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

Investigative Guidelines
August 2018

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 Health Department (LHD). This document is not intended to replace the guidance on general prophylaxis of contacts outlined in the Investigative Guidelines for those conditions that require post exposure prophylaxis of contacts. Immune globulin products available through OIP include IG (for hepatitis A and measles prophylaxis) and HBIG (for hepatitis B prophylaxis).

2. CONTACTING THE ACUTE AND COMMUNICABLE DISEASE

When contacts are identified that may need immune globulin or vaccine that is not currently accessible by LHDs, the LHD should contact the Acute and Communicable Disease Prevention (ACDP) Program on-call epidemiologist at 971.673.1111. The on-call epidemiologist and the LHD 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 LHD (detailed below). OIP cannot release immune globulin, or vaccine until ACDP has approved the request. The LHD 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

Prophylaxis 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,

prophylaxis is recommended for all previously unvaccinated staff members and daycare attendees.

Vaccine is recommended for prophylaxis in healthy contacts aged 12 months to 40 years. IG is recommended for: persons over the age of 40 or under 12 months of age; immunocompromised persons; persons with chronic liver disease; and persons for whom vaccine is contraindicated. See §5.4 of the hepatitis A investigative guidelines for further information at: 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 having 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). See §4.4.3 of the acute hepatitis B guidelines for further information (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
Percutaneous (e.g., bite or needlestick) or mucosal exposure to HBsAg-*positive* blood or body fluids	Administer hepatitis B vaccine series and hepatitis B immune globulin (HBIG)	Administer hepatitis B vaccine booster dose
Sex or needle-sharing contact of an HBsAg-*positive* person		
Victim of sexual assault/abuse by a perpetrator who is HBsAg-*positive*		
Perinatal exposure to HBsAg-*positive* mother	Initiate hepatitis B vaccine series and hepatitis B immune globulin (HBIG) within 12 hours of birth	Not applicable
Percutaneous (e.g., bite or needlestick) or mucosal exposure to potentially infectious blood or body fluids from a source with *unknown* HBsAg status	Administer hepatitis B vaccine series	No treatment
Sex or needle-sharing contact of a person with *unknown* HBsAg status		
Victim of sexual assault/abuse by a perpetrator with *unknown* HBsAg status		

In the healthcare setting, healthy patients may be colonized; transmission to others may occur via the hands of healthcare workers or 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	Source HBsAg negative	Source unknown or not available for testing
Unvaccinated	Hepatitis B immune globulin (HBIG) x 1 and initiate HB vaccine series	Initiate HB vaccine series	Initiate HB vaccine series
Previously Vaccinated			
Known responder	No treatment	No treatment	No treatment
Known nonresponder or refuser.	HBIG x 1 and initiate revaccination or HBIG x 2	No treatment	If known high risk source, treat as if source were HBsAg positive
Response unknown	Test exposed person for anti-HBs If adequate, no treatment is necessary If inadequate, administer HBIG x 1 and single vaccine dose	No treatment	Test exposed person for anti-HBs If adequate, no treatment is necessary If inadequate, administer single vaccine dose and recheck titer in 1-2 months

3.3 Measles

Although there is limited data on the effectiveness of MMR vaccine and IG for post exposure prophylaxis following exposure to measles, both should be considered for exposed, susceptible contacts. MMR vaccine should be administered within 72 hours of exposure. For contacts with contraindications to the MMR vaccine or who are considered high risk of severe infection (pregnant women, children <1 year old, compromised immune system, etc.), 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. Please see §5.4 of the Measles investigative guidelines for further information
http://www.oregon.gov/oha/PH/DiseasesConditions/CommunicableDisease/ReportingCommunicableDisease/ReportingGuidelines/Documents/measles.pdf

3.4 Vaccine for vaccine preventable diseases (VPDs)

In vaccine preventable disease (VPD) outbreak situations, the LHD may consider special vaccination clinics (e.g., pertussis in a school, measles, meningococcal disease). In these cases, a conference call will be set up with the Urgent Epidemiologic Response Team (UERT), LHD, 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. 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 LHD 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
- Insurance status of each contact.
    - LHDs 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
- 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
    - LHDs 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
    - Other persons: 0.5 mL/kg (maximum 15 mL); IM
- Insurance status of each contact
  - LHDs should bill insurance for IG if the contact has insurance

4.4 Vaccine for VPDs

- Number of contacts needing vaccine
- Insurance status of each contact
- 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 LHDs

IG is provided by ACDP for use in prophylaxis when the primary care providers are unable to obtain it. LHDs 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 PST Manager.

5.2 HBIG-Immunization Program notations for LHDs

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

5.3 State-supplied vaccine or IG questions

Any questions about vaccine or immune globulin availability should be referred to the OIP PST Manager, or another OIP Manager. Eligibility coding questions should go to a county's OIP health educator.

5.4 ACDP Instructions

The ACDP on-call epidemiologist will contact the OIP Vaccine Clerk 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 ACDP on-call epidemiologist to the OIP Vaccine Clerk. If the Vaccine Clerk is not available, the

ACDP on-call epidemiologist will contact the PST Manager, the PST VFC Coordinator, the OIP Section Manager or another manager until someone is reached. During off hours, the on-call epidemiologist will contact the OIP PST Manager or Section Manager via the Health Security, Preparedness, and Response (HSPR) Program Duty Officer. The OIP representative will contact the requesting LHD 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: Zints Beldavs	971.673.0166	N/A	zintars.g.beldavs@dhsoha.state.or.us
ACDP/Immunization Medical Director: Paul Cieslak	971.673.1082	N/A	paul.r.cieslak@dhsoha.state.or.us
OIP (Main Line)	971.673.0300	N/A	N/A
VFC Manager: Mimi Luther	971.673.0296 or 503.320.7245	Contact via the HSPR Duty Officer Cell: 971.246.1789 Pager: 503.938.6790	lydia.m.luther@dhsoha.state.or.us
OIP Section Manager: Aaron Dunn	971.673.0318		aaron.dunn@dhsoha.state.or.us
OIP Vaccine Clerk: Shelby Williams	971.673.0313 or 503.349.3859	N/A	shelby.williams@dhsoha.state.or.us

REFERENCES

1. CDC. Postexposure Prophylaxis to Prevent Hepatitis B Virus infection. MMWR 2006; 55(RR16); 30-31). https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5516a3.htm?s_cid=rr5516a3_e Accessed 11 October 2017.
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 11 October 2017.
3. CDC. Nelson, N.P. Updated dosing instructions for immune globulin (human) GamaSTAN S/D for hepatitis A virus prophylaxis. MMWR 2017;66(36): 959–960. Available at: https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6636a5.pdf Accessed 11October 2017.
4. Centers for Disease Control and Prevention. 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 11 October 2017.

UPDATE LOG

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)