

**OREGON GUIDANCE FOR COLLABORATIVE
PHARMACY-LOCAL PUBLIC HEALTH AUTHORITY RESPONSE
TO PUBLIC HEALTH INCIDENTS**

**For Use with Oregon Statewide Pharmacy – Local Public Health Authority
Memorandum of Understanding**

This work was supported by the Oregon Health Authority. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the State of Oregon.

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RECORD OF REVIEW

Change Number	Date of Review/Change	Review Led By (Reviewers noted)
0	7/2/2015	Original Guidance (Hansen [lead], Burnette, Donner, Leman, Miner, Ramirez)
01	10/30/2017	Incorporated revisions from Tabletop exercise of participating pharmacies, held 9/20/2017 (Miner [lead], Leman, Ramirez)
02	10/29/2018	Minor edits for clarity (Leman)
03	8/6/20	Incorporated feedback from pharmacy managers gathered through Tabletop exercises and during real-time response providing pharmaceutical services to displaced populations.

ACRONYMS

BoP	Oregon Board of Pharmacy
CLHO	Council of Local Health Organizations
HAN	Health Alert Network
HIPAA	Health Insurance Portability and Accountability Act
LPHA	Local Public Health Authority
MCM	Medical Countermeasures
MOU	Memorandum of Understanding
OAR	Oregon Administrative Rules
OERS	Oregon Emergency Response System
OPHD	Oregon Public Health Division at Oregon Health Authority
ORS	Oregon Revised Statutes
OSHP	Oregon Society of Health-System Pharmacists
OSPA	Oregon State Pharmacy Association
SNS	Strategic National Stockpile
SOP	Standard Operating Procedures

PHARMACY-LOCAL PUBLIC HEALTH AUTHORITY GUIDANCE

I. AUTHORITY

This guidance was developed in accordance with the *Oregon Statewide Pharmacy-Local Public Health Authority Memorandum of Understanding* (MOU). Its contents have been reviewed by the task force that developed the MOU, as well as signatory pharmacies and local public health authorities (LPHAs).

II. PURPOSE

The purpose of the guidance is to outline simple, straightforward processes through which LPHAs and pharmacies can establish partnerships to meet the medical needs of Oregonians during public health incidents. It also provides templates of forms that can be used to request pharmacy participation in response, outline the specific activities requested, and describe treatment protocols that can be used by pharmacists during event response, as described in the *Oregon Statewide Pharmacy-Local Public Health Authority MOU*.

III. POINTS OF CONTACT

If desired, signatory pharmacies can share with LPHAs contact information for preferred recipients within their organizations of requests for assistance under the MOU. Otherwise, pharmacies will be contacted using contact information maintained by Oregon Board of Pharmacy (BoP). Point of contact for activities under the MOU for BoP will be the Compliance Officer (971-673-0001) MOU point of contact for LPHAs will be the LPHA Preparedness Coordinator. MOU point of contact for the Oregon Public Health Division (OPHD) will be the Public Health Duty Officer (971-246-1789).

IV. ACTIVATION PROCESS FOR THE MOU

A. Who Can Activate the MOU

The MOU can be activated by a signatory LPHA and signatory pharmacy or pharmacies who have come to agreement on specific activities that the pharmacy will undertake in response to a public health incident. The MOU can also be activated by OPHD, in consultation with LPHAs and pharmacies.

B. Templates to Specify Requested Pharmacy Activities

Appendices A and B contain templates that can be used to clarify the specific pharmacy response activities requested. These templates are intended to support the development of appropriate, specific, feasible roles for pharmacies in incident response, and to standardize response requests across jurisdictions. *Appendix D* contains stockpile inventory tracking forms, and examples of treatment protocols that can be adapted to the specific incident and may be used by pharmacists in the case of incident response.

C. Activation Process

1. Notifications of intent to activate the MOU

Upon requesting pharmacy assistance under the MOU, LPHA(s) will immediately notify OPHD of the request by contacting the Public Health Duty Officer at 971-246-1789. When BoP receives a request for pharmacy assistance, BoP will also contact the Public Health Duty Officer.

