) or more than 2 times the baseline value.

## Resolved Hepatitis B

Previous HBV infection without further virologic, biochemical or histologic

evidence of active infection or disease.

Diagnostic Criteria:

- a. Previous known history of acute or chronic hepatitis B
- b. HBsAg negative with or without antiHBs
- c. Undetectable serum HBV DNA\*
- d. Normal ALT levels
- \* To convert IU/ml to copies/ml, multiply equivalent IU by 5.6

\*\* Very low levels may be detected by PCRbased assays

# Phases of chronic hepatitis B infections

A. Immune Tolerant Phase

This is the initial phase of chronic HBV infection and is commonly found in areas where perinatal transmission is the predominant mode of transmission. These patients have no symptoms, with normal or slightly increased serum ALT levels and minimal necroinflammation on histology signifying a lack of, or a very weak immune response against the infected hepatocytes. The rate of progression into chronic hepatitis, where the ALT increases and necroinflammation starts to appear on histology, is 2.2% per year while the rate of progression to cirrhosis is very low at 0.5% per year.<sup>25</sup>

# B. Immune Clearance Phase

During the course of chronic HBV infection, the immune system becomes activated against the hepatitis B virus and attempts to clear the virus by cytopathic or cytokinemediated means. The effects of this immune system activation are an increase in ALT levels and histologic activity, reflecting immune mediated lysis of infected hepatocytes, and a decrease in HBV DNA levels. In some individuals, this is followed by HBeAg seroconversion. However, in some, this phase is prolonged and results in the persistence of inflammatory activity and eventual increase in HBV DNA levels (HBeAg-positive chronic hepatitis B). Patients in this phase have a high likelihood of having and acute exacerbation or flare of their hepatitis (28.6% per year)<sup>26</sup> and an increased rate of developing cirrhosis (26% per year)27 if not followed up and treated at an opportune time.

#### C. Low or Nonreplicative Phase

This phase usually follows spontaneous or treatment induced seroconversion from HBeAg to antiHBe, and usually occurs in the 3rd to 4th decade in individuals infected perinatally.<sup>25,28</sup> This is marked by a reduction of serum HBV DNA below 2,000 IU/mL, followed by normalization of ALT levels and resolution of liver necroinflammation. This is also termed the inactive HBsAg carrier state, which makes up 70-80% of individuals with chronic HBV infection. These individuals have a good prognosis with a risk of developing cirrhosis of only 0.9% per year.28 However, not all individuals remain in the inactive carrier state. Around 10-30% (2.2% per year) may undergo subsequent spontaneous or immunosuppression-induced reactivation of HBV replication with reappearance of high levels of HBV DNA with or without reversion to serum HBeAgpositive status and a rise in ALT levels when followed serially over time.25,28

#### D. Reactivation Phase

Reactivation of HBV replication and liver inflammation may be observed after HBeAg seroconversion. This phase is marked by elevated ALT levels, negative serum HBeAg, and increased HBV DNA levels (usually > 2,000 IU/mL) and is appropriately termed the HBeAgnegative chronic hepatitis B phase. It is important to note that around 20-45% of individuals in this phase will have fluctuating HBV DNA and ALT levels,<sup>20,30</sup> such that serial monitoring may be needed in order to properly differentiate this phase from the inactive carrier state. The risk of having an acute flare or exacerbation of hepatitis is

<sup>&</sup>lt;sup>25</sup> Chu CM, Hung SJ, Lin J, Tai DI, Liaw YF. Natural history of hepatitis B e antigen to antibody seroconversion in patients with normal serum aminotransferase levels. Am J Med 2004; 116:82934.

<sup>&</sup>lt;sup>26</sup> Liaw YF, Tai DI, Chu CM, Pao CC, Chen TJ. Acute exacerbation in chronic type B hepatitis: comparison between HBeAg and antibodypositive patients. Hepatology 1987; 7:203.

Liaw YF, Tai DI, Chu CM, Chen TJ. The development of cirrhosis in patients with chronic type B hepatitis: a prospective study. Hepatology 1988; 8:4936.
 Hsu YS, Chien RN, Yeh CT, Sheen IS, Chiou HY, Chu CM, Liaw YF. Longterm outcome after spontaneous HBeAg seroconversion in patients with chronic hepatitis B. Hepatology 2002; 35:15227.

