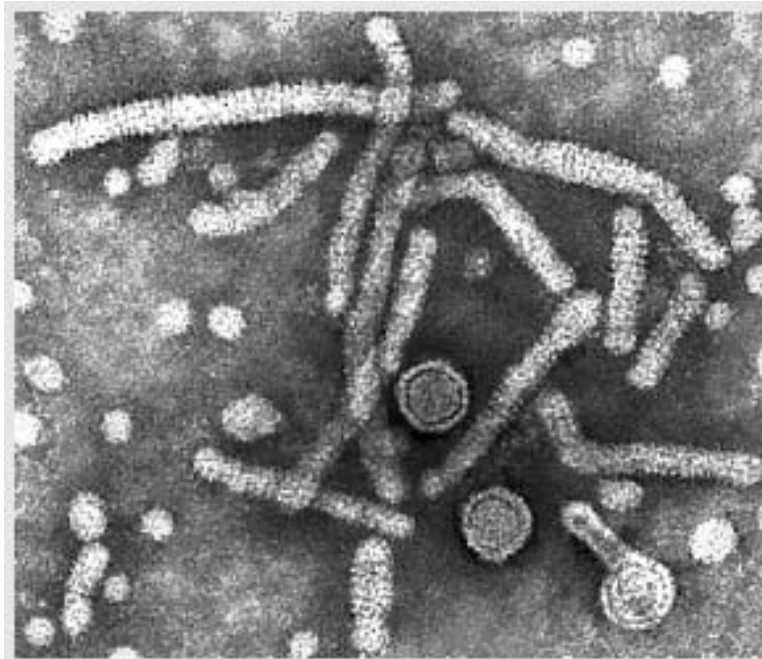


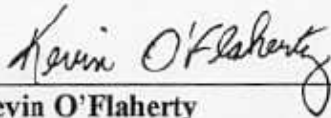
GWYNEDD MERCY UNIVERSITY
Bloodborne Pathogen
Safety and Awareness Plan



Developed October 2006 in accordance
with the OSHA Bloodborne Pathogens Standard, 29 CFR 1910.1030
H. A. Oliver-Kozup
Revised 2013
University Update 2014

GWYNEDD MERCY UNIVERSITY
BLOODBORNE PATHOGEN SAFETY
AND AWARENESS PLAN

This plan meets the recommended best management and training practices set forth by the OSHA Bloodborne Pathogen Standard 29 CFR 1910.1030. It is approved by the undersigned individuals who are in part responsible for its implementation at Gwynedd Mercy University.



Kevin O'Flaherty
Vice President of Finance and Administration

12/06/06

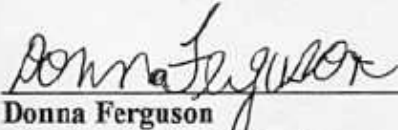
Date



Heaven Kozup
Environmental Safety and Laboratories Manager

11/9/06

Date



Donna Ferguson
Director of Health Services

12/6/06

Date

GWYNEDD MERCY UNIVERSITY

BLOODBORNE PATHOGEN SAFETY AND AWARENESS PLAN

PURPOSE

Gwynedd Mercy University recognizes the importance of providing of safe working environment for all employees which includes minimizing any potential exposure to health hazards. The purpose of this safety and awareness plan is to 1) educate our employees on bloodborne pathogens and their risk potential; 2) to eliminate or minimize employee occupational exposure to *blood* or other infectious body fluids; and 3) to maintain continuous OSHA Bloodborne Pathogen (BBP) Standard 29 CFR 1910.1030 compliance. A copy of the BBP standard summary is found at the end of this manual and can be accessed on the OSHA website www.osha.gov.

The Bloodborne Pathogen Standard addresses safety and prevention of diseases caused by bloodborne pathogens that have the potential to be present in the workplace. Two diseases specifically covered by the standard are Hepatitis B (HBV) and the Human Immunodeficiency virus (HIV). Both HBV and HIV are caused by viruses and are present in blood and other potentially infectious materials (OPIM). OPIM addressed by this plan include the following:

- ❖ semen
- ❖ vaginal secretions
- ❖ cerebrospinal fluid
- ❖ synovial fluid
- ❖ pleural fluid
- ❖ peritoneal fluid
- ❖ amniotic fluid
- ❖ saliva in dental procedures
- ❖ Urine (when contaminated with blood)

RESPONSIBILITY

Departmental supervisors shall be responsible for ensuring their employees comply with the provisions of this plan. Individual departments are responsible for providing all necessary supplies to their personnel, with direction from the Environmental Safety Manager (ESM), such as all personal protective equipment, soap, bleach, hand washing and eyewash facilities. These supplies should be readily available at any given time in each department. The ESM shall be responsible for the coordination of training all employees with potential exposure to bloodborne pathogens, for the disposal of biohazard waste contained in biohazard bags and sharps containers, and for the coordination of the hepatitis vaccination process. The Health Services Center is responsible for the arrangement of any post-exposure evaluation.

BEST MANAGEMENT PRACTICES

Universal precautions will be observed by all employees in order to prevent contact with blood or OPIM. *All blood or other potentially infectious materials will be considered infectious regardless of the source.* Best management practices will be implemented to eliminate or minimize exposure of employees working at Gwynedd Mercy University in high risk areas.