2. Type of incident

Single Jurisdiction: For incidents that affect a single county, the LPHA can request pharmacy assistance through the BoP or contact the pharmacy directly. The LPHA will outline a plan describing how the pharmacy can be incorporated into the public health response, and in consultation with OPHD as needed, will describe the specific activities that can be carried out by the pharmacy. The scope and nature of pharmacy activities can be clarified as needed through a coordination call led by the LPHA, with participation by the pharmacies involved and, if necessary, OPHD. The LPHA will follow the draft agenda that is included in *Appendix A*. Following the coordination call, requests for assistance from the LPHA and actions agreed to by participating pharmacies will be documented using an *Assistance Request Form (Appendix B)*.

Multi-Jurisdiction: When incidents affecting multiple jurisdictions necessitate response activities by pharmacies in more than one county, OPHD will serve as the contact point for any LPHAs that may need pharmacy assistance. When notified by more than one LPHA of the need for pharmacy assistance under the MOU, BoP will notify OPHD. OPHD will then alert all LPHAs throughout Oregon, notify them of the incident, and request that any LPHA arranging pharmacy assistance for the incident contact OPHD and participate in coordination conference calls. BoP and OPHD will notify appropriate pharmacies and all LPHAs requesting assistance of the time and contact number for coordination calls. OPHD will then facilitate coordination calls following the agenda included in *Appendix A*. Requests for assistance from each LPHA and actions agreed to by participating pharmacies will be documented using the *Assistance Request Form* included in *Appendix B*.

3. MOU activation

LPHAs or OPHD may activate the MOU by:

- a. contacting a signatory pharmacy, either directly or through the BoP;
- b. coming to agreement with responding pharmacies on the scope and exact nature of pharmacy activities in the context of incident response;
- c. documenting the pharmacy's activities in incident response using the *Assistance Request Form* template in *Appendix B*; and
- d. Sharing the *Request Form* with responding pharmacies. Use of the *Assistance Request Form* template by signatories is encouraged to promote clarity and specificity in the activities being requested, and standardization when similar pharmacy activities span more than one LPHA jurisdiction. Pharmacists consulted in the development of this guidance specifically request that a public health contact person be clearly designated on the *Assistance Request Form*, and that the form include a clear description of the situation that addresses

- i. The nature of the public health incident prompting the MOU activation (infectious disease outbreak, environmental health threat, etc.).
 - ii. A clear description of the target population (including age range, specific information about geographic range, and estimated number of people who will require vaccination).
 - iii. Whether or not other pharmacies are being approached to participate, and if so, how many,
 - iv. Whether there will be money available to cover the cost of vaccines or medications provided under the MOU, or if the pharmacy will be expected to come up with a plan to address costs, and
 - v. Whether or not there will be exceptions to the usual limitations on age for vaccine administration or receipt of specific medications.
- e. In a single-jurisdiction incident:
- i. LPHA may confirm pharmacy approval of response activities described in the *Assistance Request Form*, or, as needed, can request that BoP forward the form to assisting pharmacies for review and approval.
 - ii. In a single-jurisdiction incident, pharmacy will communicate directly with LPHA acknowledging approval of activities described in the *Assistance Request Form* and readiness to implement them.
- f. In multi-jurisdiction incidents:
- i. OPHD will coordinate with BoP to circulate *Assistance Request Forms* to appropriate pharmacies for review and approval.
 - ii. Pharmacy will communicate with OPHD through the Public Health Duty Officer, acknowledging approval of activities described in the *Assistance Request Form* and readiness to implement them.
 - iii. OPHD Public Health Duty Officer is then responsible for communicating approval to all affected LPHAs through their Administrator and Preparedness Coordinator.
- g. Pharmacies can then review the request and assess their ability to respond. For a checklist to help guide this process, see *Appendix C*. **If the pharmacy determines it can participate in the response, based solely on the information already provided**, a pharmacy staff person can complete Part 2 of the *Assistance Request Form* agreeing to provide the assistance as requested, and return it, or pharmacy staff can simply call the public health contact person listed. **If more information is needed**, use Part 2 of the form to request it, or call to arrange a *Coordination Call* as outlined in *Appendix A*.
- h. Any amendment to a previously approved *Assistance Request Form* shall be in writing and agreed between the parties.