<sup>&</sup>lt;sup>29</sup> Manesis EK, Papatheodoridis GV, Sevastianos V, Cholo B viremia levels determined by a quantitative polymerase chain reaction assay in patients with hepatitis B e antigennegative chronic hepatitis B virus infection. Am J Gastroenterol 2003; 98:22617.

<sup>&</sup>lt;sup>30</sup> Brunetto MR, Oliveri F, Čoco B, Leandro G, Colombatto P, Gorin JM, Bonino F. Outcome of antiHBe positive chronic hepatitis B in alphainterferon treated and untreated patients: a long term cohort study. J Hepatol 2002; 36:26370.

10.3% per year 26 while the probability of progression into cirrhosis is 8-10% per year.  $^{31,\,32}$ 

#### E. Recovery Phase

The disappearance of HBsAg and development of anti-HBs signifies the recovery phase. These individuals good prognosis. However, the age at which this phase occurs, the frequency and severity of hepatitis exacerbations and development of cirrhosis before this phase is reached may also be important determinants of prognosis. <sup>33,34</sup>

#### RISK OF HBV TRANSMISSION IN THE WORKPLACE

The risk of transmission of HBV from an infected worker to a person in the workplace is dependent on two main factors: 1) the risk of exposu re to infectious HBV particles in the workplace, which is primarily dependent on the type of occupation, and; 2) the infectivity of the infected worker, which is dependent on viral factors.

Consistent with the known modes of transmission of HB V, there has been no report of HBV transmission through casual contact in the workplace, although there have been reports of transmission where close body contact is involved such as in athletes engaged in contact sports,<sup>16,35</sup> presumabl y from exposure to infected blood from scratches and abrasions. The most common sources of HBV transmission, as well as the activities that are not known to transmit infection are enumerated in Table 3.

#### Table 3: Modes of transmission

- I. HBV can be transmitted through but not limited to the following:
  - 1. Mother to child (during pregnancy and childbirth) 2. Sexual contact
  - 2. Sexual contact
  - 3. Exposure to contaminated blood or body fluids (semen, vaginal secretions, synovial fluid, & etc.)
    - o Cuts or grazes on the skin and mucosa
    - o S haring personal items (e.g. toothbrushes, razors, etc)
    - o Needle stick & sharps injuries
    - o Acupuncture, tattooing, piercing, manicure, pedicure
    - o Inadequately sterilized dental & surgical instruments
- II. HBV has not been documented to be transmitted by the following:
- 1. Coughing, sneezing
- 2. Sharing cutlery, utensils, plates, glasses
- 3. Sharing lavatory seats
- 4. Handshaking, hugging, kissing
- 5. Swimming pools
- 6. Public dining places, crowded places
- 7. Drinking fountains

The type of occupation that carries the highest risk of exposure to HBV from an infected worker is one that entails exposure to sharp instruments/needles that have the potential to cause a break in the skin and thus expose another person to infectious blood or body fluids. These occupations include those that require workers to perform form socalled exposure-prone procedures (EPPs) and are largely limited to the health care setting. Exposureprone procedures are those that involve digital palpation of a needle tip in a body cavity, the simultaneous presence of the health care worker's (HCW) fingers and a needle or other sharp instrument in a poorly visualized or highly confined space, or having interrupted vision during a surgical procedure. <sup>36</sup> Table 4 presents a list of procedures from different health care-related occupations that are considered to be EPPs. This list, however, is only meant to be a guide. A definitive and exhaustive list of EPPs is not possible because individual working practices and risk of exposure may vary. Evidence from which these classifications were based are weak and relied mostly on case series and expert opinion.