- ❖ Employees must wash their hands or other skin with soap and water, or flush mucous membranes with water, as soon as possible following an exposure incident (such as a splash of blood to the eyes or an accidental needle stick).

- ❖ Employees must wash their hands immediately (or as soon as feasible) after removal of gloves or other personal protective equipment.
- ❖ Employees shall familiarize themselves with the nearest hand washing facilities, eyewash stations, and emergency showers for the buildings in which they work. Because most GMERCYU buildings are public access, they will have available hand washing facilities in public restrooms and custodial/janitorial closets. *(If hand washing and eyewash facilities are not available, please notify the ESM. Upon notification, either an antiseptic cleanser in conjunction with clean cloth/paper towels or antiseptic cloths will be provided until more permanent facilities are installed. If these alternatives are used, then the hands are to be washed with soap and water as soon as possible.)*
- ❖ Employees who encounter improperly disposed needles must notify ESM of the location of the needle(s). Additionally, the appropriate authorities at the location shall be notified. These needles must not be moved or recapped by any employee. If sharps containers are not available at that location, ESM will pick up and dispose of the needles in an appropriate labeled sharps container and/or provide sharps containers for additional needs.
- ❖ Breaking or shearing of needles is prohibited.
- ❖ No eating, drinking, smoking, applying cosmetics or lip balm, or handling contact lenses is allowed in a work area where there is a reasonable likelihood of occupational exposure.
- ❖ No food or drinks shall be kept in refrigerators, freezers, cabinets, shelves, or on counter tops or bench tops where blood or other potentially infectious materials are present.

GENERAL HOUSEKEEPING AND DISPOSAL METHODS

Any potentially contaminated surfaces may be decontaminated using any of the following available materials on location. If these materials are not available in your facility, please notify the ESM. Each department supervisor is responsible for providing these agents in locations of potential contamination. Decontamination agents include:

- 70% Alcohol solution
- 25% Lysol solution
- 10% Bleach solution
- Other EPA approved agents
- ❖ All contaminated work surfaces, tools, objects, etc. will be decontaminated immediately or as soon as feasible after any spill of blood or other potentially infectious materials. The above disinfectants must be left in contact with contaminated work surfaces, tools, objects, or potentially infectious materials for at least 10 minutes before cleaning.
- ❖ Equipment that may become contaminated with blood or other potentially infectious materials will be examined and decontaminated before servicing or use.
- ❖ Broken glassware will not be picked up directly with the hands. Sweep or brush material into a dustpan. Personal protective equipments including gloves, goggles, and face mask must be worn if this instance occurs.

- ❖ Known or suspected contaminated sharps shall be discarded immediately or as soon as feasible in containers that are closable, puncture-resistant, leak-proof on sides and bottom, and marked with an appropriate biohazard label. If sharps containers are not pre-labeled, biohazard labels are available through ESM.
- ❖ When containers of contaminated sharps are being moved from the area of use or discovery, the containers shall be closed immediately before removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.
- ❖ Sharps containers must not be opened, emptied, cleaned manually, or manipulated in any other manner that would expose employees to potential injury bloodborne pathogens.

BIOHAZARD WASTE

All biohazard waste shall be placed in containers that are closable, constructed to contain all contents, and prevent leakage of fluids during handling, storage, transportation or shipping. The waste must be labeled and double bagged in red biohazard marked bags which will then be transferred to a large biohazard box in KH 216. Biohazard bags, boxes, and labels are available through the ESM. Disposal of biohazard waste is conducted by the company, Stericycle, with a monthly disposal schedule.

LAUNDRY PROCEDURES

Laundry contaminated with blood or OPIM will be handled as little as possible. Such laundry will not be sorted or rinsed in the area of use. Contaminated laundry must be reported to the ESM and the coordination of its disposal will be arranged with as little employee exposure as possible.

PERSONAL PROTECTIVE EQUIPMENT

Where occupational exposure is identified, the proper personal protective equipment will be available and enforced by the department supervisors and overseen by the ESM. Each department will provide gloves, face shields, masks, eye protection, and aprons at no cost to employees upon evaluation of risk exposure. Personal protective equipment will be repaired or replaced as necessary at no cost to employees. All personal protective equipment will be chosen based on the anticipated exposure to blood or other potentially infectious materials. The protective equipment will be considered appropriate only if it does not permit blood or other potentially infectious materials to pass through or reach the employee's clothing, skin, eyes, mouth, or mucous membranes under normal conditions of use and for the duration of time for which the protective equipment will be used.

Employees must:

- ❖ Utilize protective equipment in occupational exposure situations.
- ❖ Remove garments that become penetrated by blood or other potentially infectious material immediately or as soon as feasible.
- ❖ Replace all garments that are torn, punctured, or that lose their ability to function as a barrier to bloodborne pathogens.
- ❖ Remove all personal protective equipment before leaving the work area.

- ❖ Place all garments in the appropriate designated area or container for storage, decontamination, and/or disposal.

