Acquiring state-supplied immune globulin, vaccine, and other medications

Investigative Guidelines
June 2024

1. PURPOSE

The purpose of this guidance is to advise public health staff on the process of acquiring immune globulin and vaccine from the Oregon Immunization Program (OIP) during an outbreak, acute event, or in situations where the needed prophylaxis is not otherwise available to the Local Public Health Authority (LPHA). This document is not intended to replace the guidance on general prophylaxis of contacts outlined in the Investigative Guidelines for those conditions that require postexposure prophylaxis (PEP) of contacts. Immune globulin products available through OIP's Vaccine Supply & Access Team (VSAT) include IG (for hepatitis A and measles prophylaxis) and HBIG (for hepatitis B prophylaxis).

2. CONTACTING ACUTE AND COMMUNICABLE DISEASE PREVENTION

When contacts are identified that may need immune globulin or vaccine that is not currently accessible by LPHAs, the LPHA should contact the Acute and Communicable Disease Prevention section (ACDP) on-call epidemiologist at 971-673-1111. The on-call epidemiologist and the LPHA will review the contact history and determine whether immune globulin or vaccine is indicated for each contact. After this determination, the on-call epidemiologist will contact OIP with the relevant information. OIP will then coordinate obtaining the indicated immune globulin or vaccine with the LPHA (detailed below). OIP cannot release immune globulin, or vaccine until ACDP has approved the request. The LPHA must provide OIP with the quantity of product requested and delivery instructions. All other OIP rules and regulations regarding vaccine management and accountability apply.

3. PROPHYLAXIS RECOMMENDATIONS

3.1 Hepatitis A

PEP with vaccine, IG, or both (see below) is indicated for all household and sexual contacts with no evidence of pre-existing immunity to the hepatitis A virus (HAV). In addition, persons who have shared illicit drugs with confirmed HAV cases and those with significant opportunity for fecal-oral exposure to the case should receive prophylaxis. When one or more cases are found in employees or

children attending a child care center or cases are found in two or more households of daycare attendees, PEP is recommended for all previously unvaccinated staff members and daycare attendees.

Vaccine is recommended for PEP for all persons aged 12 months and older who have recently been exposed to HAV and who have not previously received hepatitis A vaccine. These persons should receive a single dose of single-antigen vaccine as soon as possible after exposure. In addition to hepatitis A vaccine, IG may be administered to persons >40 years, depending on the provider's risk assessment. Persons aged ≥12 months of age who are immunocompromised or have chronic liver disease should be offered IG and vaccine due to concerns regarding their ability to mount an antibody response. Infants <12 months of age should receive IG. For more information, see §5.4 of the hepatitis A investigative guidelines: http://www.oregon.gov/oha/ph/DiseasesConditions/CommunicableDisease/ReportingCommunicableDisease/ReportingGuidelines/Documents/hepa.pdf

3.2 Hepatitis B

Hepatitis B immune globulin (HBIG) is recommended for new sexual contacts who had sexual intercourse during the past two weeks with an HBsAg-positive case (Table 1). Additionally, HBIG is recommended for persons with exposure to potentially infectious body fluids by percutaneous or permucosal means (e.g., needle sharing, blood splashes) during the past 7 days (Table 1). For more information, see §5.4 of the acute hepatitis B investigative guidelines: (http://public.health.oregon.gov/DiseasesConditions/CommunicableDisease/ReportingCommunicableDisease/ReportingGuidelines/Documents/hepb-acute.pdf).

Table 1. Recommended Post-exposure prophylaxis* for Non-occupational Exposure to hepatitis B Virus.[1]**

Exposure	Treatment	
	Unvaccinated person†	Previously vaccinated person§
HBsAg-positive source	Administer hepatitis B immune globulin (HBIG), 0.06 mL/kg intramuscularly; and begin hepatitis B vaccine series	Administer hepatitis B vaccine booster dose
Perinatal exposure to HBsAg-*positive* mother	Initiate hepatitis B vaccine series and give hepatitis B immune globulin (HBIG) 0.5 mL intramuscularly within 12 hours of birth	Not applicable

HBsAg status unknown for source	Administer hepatitis B vaccine series	No treatment

*When indicated, immunoprophylaxis should be initiated as soon as possible, preferable within 24 hours. Studies are limited on the maximum interval after exposure during which postexposure prophylaxis is effective, but the interval is unlikely to exceed 7 days for percutaneous exposures or 14 days for sexual exposures. The hepatitis B vaccine series should be completed.

**Examples of such exposures include bites or needlesticks, mucosal exposures to HBsAg-positive blood or body fluids; sex or needle-sharing contact; or sexual assault or abuse.

† A person who is in the process of being vaccinated but who has not completed the vaccine series should complete the series and receive treatment as indicated.