#### Table 4: ExposureProne Procedures (EPPs)

#### A. Surgery

- 1. Abdominal Surgery
  - \* All open surgical procedures, including major organ retrieval
  - \* All laparoscopic procedures that are converted to open procedures
- 2. Ca rdiothoracic surgery
- \* Any open surgical procedure

#### 3. Neurosurgery

- \* Craniotomy and intracranial procedures
- \* Openspine surgery
- 4. Obstetrics and gynecology
  - \* All open surgeries
  - \* Repairs following episio tomies or perineal tears
  - \* All laparoscopic procedures that are converted into open procedures
  - \* Cone biopsies with a scalpel
- 5. Orthopedic surgery
  - \* Open surgical procedure
  - \* Procedures involving the cutting or fixation of bones
  - \* Procedures that involve the distant transfer of tissues from a second site
  - \* Acute hand trauma
  - \* Nail avulsion of toes for in-frowing toenails and Zadek's procedure
  - \* Arthroscopic procedures that are converted into open procedures
- 6. Ophthalmology
- 7. Orbital surgery
- 8. Otorhinolaryngological surgery
  - \* All procedures except simple ear and nasal procedures provided fingertips are always visible, endoscopy provided fingertips are always (cont.)

<sup>&</sup>lt;sup>31</sup> Brunetto MR, Oliveri F, Rocca G, Criscuolo D, Chiaberge E, Capalbo M, David E, Verme G, Bonino F. Natural course and response to interferon of chronic hepatitis B accompanied by antibody to hepatitis B e antigen. Hepatology 1989;10:198202.

<sup>&</sup>lt;sup>32</sup> Fattovich G, Brollo L, Alberti A, Pontisso P, Giustina G, Realdi G. Longterm followup of antiHBepositive chronic active hepatitis B. Hepatology 1988;8:16514.

<sup>&</sup>lt;sup>33</sup> Teh I Huo, Jaw C Wu, Pui C Lee, Gar Y Chau, Wing Y Lui, Shyh H Tsay, Ling T Ting, Full Y Chang, Lee SD. SeroClearance of Hepatitis B Surface Antigen in Chronic Carriers Does Not Necessarily Imply a Good Prognosis. Hepatology 1998; 28:231236.

<sup>&</sup>lt;sup>34</sup> Ahn SH, Park YN, Park JY, Chang HY, Lee JM, Shin JE, Han KH, Park C, Moon YM, Chon CY. Longterm clinical and histological outcomes in patients with spontaneous hepatitis B surface antigen seroclearance. J Hepatol 2005;42:18894.

<sup>&</sup>lt;sup>35</sup> Tobe K, Matsuura K, Ogura T, Tsuo Y, Iwasaki Y, Mizuno M, Yamamoto K, Higashi T, Tsuji T. Horizontal transmission of hepatitis B virus among players of an American football team. Arch Intern Med 2000;160:25415.

<sup>&</sup>lt;sup>36</sup> Recommendations for preventing transmission of human immunodeficiency virus and hepatitis B virus to patients during exposure-prone invasive procedures. MMWR Morb Mortal Wkly Rep 1991;40(RR08);1-9.

#### visible, stapedectomy, stapedotomy, insertion of ventilation tubes, insertion of titanium screw for a boneanchored hearing aid

- 9. Plastic surgery
- \* Extensive cosmetic procedures
- 10. Podiatric surgery
  - \* Any surgery where part of the operator's fingers will be inside the wound and out of view
- 11. Transplantation surgery

## B. Trauma

- 1. Open head injuries
- 2. Ophthalmic trauma
- 3. Vaginal and/or rectal examination in the presence of pelvic fracture
- 4. Deep suturing to arrest internal bleeding
- 5. Open resuscitation efforts including internal cardiac massage Any surgical procedure lasting >3 hours requiring
  - glove change
- C. Anesthesia
  - 1. Placement of portacaths
  - 2. Insertion of chest tubes when a finger has to be inserted into the chest cavity

#### D. Cardiology

- Placement of pacemakers with fingers hidden from view in the presence of sharp instruments during insertion
- E. Nursing
  - 1. Nurses in the operating rooms performing roles as first assist
  - 2. Emergency room nurses
- F. Dentistry
  - All procedures except, examination using mouth mirror only, taking extra-oral radiographs, visual and digital examination of the head and neck, visual and digital examination of the edentulous mouth, taking impressions of edentulous patients, construction and fitting of full dentures
- G. Psychiatry
  - 1. Care of violent and/or biting patient
- \* Modified from Reitsma et al and Department of Health/Health Protection Division/General Health Protection