HEPATITIS B VACCINE

The HBV vaccination will be made available to any employee with the potential occupational exposure to bloodborne pathogens at no cost to the employee. The HBV Vaccine shall be offered to all staff working in the following departments upon evaluation of their risk of bloodborne pathogen exposure:

Environmental Safety	Health Services	Nursing
Public Safety and Security	Athletics	Natural Sciences/Math
Plant Services	Allied Health	Resident Life
Hobbit House		

The vaccination may be declined if 1) the employee has previously received the complete HBV vaccination series, 2) antibody testing has revealed that the employee is immune, or 3) there are medical or personal reasons to do so. If the employee initially declines the HBV vaccination, but at a later date decides to accept the vaccination, the vaccine shall then be made available. All employees whether accepting or declining the vaccine offer must sign the OSHA-required Gwynedd Mercy University Agreement/Refusal Contract indicating their preference.

POST-EXPOSURE PROCEDURES

All exposure incidents shall be reported, investigated, and documented immediately by the department supervisor and the Environmental Safety Manager. Following the completion of the Exposure Incident report found in this document, the exposed employee shall go to Health Services for a confidential medical evaluation including the following elements.

- ❖ Documentation of the route(s) of exposure.
- ❖ A description of the circumstances under which the exposure occurred.
- ❖ The identification and documentation of the source individual. (The identification is not required if the employer can establish that identification is impossible or prohibited by state or local law)
- ❖ The collection and testing of the source individual's blood for HBV and HIV serological status.
- ❖ Post-exposure treatment for the employee, when medically indicated in accordance with the U.S. Public Health Service.
- ❖ Counseling
- ❖ Evaluation of any reported illness

A licensed healthcare professional evaluating an employee will be provided with the following:

- ❖ A copy of this plan and completed Exposure Incident Report

- ❖ Results of the source individual's blood testing, if available.
- ❖ All medical records applicable to treatment of the employee, including vaccination status.

The employee will receive a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation. The healthcare professional's written opinion for HBV vaccination is limited to the following:

- ❖ Whether the employee needs Hepatitis B vaccination;
- ❖ Whether the employee has received such a vaccination.

The healthcare professional's written opinion for post-exposure evaluation and follow-up is limited to the following information:

- ❖ That the employee was informed of the results of the evaluation.
- ❖ That the employee was informed about any medical conditions resulting from exposure to blood or other infectious materials that require further evaluation or treatment.

All other findings or diagnoses will remain confidential and will not be in a written report and kept in accordance with 29 CFR 1910.1030. All medical evaluations shall be made by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional. All laboratory tests must be conducted by an accredited laboratory at no cost to the employee. All medical records will be kept for the duration of the exposed employee's employment plus 30 years.

BBP SAFETY TRAINING

All high-risk employees shall participate in a training program. Training will occur before assignment to a task where occupational exposure may take place and at least annually thereafter. Additional training will be provided when changes such as modification of tasks or procedures affect the employee's occupational exposure. Any employee who is exposed to infectious materials shall receive training, even if the employee was allowed to receive the HBV vaccine after exposure. The training program will include at least the following elements:

- ❖ A written copy of GMERCYU's Bloodborne Pathogen Safety and Awareness Plan along with access to the regulatory text 29 CFR 1910.1030.
- ❖ A general explanation of the epidemiology and symptoms of bloodborne diseases.
- ❖ An explanation of the modes of transmission of bloodborne pathogens.
- ❖ An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood or other potentially infectious materials.
- ❖ An explanation of the best management practices that will prevent or reduce exposure.

- ❖ Information on the types, proper use, location, removal, handling, decontamination, and disposal of personal protective equipment.

EMPLOYEE EXPOSURE-POTENTIAL EVALUATION

The following is a list of all GMERCYU job classifications in which employees in the following departments may have high-risk occupational exposure to bloodborne pathogens. Those employees who are determined to have occupational exposure to blood or OPIM must comply with the procedures and work practices outlined in this Bloodborne Pathogen Safety and Awareness Plan. All full-time, part-time, temporary, contract and per diem employees are covered by the standard.

Job Title	Dept/Location	Tasks/Procedures
Director/Supervisor	*All Involved Depts.	Risk Management
Env. Safety Manager	Environmental Safety	Risk Management
Lab Manager	Natural Sciences/Math	Handles biohazard waste
Campus Nurse	Health & Wellness Center	Handles biohazard waste/sharps
Lab Assistants	Natural Sciences/Math	Handles biohazard waste
Custodian/Housekeeper	Plant Services	Handles contaminated laundry/waste
Athletic Trainer	Athletics	Handles contaminated laundry/sharps
Instructors	Hobbit House	Handles potential infected laundry
Security Guard	Public Safety	Potential first responder

*Directors/Supervisors of each department that accommodates job classifications with potential infectious fluid exposure must have bloodborne pathogen training in order to provide the proper means of hazard communication, department-specific training, and regulatory authority for each job classification.

**GWYNEDD MERCY UNIVERSITY
HEPATITIS B VACCINATION AGREEMENT/REFUSAL FORM**

The hepatitis B vaccine is provided free of charge to Gwynedd Mercy University employees who are exposed to human material including blood, blood products, body fluids, tissues, cell lines, or other potentially infectious material (OPIM) in the course of conducting their job responsibilities. Federal regulations require that employers notify employees who are “at risk” that they have the right to be vaccinated. Although vaccination is optional, employers are required to confirm that their employees have been notified of this right.