V. INVENTORY TRACKING AND REPORTING

- A. Pharmacy will maintain an ongoing inventory record of all medical countermeasures supplied by public health throughout the duration of the period of activation of the MOU. These records shall be kept in accordance

with applicable rules and regulations, including OAR or ORS and Centers for Medicare and Medicaid guidance.

- B. If multiple LPHAs have activated the MOU for the same event, standardized inventory tracking and reporting forms, based on templates included in Appendix D, can be used.
- C. LPHA or, as appropriate, OPHD, shall specify the minimum detail of information needed from pharmacy for inventory tracking and reporting for dispensing of stockpile medical countermeasures.
- D. Pharmacy shall work with LPHA to determine the format, mechanism, and timing of reporting the minimum dataset. The format should accommodate the potential need for multiple methods of data submission, given internal restrictions on internet access in some pharmacies.

VI. COMMUNICATIONS AND UPDATES IN THE COURSE OF INCIDENT RESPONSE

- A. LPHAs are encouraged to provide regular updates on incident status to OPHD and pharmacies. Communication between LPHAs and pharmacies during the response may be through email, fax, or phone calls. Frequency of updates can be negotiated by the involved parties. LPHAs should further confirm at the time of MOU activation whether there will be a cost incurred by those receiving medications, and should make this fact clear in any outreach materials.
- B. Pharmacies are encouraged to provide regular updates on pharmacy activities (e.g., number of clients vaccinated or provided prophylaxis, number of displaced persons assessed and served) and any barriers to response (vaccine or medication availability, other resource limitations) to LPHAs with which they are collaborating. Frequency of updates can be negotiated.
- C. When vaccines are provided, pharmacies shall enter dispensing information into the *Oregon ALERT* Immunization Information System, as with other immunizations.
- D. When response activities involve a pharmacy dispensing medical countermeasures from the Strategic National Stockpile or State stockpile, pharmacy shall supply the Oregon Immunization Program with name and contact information for all stockpile medication recipients, as permitted under the Health Insurance Portability and Accountability Act (HIPAA), *45 CFR 164.512(b)*.

VII. DEMOBILIZATION

- A. The decision to return to normal operations and discontinue pharmacy activities under the MOU will be made by the LPHA after consultation with the appropriate parties. Triggers for demobilization will be based on the following factors:
 1. Targeted population has received needed medications,
 2. Sufficient distribution can be achieved through other mechanisms, or
 3. Mechanisms exist to supply medication to those without the ability to pay for them.

- B. As appropriate, guidance for pharmacy will be provided by LPHA for handling of and final reporting on unused state or federal stockpile drug, vaccines, or other medical products.
- C. In the event that multiple LPHAs have activated the MOU simultaneously, the coordination of demobilization activities will be facilitated by OPHD and will be communicated via conference call and website updates as necessary.

VIII. OPERATIONAL GUIDANCE REVIEW

- A. The Operational Guidance and MOU will be reviewed for possible updates at least every 5 years. This review will be convened by the OPHD Medical Countermeasures Coordinator and will include representatives from the Oregon Society of Health-System Pharmacists, the Oregon State Pharmacy Association, the Conference of Local Health Officials, the Oregon Board of Pharmacy, and Oregon Public Health Division. It will address recommendations from after-action reports of MOU activations and other issues that may arise related to the MOU.
- B. Signatory personnel who would potentially be involved in activating this MOU are encouraged to review and re-familiarize themselves with the document annually.

APPENDIX A: TEMPLATE FOR COORDINATION CALL AGENDA

The intent of the coordination call is for public health personnel to share information with pharmacies about the public health event, and to determine realistic, effective roles for pharmacies in event response.