§ A person who has written documentation of a complete hepatitis B vaccine series and who did not receive post-vaccination testing.

In the healthcare setting, transmission to others may occur via contaminated environmental surfaces, medical devices, or equipment (Table 2).

Table 2. Recommended Post-exposure Prophylaxis for Occupational Exposure to hepatitis B virus[2]

Vaccination and antibody response status of exposed workers*	**Treatment**	
	Source HBsAg positive, unknown, or not available for testing	**Source HBsAg negative**
Unvaccinated	Hepatitis B immune globulin (HBIG)† x 1 and initiate HB vaccine series	Initiate HB vaccine series
Previously Vaccinated		
Known responder§	No treatment	No treatment
Known nonresponder**	HBIG x 1 and initiate revaccination or HBIG x 2 one month apart¶	No treatment
Response unknown	Test exposed person for anti-HBs 1. If adequate, no treatment is necessary 2. If inadequate, administer HBIG x 1 and single vaccine dose	No treatment

*Persons who have previously been infected with HBV are immune to reinfection and do not require post-exposure prophylaxis.

† Dose is 0.06 mL/kg intramuscularly

§ A responder is a person with adequate levels of serum antibody to HBsAg (i.e., anti-HBs ≥10 mIU/mL).

** A non-responder is a person with inadequate levels of serum antibody to HBsAg (i.e., anti-HBs <10 mIU/mL).

¶ The option of giving one dose of HBIG and reinitiating the vaccine series is preferred for non-responders who have not completed a second 3-dose vaccine. For those who have not responded after completing two complete vaccine series, do not give additional doses of vaccine.

3.3 Measles

Although there are few data on the effectiveness of MMR vaccine and IG for PEP following exposure to measles, both should be considered for exposed, susceptible contacts. MMR vaccine should be administered, ideally within 72 hours of exposure. For contacts with contraindications to the MMR vaccine or who are considered at high risk of severe infection (pregnant women, children <1 year old, persons with compromised immune systems), IG can be used to prevent or attenuate infection. IG must be administered ASAP, but no more than six days after exposure. IG should never be used as an outbreak control measure. For more information, see §5.5 of the Measles investigative guidelines: http://www.oregon.gov/oha/PH/DiseasesConditions/CommunicableDisease/ReportingCommunicableDisease/ReportingGuidelines/Documents/measles.pdf

3.4 Vaccine for other vaccine-preventable diseases (VPDs)

During outbreaks of vaccine-preventable diseases (e.g., pertussis in a school, measles, meningococcal disease), the LPHA may consider special vaccination clinics. In these cases, a conference call will be set up with the Urgent Epidemiologic Response Team (UERT), LPHA, and the OIP Provider Services Team (PST) or Section Manager, to discuss availability of vaccine and other issues.

3.5 Immune globulin for other diseases

Immune globulin for diseases other than those listed above (including varicella, tetanus, rabies, and botulism) are not available through OIP, but can be purchased from private vendors or provided by CDC. OIP can assist with locating these products. ACDP on-call staff is available for consultation to discuss whether the immune globulin is indicated and to facilitate procurement, as needed. Please refer to the disease specific guidelines for more information.

4. INFORMATION NECESSARY FOR OBTAINING PROPHYLACTIC IG OR VACCINE

If prophylaxis is indicated, the following information should be gathered by the LPHA and provided to the ACDP on-call epidemiologist.

4.1 IG for hepatitis A[3]

- Number of contacts needing IG
- Weight and age of each contact eligible for IG
- IG is supplied in 2-mL and 10-mL vials
- IG dosage recommendation: 0.10 mL/kg IM
- Latest possible date where IG would be appropriate
- Insurance status of each contact.
    - LPHAs should bill insurance for IG if the contact has insurance

4.2 HBIG for hepatitis B

- Number of contacts needing HBIG
- Weight and age of each contact eligible for HBIG
- Latest possible date where IG would be appropriate
- Exact dosing for each contact eligible for HBIG
    - HBIG is supplied in 5-mL vials. HBIG costs >$600 per 5-mL vial, and OHA has a very limited supply.
    - HBIG dosage recommendations
        - Adults: 0.06 mL/kg IM
        - Infants <12 months: 0.5 mL single dose
- Insurance status of each contact
    - LPHAs should bill insurance for HBIG if the contact has insurance

4.3 IG for measles

- Number of contacts needing IG
- Weight and age of each contact eligible for IG
- Exact dosing for each contact eligible for IG
    - IG is supplied in 2-mL and 10-mL vials.
    - IG dosage recommendations
        - Infants <12 months: 0.5 mL/kg IM
        - Pregnant women and severely immunocompromised: 400 mg/kg IV
- Insurance status of each contact
    - LPHAs should bill insurance for IG if the contact has insurance