The vaccination series is available through the healthcare provider Patient First. You will be issued an authorization form to set up your own vaccine schedule. If enough employees accept this vaccine, it will be administered on campus at a designated location, date, and time. You must be present at this time to receive services. Should you not be available or able to receive the vaccination at this time, you may go to one of the Patient First locations listed below, by appointment, to obtain the missed inoculation. Travel to and from these medical centers will not be provided by Gwynedd Mercy University.

<i>Hours: Call to set up an appointment</i>	<i>Rte. 309, just north of the Five Points intersection 713 Bethlehem Pike Montgomeryville, PA 18936</i>	<i>(267) 695-3944</i>
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PLEASE CHECK ANY OF THE FOLLOWING THAT APPLY:

I **accept** the offer of the hepatitis B vaccination. I understand that it will be provided at no charge to me and that it is comprised of a series of three inoculations. In the event that I do not complete the series, Gwynedd Mercy University reserves the right to request reimbursement for costs pertaining to missed inoculations if these inoculations have been prepaid by the University.

I have **previously completed** a hepatitis B vaccination series and have laboratory confirmation of immunity.

I understand that Gwynedd Mercy University does provide the hepatitis B antibody titer **follow-up evaluation** after completion of the vaccine series. I am interested in a voucher for this test.

I understand that due to my occupational exposure to blood or other potentially infectious material, I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with the hepatitis B vaccine at no charge. However, I **decline** the hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If I continue to have occupational exposure to blood or OPIM and wish to be vaccinated with hepatitis B vaccine in the future, I can receive the vaccination at no charge at one of the above Patient First locations.

ADDITIONAL ATTESTATIONS

I understand that my acceptance or refusal to be vaccinated does not affect my health benefits or employment status. I recognize that I will be required to follow established safety procedures regardless of my vaccination status. I understand that Gwynedd Mercy University is not liable for pre-existing infections that any employee has at the time of his or her employment with the University. I understand that I also have the right to be tested for HIV if I am exposed to blood or bodily fluids. However, the HIV test will be conducted separately only upon my request, and not as part of the hepatitis B screening process.

Employee Name:	Job Title:
Employee Signature:	Date:

EXPOSURE INCIDENT REPORT

This form must be completely filled out after any employee exposure incident. This form is to remain confidential and placed in employee's medical records for the remainder of employment plus 30 years.

EXPOSED EMPLOYEE

Name Employee Number (if applicable)

Date of Incident Type of Incident

Employee's Duties as they relate to the incident:

Description of exposure routes and circumstances under which incident occurred:

Check appropriate responses below:

Yes No Exposed employee has been counseled as to applicable laws and regulations concerning disclosure of the identity and infectious status of the source patient.

Yes No Exposed employee has legally consented to blood testing.

Yes No Exposed employee has agreed to have baseline blood collection, but does not give consent at this time for HIV serologic testing and understands that the sample shall be preserved for 90 days in case employee decides to complete testing.

MEDICAL ATTENTION

The exposed employee was referred to the following doctor for medical evaluation, counseling and follow-up:

Name

Address/Phone

Date of Exam

Date of Follow-up

Exposed employee's Vaccination records were made available to the attending doctor on:

A copy of the doctor's written opinion was delivered to the employee on:

SOURCE PATIENT

Name	Phone
------	-------

Address

City	State	Zip Code
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Check appropriate responses below:

- Yes No Source Patient has legally consented to have his/her blood tested for HIV and HBV infectivity.
- Yes No Legally required consent cannot be obtained.
Reason: _____
- Yes No Source Patient is known to be infected with HBV.
- Yes No Source Patient is known to be infected with HIV.
- Yes No Results of source patient's tests have been made to the exposed employee.

RECORD KEEPING

The following items will be maintained IN STRICT CONFIDENTIALITY and not disclosed without the employee's expressed written consent to anyone within or outside the workplace.

Records must be kept for duration of employment plus 30 (thirty) years.

1. The employee Exposure Incident Report.
2. A record of the employee's hepatitis B vaccination status including the dates of all vaccinations and any medical records relative to the employee's ability to receive vaccination.
3. A copy of all results of examinations, medical testing and follow-up procedures
4. The employer's copy of all results of the Healthcare professional's written opinion.
5. Identity of source patient and source patient's blood test results.

Form Completed by:

Name	Title
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Exposed Employee Signature	Date
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Employer Signature	Date
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**Gwynedd Mercy University
Bloodborne Pathogen Safety and Awareness Plan
Department-Specific Training**

Bloodborne Pathogens

Bloodborne Pathogens Refresher Training

_____ has completed the following training as required by the
(Print Employee's Name Here)

Bloodborne Pathogen Standard (29 CFR 1910.1030) on _____:
(Date of Training)

Supervisors:

In order to complete the training requirements of the Bloodborne Pathogens Standard (29 CFR 1910.1030), please review the department specific training items listed below with the employee. Please check each item as it is reviewed or write N/A if it is not applicable to your work area. Once completed, please sign and date the bottom of the checklist. Keep a copy of the completed form for your files. Return the original to: Environmental Safety Manager, KH 236. Once the form is received, the employee's training will be documented and a training certificate will be issued. Thank you for your cooperation and assistance.