Topic	Summary of Topic Discussion	Time Allotted
1. Introductions		5 min.
2. General description of public health hazard (i.e. type of disease outbreak, environmental health threat, infrastructure issues, etc.)		
3. Type of assistance needed. (Types of medications to be dispensed; specific populations or priority groups to be served; including estimated number of recipients; types of information to be communicated to the public)		
4. When and where assistance is needed		
5. Initial assessment of pharmacy resources available from public health for response (if any)		
6. Information or other support required by pharmacy from public health to clarify and accomplish mission		
7. Other issues to be addressed		
8. Next Steps, with responsible parties and timelines		

APPENDIX B: ASSISTANCE REQUEST FORM TEMPLATE

Local Public Health Authority-Pharmacy MOU Assistance Request Form				
Request to dispense or administer medical countermeasures				
PART 1: BY THE REQUESTING LOCAL PUBLIC HEALTH AUTHORITY (LPHA)	COMPLETED	Date:	Time:	OERS # (if issued):
<p style="color: red; margin: 0;">Request completion of Part 2 of this form and return by ___:___ on ___/___/___</p> <p style="color: red; margin: 0;">Please reply by: <input type="radio"/> Return fax <input type="radio"/> E-mail <input type="radio"/> Phone Call</p>				
<p>Public Health Authority Requesting Assistance:</p> <p>Name/Title of Person Pharmacies Can Contact:</p> <p>Telephone: () FAX ()</p> <p>Email:</p>				
<p>Description of public health incident and current situation (i.e., type of outbreak, environmental health threat, infrastructure issues, other pharmacies approached, etc.):</p> 				
<p>Type of Assistance Requested (use additional pages if needed).</p> <p>Name of medicine or vaccine: _____</p> <p>Dose: _____</p> <p>Route of Administration: _____</p> <p>Venue for administration/dispensing: <input type="checkbox"/> POD <input type="checkbox"/> Community pharmacy setting</p> <p><input type="checkbox"/> Other (specify): _____</p> <p>Who should receive this medication?</p> <p>Description of target population (Defining traits, age, estimated number, geographic range, etc.):</p> <p>_____</p> <p>_____</p> <p>_____</p>				
<p>Amount of Stockpile medication available for response (if any): _____</p> <p>Anticipated # of doses and duration of pharmacy involvement: _____</p>				

Appendix C:

Key Points for Common MOU Response Activities

C-1 – Community Medical Countermeasures Campaign

Key points for public health

Be sure that *Request for Assistance* states:

- Specific vaccine or medication to be administered or dispensed
- Dosage and route of administration
- Target population to be vaccinated (geographic distribution and age range of those to receive medical countermeasure)
- Whether or not response will involve state-supplied Strategic National Stockpile medications (unlikely in most cases)

Consider supplying link to the relevant state-issued pharmacy protocol, if applicable

Key points for pharmacists

Assess refrigeration capacity to ensure ability to store vaccine or other temperature-sensitive medications.

In unlikely event that Strategic National Stockpile vaccines are involved, have plan to document and share with public health, in a timely fashion, person vaccinated, date of vaccination, and lot number of vaccine.

Discuss up-front with customers whether there will (or might) be a cost incurred for receipt of the vaccine or other medical countermeasure.

C-2 – Point of Dispensing (POD)-Based Mass-dispensing Campaign

Key points for public health

Be sure that *Request for Assistance* states:

- Specific vaccine or medication to be administered or dispensed
- Dosage and route of administration
- Target population for prophylaxis (geographic distribution and age range of those to receive medical countermeasure)
- Whether or not response will involve Strategic National Stockpile medications (likely)
- Whether or not pharmacy is requested to supply the medication to be dispensed
- Requested timeframe
- Whether PODs are asking for:
 - a. pharmacists to work in PH-run PODs, or
 - b. Pharmacies to set up and staff PODs independently
- Specific roles for pharmacists requested, and number for each role needed
- Physical addresses and locations of PODs
- How medication counselling and dispensing will be recorded and documented
- How medications will be transported
- Specific requirements for reporting of dispensing to public health
- Acceptable fee that can be charged (if SNS)

Supply link to relevant state-issued pharmacy protocol, if applicable

Key points for pharmacists

Assess refrigeration capacity to ensure ability to store vaccine or other temperature-sensitive medications.

If Strategic National Stockpile medications are used, develop plan to document and share with public health, in a timely fashion, person dispensed to, date of dispensing, and lot number of medications.

Discuss up-front with customers whether there will (or might) be a cost incurred for receipt of the vaccine or other medical countermeasure.