4.4 Vaccine for other VPDs

- Number of contacts needing vaccine
- Number of doses needed
- Age of contacts (some vaccine dosage is based on age)

4.5 Immune globulin for other diseases

- Number of contacts needing IG

- Age and weight of contacts
- Exact dosing for each contact eligible for IG

5. POST-APPROVAL PROCESS

5.1 IG-Immunization Program notations for LPHAs

IG is provided by ACDP for use in prophylaxis when the primary care providers are unable to obtain it. LPHAs should contact ACDP if they need this product. Questions about eligibility coding in ALERT IIS and insurance billing can be directed to a county's OIP health educator or the VSAT Manager.

5.2 HBIG-Immunization Program notations for LPHAs

Obtain the insurance status of the contact in need of HBIG. Bill the insurance company if they have insurance or Oregon Health Plan. Questions about eligibility coding in ALERT IIS and insurance billing should be referred to the county's OIP health educator or the VSAT Manager.

5.3 State-supplied vaccine or IG questions

Any questions about vaccine or immune globulin availability and eligibility coding should be referred to the OIP VSAT Manager, or another OIP Manager.

5.4 ACDP Instructions

The ACDP on-call epidemiologist will contact the OIP VSAT Manager with notification of approval for prophylaxis during work hours. If IG is needed for 5 or more persons, additional approval must be obtained from the ACDP Section Manager (or acting manager) or the ACDP/Immunization Medical Director. Information obtained in section 4 will be provided by the ACDP on-call epidemiologist to the OIP VSAT Manager. If the VSAT Manager is not available, the ACDP on-call epidemiologist will contact the OIP Section Manager or other OIP managers until someone is reached. During off hours, the on-call epidemiologist will contact the OIP Section Manager via the Health Security, Preparedness, and Response (HSPR) Program Duty Officer. The OIP representative will contact the requesting LPHA with shipping details. All contact information is listed below.

Name	Phone-Day	Phone-Off Hours	Email
ACDP (on-call)	971-673-1111	971-673-1111	N/A
ACDP Section Manager: Zintars Beldavs	971-673-1111	N/A	N/A
ACDP/Immunization Medical Director: Paul Cieslak	971-673-1111	N/A	N/A
OIP (Main Line)	971-673-0300	N/A	N/A

Vaccine Supply & Access Team Manager: Erin Corrigan	971-349-2322	Contact via the HSPR Duty Officer Cell: 971-246-1789 Pager: 503-938-6790	erin.e.corrigan@oha.oregon.gov
OIP Section Manager: Mimi Luther (interim)	503-309-1462 Personal phone: 503-320-7245		lydia.m.luther@oha.oregon.gov
OIP Vaccine Clerk	971-673-0300	N/A	N/A

REFERENCES

1. CDC. Postexposure Prophylaxis to Prevent Hepatitis B Virus infection. MMWR 2006; 55(RR16); 30–1). https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5516a3.htm. Accessed 18 June 2024.
2. CDC. CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management MMWR 2013;62(No. RR-#):1–18. Available at: https://www.cdc.gov/mmwr/pdf/rr/rr6210.pdf. Accessed 18 June 2024.
3. CDC. Nelson NP. Updated dosing instructions for immune globulin (human) GamaSTAN S/D for hepatitis A virus prophylaxis. MMWR 2017;66: 959–60. Available at: https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6636a5.pdf. Accessed 18 June 2024.
4. CDC. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. MMWR 2001; 50(RR11); 1–42. Available at: https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm. Accessed 18 June 2024.

UPDATE LOG

June 2024 – Updated OIP contacts, HAV PEP guidelines, and general review of IGs (Corrigan, Martin)

August 2018 – Updated section 5.4 (ACDP Instructions) - ACDP on-call epidemiologist must get approval from ACDP Section Manager or ACDP/Immunization Medical Director if IG is requested for 5 or more persons. (Poissant)

October 2017 – Updated hepatitis A IG dosage. (Poissant)

August 2016 – Applied new Word formatting. Updated post-exposure prophylaxis recommendations for hepatitis B. (Poissant)

April 2015 – Clarified approval process as OIP no longer has an on-call person. (Poissant)

June 2014 – Removed perinatal hepatitis B prophylaxis from table 1 because the state does not provide HBIG for that purpose. Hospitals are required to have it on hand. Measles information added. Removed varicella section. Section on immune globulin for other diseases added. Updated contact information in section 5.3 – individual names replaced with position title, and off hours contact for the Immunization Program has been directed to the HSPR Duty Officer. (Poissant/Schrauben)

July 2012 – Guidelines created. (Poissant)