Specific Work Practices

Please discuss with your employee the specific tasks that may involve the potential for exposure to bloodborne pathogens using the below categories. Be sure to provide your employees with the proper PPE and knowledge of the operations for engineering controls in their department or work area.

Personal Protective Equipment (PPE)

- _____ Explanation of what kinds of PPE are required for specific tasks
- _____ How to use the PPE
- _____ Location and Availability of PPE
- _____ Maintenance and reusable PPE (cleaning, storage, and inspection)

Engineering Controls

- _____ Location and operation of eyewash facilities
- _____ Explanation of engineering controls that are specific to the work environment (e.g., sharps containers, biological safety cabinets, mechanical pipettes, safer sharps devices, etc)

Biohazard Waste Handling

- _____ Discussion and clarification of which wastes generated in the work area are biohazard and how those items are to be segregated, stored, transported, treated, and disposed of.

- _____ Review of procedures for on-site treatment methods (e.g., proper use of autoclave for waste decontamination purposes)
- _____ Review of hazardous waste labeling and Pick-up procedures as they apply to the work area.

Spill Response/Exposure Incident Response/Exposure Control Plan

- _____ Review of work area’s procedure for handling spills of potentially infectious materials (including the location and availability of biohazard spill kits)
- _____ Review of exposure incident response procedure
- _____ Location of the Gwynedd Mercy University BBP Safety and Awareness Plan

Verification of Training

I certify that the employee above has received BBP Department-Specific Training as required by 29 CFR 1910.1030 and the Gwynedd Mercy University Bloodborne Pathogen Safety and Awareness Plan.

Department Name: _____

Employee Name (printed)

Employee Signature/Date

Supervisor Name (printed)

Supervisor Signature/Date

The “Hepatitis B Fact Sheet” and the “Hepatitis B Vaccine – What You Need to Know” documents contained in the following pages have been provided by the World Health Organization and the U.S. Department of Health and Human Services as public access for information and training purposes on HBV and the HBV vaccine.

HEPATITIS B

Hepatitis B is one of the major diseases of mankind and is a serious global public health problem. It is preventable with safe and effective vaccines that have been available since 1982. Of the 2 billion people who have been infected with the Hepatitis B virus (HBV), more than 350 million have chronic (lifelong) infections. These chronically infected persons are at high risk of death from cirrhosis of the liver and liver cancer, diseases that kill about one million persons each year. Although the vaccine will not cure chronic hepatitis, it is 95% effective in preventing chronic infections from developing, and is the first vaccine against a major human cancer. In 1991, the World Health Organization (WHO) called for all children to receive the Hepatitis B vaccine, and 116 countries have added this vaccine to their routine immunization programs.

WHAT IS HEPATITIS?

Hepatitis means *inflammation (itis) of the liver (hepa)*. The most common cause of this inflammation is from one of five viruses called Hepatitis A, B, C, D, and E. All of these viruses can cause an acute disease with symptoms lasting several weeks including yellowing of the skin and eyes (jaundice), dark urine, extreme fatigue, nausea, vomiting and abdominal pain. These symptoms are sometimes sporadic over several months. Hepatitis B virus can cause chronic and many years later develops cirrhosis of the liver or liver cancer. HBV is the most serious type of viral hepatitis and the only type causing chronic hepatitis for which a vaccine is available.

WHO IS AT RISK FOR HEPATITIS B?

Hepatitis B virus is transmitted by contact with blood or body fluids of an infected person in the same way as human immunodeficiency virus (HIV), the virus that causes AIDS. However, HBV is 50 to 100 times more infectious than HIV.

The main ways of getting infected with HBV are:

- Perinatal (from mother to baby at the birth)
- Open wound to infectious fluid transmission
- Unsafe injections and transfusions
- Sexual contact

Worldwide, most infections occur from infected mother to child, from child to child contact in household settings, and from reuse of needles and syringes.

In many industrialized countries (e.g. Western Europe and North America), the pattern of transmission is different. In these countries, mother-to-infant and child-to-child transmission account for up to one third of chronic infections before childhood hepatitis B vaccination programs were implemented. However, the majority of infections in these countries are acquired during young adulthood by sexual

activity and injection drug use. In addition, Hepatitis B virus is the major infectious, occupational hazard of health workers. Most health care workers have received hepatitis B vaccine.

Hepatitis B virus is not spread by contaminated food or water. Additionally, it cannot be spread casually in the workplace. However, employers must provide protection against the virus when the employee has the potential to come into contact with infectious fluid. Custodians and first responders in medical emergencies are of priority.

WHAT ARE THE SIGNS AND SYMPTOMS OF HEPATITIS B?

The incubation period averages six weeks but may be as long as six months. Infection in young children usually is asymptomatic. However, a larger proportion of children may become chronic carriers compared to adults. People who do show symptoms may feel weak and may experience stomach upsets and other flu-like symptoms. They may also have very dark urine or very pale stools. Jaundice is common (yellow skin or a yellow color in the whites of the eyes). The symptoms may last several weeks or months. A laboratory blood test is required for confirmation. Most acute infections in adults are followed by complete recovery. However, many children become chronic carriers. People who recover from acute Hepatitis B (and who do not become chronic carriers) are protected from becoming infected again throughout their lives.