C-3 – Meeting Pharmaceutical Needs of Displaced Populations

Key Points for Public Health

- If possible, identify a clinical consultant to support pharmacist activities [Health Officer? EMS Med. Director?] State in *Request for Assistance* whether clinical consultation is available
- If a disaster has been declared, share the pharmacist scope of activities under Board of Pharmacy Division 7 Administrative Rules (below)
- State, as completely as possible, location and street address of shelters for which services are requested and estimated number of sheltered people requiring pharmaceutical services
- Include desired timeline for response back and preferred mode of response (return fax, e-mail, phone call)

Key Points for Pharmacists

- Consider on-site assessment of patient needs by staff deployed from nearby pharmacy, using *Assessment* form, below
- Identify reasonably private space for medication assessment, dispensing, and counselling
- Consider substituting non-narcotic analgesics for requested narcotics
- Consider filling prescriptions at nearby pharmacy, with transport back to shelter for dispensing
- Consider bringing cache of over-the-counter medications/band-aid/eye care supplies

Pharmacy Intake Assessment for Displaced People

Initials of Pharmacist _____

Patient Name: _____ DOB: _____

Shelter Location: _____

Primary Clinician: _____ Usual Pharmacy _____

Patient Phone #: ____ - ____ - ____ BIN: _____ PCN: _____

Allergies: _____

Expedited Meds (Deliver ASAP: Includes meds for asthma or diabetes, anti-anginals, anti-arrhythmics, anti-convulsants, and antimicrobials for acute infection. For any shelter with patients with severe allergies, consider epinephrine auto-injector.)

Name	Dose	Route	Frequency
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Other Medications

Name	Dose	Route	Frequency
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Outline of Authorized Pharmacist Activities under OAR 855-007-0090 ("Division 7")

Under the Board of Pharmacy's Oregon Administrative Rule 855-007-0090, you, as a pharmacist, can help people displaced from a declared disaster in a number of ways. You could:

- Assess evacuees' needs for prescription medications,
- As long as certain conditions are met*, dispense an emergency refill for a 30-day supply of a non-narcotic medication, without a valid prescription,
- Assess and provide for immunization needs (for instance, tetanus boosters), or
- Participate in assessment of general health situation at evacuee shelters.

Once you've determined the medications and dosage, you can create an emergency prescription for up to a 30-day supply of non-narcotic medication. Note on the prescription that it was written under the emergency provisions of Division 7 of the Board of Pharmacy Administrative Rules, and file it separately with other emergency prescriptions.

Additionally, on consultation with an authorized prescriber (in person, or through tele-communication) a pharmacist can initiate or modify any drug therapy and dispense an amount to meet the patient's needs until the patient can be seen by a healthcare provider.

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- * 1) The person receiving the prescription has evacuated from an area affected by a declaration of emergency,
2) It is the pharmacist's professional judgment that the drug is essential to the maintenance of the patient's health or the continuation of therapy;
3) The pharmacist records all relevant information and indicates that it is an Emergency Prescription; and
4) The pharmacist informs the patient or the patient's agent that the drug is being provided without a prescriber's authorization and that a prescriber authorization is required for any additional refill.

APPENDIX D:

SAMPLE TREATMENT PROTOCOL AND INVENTORY TEMPLATES

**These Are Examples Only. Actual Protocols Will Be Issued, as Needed,
by Oregon Health Authority in Response to Public Health Incidents**

The Oregon Immunization Program (OIP) produces vaccination standing orders for public providers and vaccination protocols for pharmacists. During an incident that requires activation of this memorandum of understanding, routine orders and protocols may be used, or OIP may release emergency documents if the event involves a new vaccine or specific populations are targeted. Routine and emergency orders and protocols are posted at the following websites:

Model vaccine standing orders: <http://1.usa.gov/OregonStandingOrders>

Pharmacy vaccine protocols:

<https://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/Pages/p-harmpro.aspx>

OREGON HEALTH AUTHORITY
IMMUNIZATION PROTOCOL FOR PHARMACISTS
RECOMBINANT MENINGOCOCCAL B VACCINE

Date: 03-13-2015

On February 27, 2015, ACIP made recommendations for the use of the following recombinant meningococcal B vaccines:

- Bexsero[®] (Novartis); 2-dose series at days 0 and ≥ 1 month¹ (See page 3, section III A for further information about this vaccine)
- Trumenba[™] (Pfizer); 3-dose series at days 0, 2 months, and 6 months² (See page 3, section III B for further information about this vaccine)

The Oregon Health Authority, Immunization Program Medical Director authorizes use of Bexsero[®] and Trumenba[™] under the following parameters:

- For high-risk individuals ≥ 11 years of age (ACIP recommendation, Feb. 27, 2015).
- To control the outbreak of meningitis B associated with the University of Oregon. This use of the vaccine will expire on June 30, 2015, at which point ACIP should have released its general recommendations for these vaccines.

I. Order:

1. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.
2. Screen clients ≥ 11 years of age for contraindications.
3. Provide an Adolescent Well Visit Flyer to those 11–18 years of age.
4. Provide the vaccine-specific package insert, answering any questions.
5. Obtain a signed Vaccination Administration Record (VAR)
6. Give a single 0.5-mL intramuscular (IM) dose of meningococcal B vaccine according to recommendations and appropriate schedules.
 - Bexsero[®]:
www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM431447.pdf¹
 - Trumenba[™]:
www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM421139.pdf²

Immunizing Pharmacist Signature

Date

For multiple signatures see: 1.usa.gov/PharmacyImmunizationProtocols

August 06, 2020

II. LICENSED RECOMBINANT MENINGOCOCCAL B VACCINES^{1, 2}

Product Name	Vaccine Components	Acceptable Age Range	Thimerosal	Latex
Bexsero[®] (4CMenB)	50 µg each of Neisserial adhesion A (NadA), Neisserial Heparin Binding Antigen (NHBA), and factor H binding protein (fHbp) = 150 µg protein plus 25 µg of Outer Membrane Vesicles (OMV) 1.5 mg aluminum hydroxide (0.519 mg of Al ³⁺) 3.125 mg NaCl 0.776 mg histidine 10 mg sucrose at pH 6.4–6.7 0.01 µg kanamycin (by calculation)	≥11 years	No	Tip caps of pre-filled syringes (plungers are <u>not</u> made with natural rubber latex)

Trumenba™ (rLP2086)	60 µg of each of 2 fHBP variants = 120 µg protein 0.018 mg of Polysorbate 80 0.25 mg of Al ³⁺ = AlPO ₄ in 10 mM histidine buffered saline at pH 6.0	≥11 years	No	No
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III. RECOMMENDATIONS FOR USE^{1, 2}

A. Approved for the following high-risk individuals ≥11 years of age. Those with:

- functional or anatomic asplenia
- sickle cell disease
- terminal complement component deficiency (e.g., C5–C9, properdin, factor H, factor D, and patients taking Eculizumab [Soliris®]) AND
- microbiologists who work routinely with isolates of *Neisseria meningitidis*

B. University of Oregon outbreak control (expires 6/30/2015): Approved for the following individuals ≥11 years of age:

- 1.) University of Oregon undergraduate students.
- 2.) University of Oregon graduate students, faculty and staff who:
 - a. live in campus residence halls, fraternities, or sororities
 - b. who are at high risk (see above)
- 3.) Undergraduate students of any college living in the 13th & Olive apartments (Capstone Buildings), including but not limited to undergraduates from the University of Oregon, Lane Community College, and Northwest Christian University

4.) Refer younger children to their private providers

C. Others may be vaccinated only with a specific physician prescription.

IV. VACCINE SCHEDULE

Vaccine	Dose and Route: 0.5mL IM		
Bexsero ^{®1}	DOSE	MINIMUM SPACING	Recommended Age
	1		≥11years
	2	1 month after dose 1	

Vaccine	Dose and Route: 0.5mL IM		
Trumenba ^{™2}	DOSE	MINIMUM SPACING	Recommended Age
	1		≥11 years
	2	2 months after dose 1	
	3	4 months after dose 2	

V. CONTRAINDICATIONS

Hypersensitivity, including severe allergic reaction, to any component of the vaccine, or after a previous dose of either Bexsero[®] or Trumenba[™] 1, 2

VI. A. PRECAUTIONS

Bexsero[®] 1:

- Individuals with altered immunocompetence may have reduced immune responses.
- Syncope can occur in association with administration. Ensure that procedures are in place to avoid injury from falling.
- Tip caps of the pre-filled syringes contain natural rubber latex.
- Use in pregnancy only if clearly indicated. Pregnancy registry: 1-877-683-4732
- Use with caution in nursing mothers.

