BUILDING
TOWARD INSTITUTIONAL PREPAREDNESS[1]

PHARMACIST **Checklist**

Research into potential gene therapies for a range of conditions is ongoing. Institutions evaluating their interest and preparedness for any of these gene therapies may benefit from multidisciplinary partnerships and comprehensive process development. Identifying the right processes and champions in gene therapy preparedness may take time and may vary depending on the provider, institution, and potential gene therapy products. Timely and proactive exploration of institutional protocols may make the implementation process easier and more effective.

Note that any potential therapy will have its own specific attributes and requirements. The following content does not provide requirements or guidance for any specific gene therapies; rather, it provides general information for your evaluation and consideration. No gene therapies for hemophilia A or B have been approved for use or determined to be safe or

PREPPING THE LAND | Educational Topics to Explore[2]

- ☐ The science behind gene therapies and related molecular biology principles
- ☐ Centers for Disease Control and Prevention (CDC) biosafety level (BSL) and National Institutes of Health (NIH) risk groups for different viral vectors
- ☐ Gene therapy concepts, eg, viral shedding, immune response, seroconversion
- ☐ Identify USP <800> implications (if any)
- ☐ Explore manufacturer-specific information for each gene therapy
- ☐ Seek and understand institutional polices (if available) that may pertain to gene therapies

ESTABLISHING THE STRUCTURE | Site Preparedness[1]

Obtain feedback from the biosafety committee across 3 key areas

01 PROCEDURES AND POLICIES FOR PRODUCT DISPOSITION AND ACCIDENTAL EXPOSURE FOR CONSIDERATION

Product disposition

- ☐ Receipt
- ☐ Dedicated freezer space
- ☐ Preparation
- ☐ Dispensing
- ☐ Transportation
- ☐ Administration

Exposure

- ☐ Accidental exposure
- ☐ Infectious control
- ☐ Employee rights
- ☐ Disinfection and decontamination of biosafety cabinet
- ☐ Disposing of waste
- ☐ Emergency spills

02 POTENTIAL PERSONNEL TRAINING FOR SAFE HANDLING

Identify and train personnel who would

- ☐ Ensure gene therapy is transported to pharmacy
- ☐ Place gene therapy in designated storage space
- ☐ Prepare and dispense gene therapy product
- ☐ Transport gene therapy to infusion site

03 POTENTIAL INFRASTRUCTURE SETUP

Storage

- ☐ Hazardous storage
- ☐ Ducted exhaust (USP <800>)
- ☐ Calibrated temperature-monitoring device
- ☐ Ultra cold freezer

Handling

- ☐ Class II biological safety cabinet
- ☐ Negative pressure *(based on risk assessment)*

Other

- ☐ Hazardous signage/ biohazard labels
- ☐ Personalized protective equipment
- ☐ Secured spill/ leak-proof container
- ☐ Spill kits

ESTABLISHING THE STRUCTURE | Site Preparedness[1] (cont'd)

PHARMACIST **Checklist**

04 POTENTIAL BIOSAFETY CONSIDERATIONS

- ☐ To date, federal agencies such as the National Institute for Occupational Safety and Health have not specified safe handling, storage, and usage practices that minimize risk, ie, BSL, for current US Food and Drug Administration–licensed gene therapies
  - BSL designation along with eventual incorporation of safe handling guidance, USP <800>, into pharmacies may further shape individual institution handling practices for gene therapies
  - In the interim, institutions may develop handling procedures with support from their respective biosafety committee
- ☐ Feedback from the biosafety committee may be informed by the agent's NIH-identified risk group and associated CDC BSL
- ☐ One publication discussing handling and administration of gene therapies for pharmacists has proposed that a BSL-1 classification may be acceptable assuming (1) the gene therapy product was manufactured without using adenovirus or any other helper virus of human origin and (2) the transgene is nontoxic or oncogenic

05 ADDITIONAL CONSIDERATIONS

- ☐ Ensure availability of crash cart
- ☐ Review biocompatibility between equipment, eg, tubing, infusion pump, and treatment
- ☐ Consider the workflow management parameters associated with treatment, which may include:
  - Managing the use of shared staff or resources, eg, facility space, hoods
  - Identifying time implications associated with gene therapy preparation, transportation, and infusion
  - Adopting checks and balances to ensure efficiency and quality
- ☐ **Identify opportunities to ensure close communication between pharmacy and infusion team; this may mitigate time constraint–related challenges that may arise and impact product stability during day of infusion**

MOVING DAY | Preinfusion (Peri-infusion)

01 TASKS TO COMPLETE BEFORE/DURING INFUSION DAY

- ☐ Acquire the correct dose of the treatment
- ☐ Track shipment, confirm integrity, ie, in-transit temperature deviations, and ensure transport to pharmacy and final storage location
- ☐ Prepare and dispense treatment
- ☐ Transport treatment to infusion site

02 LOGISTIC CONSIDERATIONS BEFORE/DURING INFUSION DAY

- ☐ Delivery location and receiving hours for shipment
- ☐ Location of infusion site

CLICK OR SCAN

Additional Resources

References: 1. Petrich J, et al. *J Pharm Pract.* 2020;33(6):846-855.
2. Pipe SW. *Haemophilia.* 2021;27(suppl 3):114-121.

FOR ADDITIONAL INFORMATION PLEASE CONTACT:

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