CAN CHRONIC HEPATITIS B AND LIVER CANCER BE TREATED?

Liver cancer is almost always fatal, and usually develops between 35 and 65 years of age. In developing countries, most people with liver cancer die within months of diagnosis. In industrialized countries, surgery and chemotherapy can prolong life up to a few years. Chronic Hepatitis B in some patients is treated with drugs called *interferon* or *lamivudine*, which can help some patients. However, *interferon* or *lamivudine* therapy is expensive and will never be available to most patients in developing countries. Patients with cirrhosis are sometimes given liver transplants, with varying success. For Hepatitis B, prevention is the key.

HOW SAFE IS HEPATITIS B VACCINE AND WHAT ARE ITS POTENTIAL SIDE-EFFECTS?

The Hepatitis B vaccine is one of the safest vaccines. Mild reactions include:

- **Soreness:** About 15% of adults and 5% of children have tenderness, redness, or mild swelling at the injection site.
- **Fever:** About 1% to 6% of those who receive the vaccine develop a mild fever that lasts one or two days after injection of the vaccine.

Reactions and complications due to the vaccine are rare. Allergic reactions, such as a rash, difficulty in breathing, and choking, occur about once every 600,000 doses. No fatal allergic reaction has been reported.

KEY POINTS AND VACCINE SUMMARY

- There are about 350 million carriers of Hepatitis B virus worldwide. Most of them are unaware they are carriers.
- People who carry the virus often have no symptoms.

- The Hepatitis B virus is often spread through unsafe injection practices and needle stick injuries.
- Most infants born to mothers who are carriers are at risk of being infected.
- All children should receive Hepatitis B vaccine starting at birth or at the age of four to six weeks.
- A chronic carrier is more likely to develop severe chronic liver disease or liver cancer in later life.

VACCINE SUMMARY

- **Type of vaccine:** Recombinant DNA or plasma-derived
- **Number of doses:** Three doses
- **Booster:** None
- **Contraindications:** Anaphylactic reaction to a previous dose
- **Adverse reactions:** Local soreness and redness, rarely anaphylactic reaction
- **Special precautions:** Birth dose must be given if there is a risk of perinatal transmission
- **Dosage:** 0.5ml
- **Injection site:** Outer mid-thigh (infants)/outer upper arm (children and adults)
- **Injection type:** Intramuscular

HOW SAFE AND EFFECTIVE IS THE VACCINE?

Hepatitis B vaccine has an outstanding record of safety and effectiveness. Since 1982, over one billion doses of the vaccine have been used worldwide. The vaccine is given as a series of three intramuscular doses. Studies have shown that the vaccine is 95% effective in preventing children and adults from developing chronic infection if they have not yet been infected. In many countries where 8% to 15% of children become chronically infected with HBV, the rate of chronic infection has been reduced to less than 1% in immunized groups of children.

HOW IS WHO TRYING TO CONTROL HEPATITIS B?

Since 1991, WHO has called for all countries to add Hepatitis B vaccine into their national immunization programs. As of March 2000, 116 countries had included the vaccine in their national programs including most countries in Eastern and Southeast Asia, the Pacific Islands, Australia, North and South America, Western Europe and the Middle East. However, many low income countries in sub-Saharan Africa, the Indian subcontinent and in the Newly Independent States do not use the vaccine. The price of the vaccine has been one of the main obstacles to its introduction in many of these countries.

The Global Alliance for Vaccines and Immunization (GAVI) was created in 1999. It is a unique coalition of public and private institutions where WHO has taken a leading role. The main mission of GAVI is to vaccinate as many children as possible against vaccine-preventable diseases. GAVI has introduced a new approach to international health funding: the Global Fund for Children's Vaccines (GFCV). This fund will help 74 low-income countries to reinforce their national vaccine programs and introduce Hepatitis B, Yellow fever and *Haemophilus influenzae* type b (Hib) vaccines into their national immunization programs.

HEPATITIS B VACCINE

WHAT YOU NEED TO KNOW

1 Why get vaccinated?

Hepatitis B is a serious disease.

The hepatitis B virus (HBV) can cause short-term (acute) illness that leads to:

- loss of appetite
- diarrhea and vomiting
- tiredness
- jaundice (yellow skin or eyes)
- pain in muscles, joints, and stomach

It can also cause long-term (chronic) illness that leads to:

- liver damage (cirrhosis)
- liver cancer
- death

About 1.25 million people in the U.S. have chronic HBV infection.

Each year it is estimated that:

- 80,000 people, mostly young adults, get infected with HBV
- More than 11,000 people have to stay in the hospital because of hepatitis B
- 4,000 to 5,000 people die from chronic hepatitis B

Hepatitis B vaccine can prevent hepatitis B. It is the first anti-cancer vaccine because it can prevent a form of liver cancer.

2 How is hepatitis B virus spread?

Hepatitis B virus is spread through contact with the blood and body fluids of an infected person. A person can get infected in several ways, such as:

- by having unprotected sex with an infected person
- by sharing needles when injecting illegal drugs
- by being stuck with a used needle on the job
- during birth when the virus passes from an infected mother to her baby

About 1/3 of people who are infected with hepatitis B in the United States don't know how they got it.