The lifetime risk of workers performing EPPs to have at least one needle stick injury has been reported to be as high as 76% in nurses<sup>37</sup> and 83% in surgeonsintraining<sup>38</sup>. However, the risk of a needlestick injury occurring in an infected worker per surgical procedure is substantially lower at 6.9%, about a third of which will involve recontact of the instrument with the patient's body cavity. The risk of contact from an infected HCW's blood to the patient per procedure therefore ranges from 2.02% to 2.21%.<sup>39.40</sup>

It is interesting to note that while the risk of transmission from an infected worker to a patient is relatively low, the risk of transmission from an infected patient to a HCW can be as high as 30%,<sup>36</sup> which stresses the need for HBV vaccination in all susceptible health care workers. Table 5 gives a summary of the types of occupations according to the risk of HBV exposure, where Category 1 poses the highest and Category 3 poses the lowest risk of exposure to HBV from infected workers.

Table 5: Categories of occupations according to

risk of HBV exposure from infected workers				
Category 1	Category 2	Category 3		
Health care workers (HCWs) who are performing or who have reasonable expectation of perfor- ming exposure-prone procedures (EPP's)	• HCW's who are not performing or who do no have a reason- able expectation of performing EPP's	Non-HCW     All other     occupations     that do not     fall into     Categories     1 & 2		
Other workers whose occupation involves potential for exchange of bodily fluids (e.g., commercial sex workers)	9			

The infectivity of an HBsAgpositive worker is highly dependent on the serum HBV DNA level and the phase of HBV infection. However, determining a serum HBV DNA cutoff considered safe in the workplace and with a zero probability of HBV transmission is not possible because there are no randomized controlled studies looking at this particular question. In addition, the determination of fluctuations of HBV DNA levels over time and assay variability between laboratories.

Policy statements from other countries have based their recommendations on data extrapolated from studies on vertical and perinatal transmission. In the United Kingdom and Ireland, HCWs who are HBeAg-positive or have HBV DNA greater than 2,000 IU/mL are not allowed to perform EPPs,<sup>10</sup> while in the United States, HBeAg positivity alone is the basis for exclusion from performing EPPs.<sup>9</sup>

We have categorized the infectivity of an HBsAgpositive worker as either high or low according to HBeAg status and HBV DNA level. Table 6 shows the risk of HBV transmission in the workplace, which is a composite of the infectivity of the worker and the risk of exposure according to the type of occupation. Recommendations regarding HBV transmission in the workplace are further discussed in the section on policy statements. A proposed algorithm on the evaluation of HBsAg-positive workers for employment is presented in Figure 1.

<sup>&</sup>lt;sup>37</sup> Kosgeroglu N, Ayranci U, Vardareli E, Dincer S. Occupational exposure to hepatitis infection among Turkish nurses: frequency of needle exposure, sharps injuries and vaccination. Epidemiol Infect 2004;132:2733.

<sup>&</sup>lt;sup>38</sup> Makary MA, AlAttar A, Holzmueller CG, Sexton JB, Syin D, Gilson MM, Sulkowski MS, Pronovost PJ. Needlestick injuries among surgeons in training. N Engl J Med 2007;356:26939.

<sup>&</sup>lt;sup>39</sup> Tokars JI, Bell DM, Culver DH, Marcus R, Mendelson MH, Sloan EP, Farber BF, Fligner D, Chamberland ME, McKibben PS, et al. Percutaneous injuries during surgical procedures. Jama 1992;267:2899904.

<sup>&</sup>lt;sup>40</sup> Bell DM, Shapiro CN, Ciesielski CA, Chamberland ME. Preventing bloodborne pathogen transmission from healthcare workers to patients. The CDC perspective. Surg Clin North Am 1995;75:1189203.