VI. B. PRECAUTIONS

Trumenba[™] 2:

- Individuals with altered immunocompetence may have reduced immune responses.
- Use in pregnancy only if clearly indicated.
- Use with caution in nursing mothers.

VII. A. SIDE EFFECTS AND ADVERSE REACTIONS: BEXSERO®¹

Study Number: NCT01272180				
Number followed for Safety	N=110–114	N=94–96	N=107–109	N=90–92
Any adverse reactions after dose 1 or dose 2 of Bexsero®	Adverse Reaction %	Adverse Reaction %	Adverse Reaction %	Adverse Reaction %
Age in Years	10–25 years	10–25 years	10–25 years	10–25 years
	Dose 1	Placebo	Dose 2	Menveo®
Local Reaction, Injection site				
Pain	90	27	83	43
Redness	50	13	45	26
Swelling	32	10	28	23
Rash				
Systemic Complaints				
Irritability				
Fever 38.0–38.9°C	1	1	4	0
Alteration in appetite				
Alteration in sleep				
Tiredness	37	22	35	20
Headache	33	20	34	23
Muscle pain	49	26	48	25
Joint pain	13	4	16	4
Nausea	19	4	18	4

- Bexsero® was used for the outbreak at Princeton University and the University of California at Santa Barbara in 2014 for individuals 16–65 years of age (N=15,351). Overall, 50 individuals (0.3%) reported serious adverse events, including one case of anaphylaxis within 30 minutes of vaccination.¹
- Blisters at or around the injection site, rash, and eye swelling were reported from post-marketing experience outside of the United States.¹

VII. B. SIDE EFFECTS AND ADVERSE REACTIONS: TRUMENBA™ 2

Any adverse reactions after dose 1, 2 or dose 3 of Trumenba™												
Number followed for Safety	Study Number: NCT01461993											
	N =1970	N=1826	N=1688	N=496	N=468	N=438						
	Adverse Reaction %	Adverse Reaction %	Adverse Reaction %	Adverse Reaction %	Adverse Reaction %	Adverse Reaction %						
Age in Years	11– <18 years	11– <18 years	11– <18 years	11– <18 years	11– <18 years	11– <18 years						
	Dose 1	Dose 2	Dose 3	Saline 1	Saline 2	Saline 3						
Local Reaction, Injection site												
Pain							92.8	86.1	84.5	36.9	29.1	23.3
Redness							20.4	14.9	15.8	1.2	1.7	1.1
Swelling							21.6	18.2	20.1	2.8	2.8	1.8
Systemic Complaints	Trumenba + Saline											
Use of antipyretic	27	17.5	17									
Fever ≥38.0°C	6.4	1.3	1.1									
Tiredness	62.4	44.8	42.9									
Headache	54.8	40.8	34.8									
Muscle pain	42.4	30.5	30.9									
Joint pain	21.6	15.4	17									
Vomiting	7.4	2.4	2.5									
Diarrhea	15.2	9.3	8.9									

VIII. STORAGE AND HANDLING ^{1, 2}

Bexsero[®]	Store at 2°–8°C	Discard if vaccine has been frozen Do not use after expiration date	Protect from light
Trumenba[™]	Store at 2°–8°C (May arrive at 2°–25°C)	Discard if vaccine has been frozen Do not use after expiration date	Store flat (horizontally)

IX. ADVERSE EVENTS REPORTING

Adverse events

following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS). The VAERS online report form is available at vaers.hhs.gov/esub/step1. In addition, a copy of the reporting form should be reported to the patient's primary provider, per Oregon Revised Statute (ORS) 855-019-0280(4).³

REFERENCES

1. Bexsero[®] (2015) package insert, available at www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM431447.pdf, accessed 10 February 2015.
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To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 971.673.0300 and 711 for TTY. For other questions, consult with the vaccine recipient's primary health care provider or a consulting physician.

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