Hepatitis B

7/11/2001

3 Who should get hepatitis B vaccine and when?

- 1) Everyone 18 years of age and younger
- 2) Adults over 18 who are at risk

Adults at risk for HBV infection include:

- people who have more than one sex partner in 6 months
- men who have sex with other men
- sex contacts of infected people
- people who inject illegal drugs
- health care and public safety workers who might be exposed to infected blood or body fluids
- household contacts of persons with chronic HBV infection
- hemodialysis patients

If you are not sure whether you are at risk, ask your doctor or nurse.

- ✓ **People should get 3 doses of hepatitis B vaccine according to the following schedule.** *If you miss a dose or get behind schedule, get the next dose as soon as you can. There is no need to start over.*

Hepatitis B Vaccination Schedule		WHO?		
		Infant whose mother is infected with HBV	Infant whose mother is not infected with HBV	Older child, adolescent, or adult
WHEN?	First Dose	Within 12 hours of birth	Birth - 2 months of age	Any time
	Second Dose	1 - 2 months of age	1 - 4 months of age (at least 1 month after first dose)	1 - 2 months after first dose
	Third Dose	6 months of age	6 - 18 months of age	4 - 6 months after first dose

- The second dose must be given at least 1 month after the first dose.
- The third dose must be given at least 2 months after the second dose and at least 4 months after the first.
- The third dose should *not* be given to infants under 6 months of age, because this could reduce long-term protection.

Adolescents 11 to 15 years of age may need only two doses of hepatitis B vaccine, separated by 4-6 months. Ask your health care provider for details.

Hepatitis B vaccine may be given at the same time as other vaccines.

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Some people should not get hepatitis B vaccine or should wait

People should not get hepatitis B vaccine if they have ever had a life-threatening allergic reaction to baker's yeast (the kind used for making bread) or to a previous dose of hepatitis B vaccine.

People who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting hepatitis B vaccine.

Ask your doctor or nurse for more information.



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What are the risks from hepatitis B vaccine?

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of hepatitis B vaccine causing serious harm, or death, is extremely small.

Getting hepatitis B vaccine is much safer than getting hepatitis B disease.

Most people who get hepatitis B vaccine do not have any problems with it.

Mild problems

- soreness where the shot was given, lasting a day or two (up to 1 out of 11 children and adolescents, and about 1 out of 4 adults)
- mild to moderate fever (up to 1 out of 14 children and adolescents and 1 out of 100 adults)

Severe problems

- serious allergic reaction (very rare)

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What if there is a moderate or severe reaction?

What should I look for?

Any unusual condition, such as a serious allergic reaction, high fever or unusual behavior. Serious allergic

reactions are extremely rare with any vaccine. If one were to occur, it would be within a few minutes to a few hours after the shot. Signs can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS web site at www.vaers.org, or by calling 1-800-822-7967.

VAERS does not provide medical advice

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The National Vaccine Injury Compensation Program

In the rare event that you or your child has a serious reaction to a vaccine, a federal program has been created to help you pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit the program's website at www.hrsa.gov/osp/vicp

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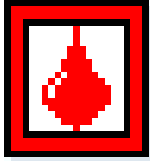
How can I learn more?

- Ask your doctor or nurse. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department's immunization program.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or 1-888-443-7232
 - Visit the National Immunization Program's website at www.cdc.gov/nip or CDC's Division of Viral Hepatitis website at www.cdc.gov/hepatitis



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Disease Control and Prevention
National Immunization Program

Vaccine Information Statement
Hepatitis B (7/11/01) 42 U.S.C. § 300aa-26



SUMMARY OF OSHA'S BLOODBORNE PATHOGENS STANDARD

In March 1992, OSHA's Bloodborne Pathogen Standard, 29 CFR 1910.1030 took effect. This standard was designed to prevent more than 200 deaths and 9,000 bloodborne infections every year. While the standard was primarily aimed at hospitals, funeral homes, nursing homes, clinics, law enforcement agencies, emergency responders, and HIV/HBV research laboratories, anyone who can "reasonably expect to come in contact with blood or potentially infectious materials" as part of their job is covered by the standard. OSHA's summary of the standard is below.

U.S. Department of Labor
Program Highlight
Fact Sheet No. OSHA 92-46

Bloodborne Pathogens Final Standard: Summary of Key Provisions

PURPOSE: Limits occupational exposure to blood and other potentially infectious materials since any exposure could result in transmission of bloodborne pathogens which could lead to disease or death.

SCOPE: Covers all employees who could be "reasonably anticipated" as the result of performing their job duties to face contact with blood and other potentially infectious materials. OSHA has not attempted to list all occupations where exposures could occur. "Good Samaritan" acts such as assisting a co-worker with a nosebleed would not be considered occupational exposure.

Infectious materials include semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid visibly contaminated with blood and all body fluids in situations where it is difficult or impossible to differentiate between body fluids. They also include any unfixed tissue or organ other than intact skin from a human (living or dead), human immunodeficiency virus (HIV)- containing cell or tissue cultures, organ cultures and HIV or hepatitis B (HBV)-containing culture medium or other solutions as well as blood, organs or other tissues from experimental animals infected with HIV or HBV.