Table 6: Risk of transmission of HBV in relation to exposure risk and infectivity						
Infectivity		OCCUPATION				
	Category 1 *	Category 2 **	Category 3 ***			
High (HBV DNA > 2,000 lU/ml)	High risk of transmission	Low risk of	Nogligible rick of			
Low HBV DNA < 2,000 IU/ml)	Low risk of transmission	transmission ****	transmission ****			

Legend:

\* Health care workers (HCWs) who are performing or who have a reasonable expectation of performing exposure – prone procedures (EPP's). Other workers whose occupation involves potential for exchange of bodily fluids (e.g., commercial sex workers)

\*\* HCW's who are not performing or who do not have a reasonable expectation of performing EPP's

\*\*\* NonHCW. All other occupations that do not fall into Categories 1 or 2

\*\*\*\* HBV DNA determination not a prerequisite

Figure 1: Proposed Algorithm for the evaluation of HBsAg positive workers for employment



Legend:

<sup>\*</sup> Hepatic decompensation or hepatocellular carcinoma

<sup>\*\*</sup> Health care workers (HCWs) who are performing or who have a reasonable expectation of performing exposure-prone procedures (EPP's). Other workers whose occupation involves potential for exchange of bodily fluids (e.g., commercial sex workers)

<sup>\*\*\*</sup> HCW's who are not performing or who do not have a reasonable expectation of performing EPP's and NonHCW

# Evaluation of HBsAg(+) Workers (HSP)

These recommendations are made with the intention to balance the risk of HBV transmission in the workplace and the probability of losing highly-skilled workers due to unduly stringent restrictions. To avoid the loss of highly-skilled workers and minimize the risk of HBV transmission in the workplace, particularly in the health care setting, a study has evaluated the use of antiviral therapy to allow HCWs to resume performing EPPs.41 Potent antiviral therapy for HBV is currently available and data extrapolated from vertical transmission studies suggest that antiviral therapy may be effective in reducing the risk of HBV transmission.<sup>42</sup> However, data on this issue are sparse and inconclusive. No recommendation can be made at this time on the use of antiviral therapy to allow HBsAg-positive HCWs to resume the performance of EPPs. This should be made on a casetocase basis in consultation with a specialist and the respective institutional advisory panel. In addition, there are currently no data on the use of antiviral therapy in infected workers who do not perform EPPs.

# **POLICY STATEMENTS**

#### **Policy Statement 1**

A positive Hepatitis B surface antigen result should not be a basis to discriminate, restrict, or disqualify a job applicant from being gainfully employed. A Hepatitis B positive applicant should not be declared unfit to work and denied employment without appropriate medical evaluation and counseling.

#### **Policy Statement 2**

Hepatitis B screening in the pre-employment setting should NOT be made mandatory. Screening for hepatitis B should be performed only if applying for occupations known to be at high risk for transmission of hepatitis B in the workplace. No screening is recommended for low risk occupations.

#### **Policy Statement 3**

Minimum requirements for a confirmed HBsAg-positive person undergoing pre-employment evaluation should include all of the following tests:

o Serum HBeAg and AntiHBe

o Serum ALT

o Ultrasound of the liver

(Level of Evidence: III-Expert opinion, descriptive epidemiology)

#### **Policy Statement 4**

If the HBsAg is positive, HBeAg is positive, and ALT is normal, the person is likely to have chronic HBV infection (Immune Tolerant Phase)

(Level of Evidence: II-2 Cohort or casecontrolled analytic studies)

Monitoring of ALT levels should be performed every 3 to 6 months. Referral to a specialist may be considered for further evaluation and management.

(Level of Evidence: III-Expert opinion, descriptive epidemiology)

#### **Policy Statement 5**

If the HBsAg is positive, HBeAg is positive, and the ALT is greater than normal, then the person is likely to have

HBeAg positive chronic hepatitis B (Immune Clearance Phase).

(Level of Evidence: II-2 Cohort or casecontrolled analytic studies)

Serum HBV DNA determination using a PCR-based assay is recommended. Other causes of elevated ALT levels should be considered. Those persons with high HBV DNA levels and abnormal ALT may be eligible for treatment. Referral to a specialist may be an option.