EXPOSURE CONTROL PLAN: Requires employers to identify, in writing, tasks and procedures as well as job classifications where occupational exposure to blood occurs--without regard to personal protective clothing and equipment. It must also set forth the schedule for implementing other provisions of the standard and specify the procedure for evaluating circumstances surrounding exposure incidents. The plan must be accessible to employees and available to OSHA. Employers must review and update it at least annually--more often if necessary to accommodate workplace changes.

METHODS OF COMPLIANCE: Mandates universal precautions, (treating body fluids/materials as if infectious) emphasizing engineering and work practice controls. The standard stresses hand washing and requires employers to provide facilities and ensure that employees use them following exposure to blood. It sets forth procedures to minimize needle sticks, minimize splashing and spraying of blood,

ensure appropriate packaging of specimens and regulated wastes and decontaminate equipment or label it as contaminated before shipping to servicing facilities.

Employers must provide, at no cost, and require employees to use appropriate personal protective equipment such as gloves, gowns, masks, mouthpieces and resuscitation bags and must clean, repair and replace these when necessary. Gloves are not necessarily required for routine phlebotomies in volunteer blood donation centers but must be made available to employees who want them.

The standard requires a written schedule for cleaning, identifying the method of decontamination to be used, in addition to cleaning following contact with blood or other potentially infectious materials. It specifies methods for disposing of contaminated sharps and sets forth standards for containers for these items and other regulated waste. Further, the standard includes provisions for handling contaminated laundry to minimize exposures.

HIV AND HBV RESEARCH LABORATORIES AND PRODUCTION FACILITIES: Calls for these facilities to follow standard microbiological practices and specifies additional practices intended to minimize exposures of employees working with Patient Firsttred viruses and reduce the risk of accidental exposure for other employees at the facility. These facilities must include required containment equipment and an autoclave for decontamination of regulated waste and must be constructed to limit risks and enable easy clean up. Additional training and experience requirements apply to workers in these facilities.

HEPATITIS B VACCINATION: Requires vaccinations to be made available to all employees who have occupational exposure to blood within 10 working days of assignment, at no cost, at a reasonable time and place, under the supervision of licensed physician/licensed healthcare professional and according to the latest recommendations of the U.S. Public Health Service (USPHS). Prescreening may not be required as a condition of receiving the vaccine. Employees must sign a declination form if they choose not to be vaccinated, but may later opt to receive the vaccine at no cost to the employee. Should booster doses later be recommended by the USPHS, it must be offered to employees.

POST-EXPOSURE EVALUATION AND FOLLOW-UP: Specifies procedures to be made available to all employees who have had an exposure incident plus any laboratory tests must be conducted by an accredited laboratory at no cost to the employee. Follow-up must include a confidential medical evaluation documenting the circumstances of exposure, identifying and testing the source individual if feasible, testing the exposed employee's blood if he/she consents, post-exposure prophylaxis, counseling and evaluation of reported illnesses. Healthcare professionals must be provided specified information to facilitate the evaluation and their written opinion on the need for hepatitis B vaccination following the exposure. Information such as the employee's ability to receive the hepatitis B vaccine must be supplied to the employer. All diagnoses must remain confidential.

HAZARD COMMUNICATION: Requires warning labels including the orange or orange-red biohazard symbol affixed to containers of regulated waste, refrigerators and freezers and other containers which are used to store or transport blood or other potentially infectious materials. Red bags or containers may be used instead of labeling. When a facility uses universal precautions in its handling of all specimens, labeling is not required within the facility. Likewise, when all laundry is handled with universal precautions, the laundry need not be labeled. Blood which has been tested and found free of HIV or HBV and released for clinical use, and regulated waste which has been decontaminated, need not

be labeled. Signs must be used to identify restricted areas in HIV and HBV research laboratories and production facilities.

INFORMATION AND TRAINING: Mandates training within 90 days of effective date, initially upon assignment and annually - employees who have received appropriate training within the past year need only receive additional training in items not previously covered. Training must include making accessible a copy of the regulatory text of the standard and explanation of its contents, general discussion on bloodborne diseases and their transmission, exposure control plan, engineering and work practice controls, personal protective equipment, hepatitis B vaccine, response to emergencies involving blood, how to handle exposure incidents, the post-exposure evaluation and follow-up program, signs/labels/color-coding. There must be opportunity for questions and answers, and the trainer must be knowledgeable in the subject matter. Laboratory and production facility workers must receive additional specialized initial training.

RECORDKEEPING: Calls for medical records to be kept for each employee with occupational exposure for the duration of employment plus 30 years, must be confidential and must include name and social security number; hepatitis B vaccination status (including dates); results of any examinations, medical testing and follow-up procedures; a copy of the healthcare professional's written opinion; and a copy of information provided to the healthcare professional. Training records must be maintained for three years and must include dates, contents of the training program or a summary, trainer's name and qualifications, names and job titles of all persons attending the sessions. Medical records must be made available to the subject employee, anyone with written consent of the employee, OSHA and NIOSH--they are not available to the employer. Disposal of records must be in accord with OSHA's standard covering access to records.