(Level of Evidence: III-Expert opinion, descriptive epidemiology)

#### **Policy Statement 6**

If the HBsAg is positive, HBeAg is negative, anti-HBe is positive and ALT is greater than normal, then the person is likely to have HBeAg negative chronic hepatitis B.

(Level of Evidence: II-2 Cohort or casecontrolled analytic studies)

Serum HBV DNA determination using a PCR-based assay is recommended. Other causes of elevated ALT levels should be considered. Those persons with high HBV DNA levels and abnormal ALT may be eligible for treatment. Referral to a specialist may be an option.

(Level of Evidence: III-Expert opinion, descriptive epidemiology)

#### Policy Statement 7

If the HBsAg is positive, HBeAg is negative and the antiHBe is positive and ALT is normal, this person is likely to have chronic HBV infection, inactive HBsAg carrier state. A serum HBV DNA <2,000 IU/mL strongly supports the diagnosis.

(Level of Evidence: II-2 Cohort or casecontrolled analytic studies)

Monitoring of the serum ALT every 6 to 12 months is recommended. Referral to a specialist should be considered when the serum ALT becomes persistently elevated. Other causes of elevated ALT levels should also be considered.

(Level of Evidence: III-Expert opinion, descriptive epidemiology)

#### **Policy Statement 8**

If the ultrasonographic finding of the liver is abnormal, appropriate management should be instituted

(Level of Evidence: III-Expert opinion, descriptive epidemiology)

#### **Policy Statement 9**

A. For Category 1 occupations (refer to Table 5) All HBsAg-positive persons should have mandatory HBVDNA testing.

(Level of Evidence: II-2 - Cohort or case-controlled analytic studies)

a. If HBV DNA is □2,000 IU/mL, they are cleared for employment with work restrictions.

(Level of Evidence: II-3 - Multiple case series, dramatic (Level of Evidence: III-Expert opinion, descriptive epiuncontrolled experiments) demiology) They are not allowed to perform EPPs. due to high risk 3. Not cleared for employment (state specific reason) of HBV transmission. **Policy Statement** 11 (Level of Evidence: III - Expert opinion, descriptive The attending physician should educate the patient on epidemiology) the following: - current status of hepatitis B infection, b. If HBV DNA is <2,000 IU/ml, they are cleared for - modes of transmission employment with no work restrictions due to low risk of - adherence to standard precautions (refer to Table 1), HBV transmission. - risk of transmission, risk for complications - the need for monitoring (Level of Evidence: III-Expert opinion, descriptive epi-- screening of first degree relatives, close personal and demiology) household contacts - options for treatment when deemed appropriate In all HBsAg positive HCWs performing EPP 's, annual HBV D DNA testing is recommended. If HBVDNA Policy Statement 12 becomes 2,000 IU/ml they should not be allowed to The hepatitis B status of a job applicant or employee perform EPPs. should be kept confidential. (Level of Evidence: III-Expert opinion, descriptive epi-Policy Statement 13 demiology) Each healthcare institution is encouraged to form an Advisory Panel to discuss issue s on Hepatitis B and B. For Category 2 and 3 occupations (refer to Table 5) employment particularly those not covered by these a. All HBsAgpositive persons are cleared for employquidelines. ment with no work restrictions due to negligible risk of REFERENCES HBV transmission. (Level of Evidence: III-Expert opinion, descriptive epi-Ahn SH, Park YN, Park JY, Chang HY, Lee JM, Shin JE, Han KH, Park demiology) C, Moon YM, Chon CY. Longterm clinical and histological outcomes in patients with spontaneous hepatitis B surface antigen seroclearance. J Hepatol 2005;42:18894. b. Serum HBV DNA testing is not a prerequisite for Bell DM, Shapiro CN, Ciesielski CA, Chamberland ME. Prevent ing employment. bloodborne pathogen transmission from healthcare workers to patients. (Level of Evidence: III-Expert opinion, descriptive epi-The CDC perspective. Surg Clin North Am 1995;75:1189203. demiology) Brunetto MR, Oliveri F, Coco B, Leand ro G, Colo mbatto P, Gorin JM, Bonin o F. 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