ashp® MIDYEAR 2016
Clinical Meeting & Exhibition

(Management Case Study) Development of a Collaborative Workflow for Oncologic Viral Therapy

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Disclosure

- The program chair and presenters for this continuing education activity have reported no relevant financial relationships.

Learning Objectives

- Describe barriers to ordering, dispensing, and administering biologically hazardous medications in the clinic setting.
- Identify key stakeholders for development of a high risk biologic medication dispensing and administration workflow.
- Describe how the development of a workflow for high risk biologic medication dispensing can streamline the process for other high risk biologic medications with similar characteristics.

Self-Assessment Questions

- True or False: The absence of clear safe handling guidelines is a barrier to dispensing and administering a high risk biologic medication in the clinic setting.
- True or False: Multidisciplinary collaboration is crucial for designing a successful workflow for the preparation and administration of a high hazard biologic.
- True or False: The development of one workflow for a high risk biologic medication cannot be translated to any other high risk biologic medications.

Definitions

- **Biological Hazard**: living organisms that can cause infectious diseases and allergies
- **High Hazard**: a product with infectious properties that require use of special isolation techniques in handling, administration or disposal

Dispensing Process Development Timeline

Talimogene laherparapvec requested for patient use. Initial pharmacist review of product information.

Pharmacy consultation with prescribing and administering physicians

Pharmacy & clinic consultation with Infection Prevention Team

Education of clinic and pharmacy staff

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Talimogene laherparepvec Indication

- **Indication:** Local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery.
- **FDA Approval:** First oncolytic viral therapy

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Talimogene laherparepvec Dosage & Administration

- **Dosage:**
  - Maximum starting dose is 4 ml of 10^6 PFU/ml with subsequent doses up to 4 ml of 10^8 PFU/ml
  - Second dose is 3 weeks after first, then every 2 weeks.
- **Administration**: Inject intralesionally into cutaneous, subcutaneous, and/or nodal lesions that are visible, palpable, or detectable by ultrasound guidance. Injection based on lesion size.

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Talimogene laherparepvec Storage & Stability

- **Storage:** Store and transport at **-90 to -70˚C** (-130 to -94˚F). Protect from light.
- **Stability**:
  - Thaw immediately prior to administration. Do not refreeze.
  - Storage times for thawed vials
    - 10^6 PFU/mL: 12 hours
    - 10^8 PFU/mL: 48 hours
  - Syringe stability (at room temp): **4 hours** (protect from light)

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Obstacles Identified

- No pre-existing procedure for dispensing this type of high biologic hazard medication at our institution
- Drug ordering/turnaround time
- Drug storage requirements
- Dispensing pharmacy resources
- Safe drug handling/preparation/disposal (Pharmacy & Clinic)
- Coordination among dispensing pharmacy, prescribing (melanoma) clinic, and administering (dermatology) clinic

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Physician & Pharmacy Meeting

- **Points for Discussion**
  - Who will prescribe and administer the product?
  - What is the desired dispensable (i.e. number of syringes, volume)?
  - What should be the communication pathway for this workflow?
- **Limitations Identified**
  - Clinic schedule overlap and appointment timing
  - Pharmacy workload capacity (i.e. hood space)
  - Use of closed system transfer device
  - Electronic ordering system “split syringe” capabilities vs. syringe size suitable for injections

Physician & Pharmacy Meeting

- **Outcome**
  1. Melanoma clinic → determines if patient will be treated & contacts pharmacy
  2. Pharmacy obtains drug and prepare product (4 syringes, 1 mL each) to have ready for Dermatology clinic visit. Contacts Dermatology physician when product ready.
  3. Dermatology clinic (last visit of day) → picks up drug at pharmacy, administers immediately
- **Action Items**
  - Pharmacy to create workflow and procedure documents for clinic and pharmacy staff education pending approval from Infection Prevention Committee
  - Pharmacy to work with informatics group to create desired orderable

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Infection Prevention Meetings (Pharmacy & Clinic)

- **Points for Discussion**
  - Orient Infection Prevention to pharmacy and clinic space
  - Cleaning schedule, supplies, compounding process, and waste disposal
  - Risk of exposure / personal protective equipment (PPE) in compounding and administration
- **Limitations Identified**
  - No previous experience of Infection Prevention with this type of agent (high biologic hazard)

Infection Prevention Meetings (Pharmacy & Clinic)

- **Outcome**
  - Approved PPE, cleaning schedule / products, compounding process as detailed in drafted procedure guidelines pending action items below
- **Action Items**
  - Infection Prevention to confirm appropriate waste disposal pathway
  - Pharmacy to reach out to colleagues at outside institutions to compare procedures (if available)

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Staff Education

- Four documents developed:
  - Overall work procedure
  - Safe handling (Pharmacy)
  - Safe handling (Clinic)
  - Patient Education

General Guidance for Handling per Manufacturer

- Follow universal biohazard precautions for preparation and administration.
- Care should be taken to avoid direct contact with injected lesions, dressings or body fluids to avoid risk of transfer of the infectious agent to other areas of the body.
- Wear gown, safety glasses or face shield and gloves.
- Cover exposed wounds before handling.
- Treat spills with a virucidal agent.
- Dispose of all materials that may have come into contact with the agent per universal biohazard precautions.
- Patients should place used dressings and cleaning materials into sealed plastic bag and dispose of with household waste

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General Guidance for Accidental Exposure per Manufacturer

- If there is an accidental occupational exposure (e.g., splash to eyes or mucous membranes), flush with water for > 15 minutes.
- For exposure through broken skin or needle stick, clean the affected area with soap and water and/or a disinfectant.

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Talimogene laherparepvec: U of M Process

- Days of preparation: Wednesday
- Ordering from manufacturer: Order 24 (if ordered by 7am) to 48 hours prior to treatment
- Storage: -80°C freezer in main hospital pharmacy area (~15 minute walk from infusion pharmacy space)
- Administration/Patient Location: Dedicated room in the Dermatology clinic

Day of Treatment

1. Patient seen in melanoma clinic early in the day. Decision to treat will be made and orders are signed.
2. Clinic pharmacist or other designee notifies infusion pharmacy that patient will be treated with medication ready by 2PM.
3. Pharmacy technician picks up medication in main hospital freezer and brings to infusion pharmacy. Pharmacy prepares dose.
4. Patient checks in with dermatology clinic.
5. Dermatology prepares patient for injection.
6. Pharmacy pages dermatology physician that medication is ready for pick-up.
7. Dermatology designee picks up medication at infusion pharmacy.
8. Dermatology provider administers medication.

Pharmacy Preparation Process

Hood Cleaning	- Remove all items from hood and clean/sterilize. - Only materials needed for preparation of product will be placed in the hood. - Closed system transfer device will be used to minimize risk of needle stick. - After compounding, clean with bleach (minimum of 10% sodium hypochlorite), sterile water, and 70% isopropyl alcohol. - Wait a minimum of 30 minutes between cleaning and resumption of compounding of other agents. - Document hood cleaning in DoseEdge®

Pharmacy Preparation Process

PPE	- Face shield, gown, and double gloves - No pregnant or breastfeeding employees will be involved in the preparation of this product
Waste Disposal	- Medical waste (including sharps) are steam autoclaved and rotaclaved - Pharmaceutical waste is treated as hazardous waste and sent via the Department of Occupational Safety and Environmental Health for disposal

Self-Assessment Question 1

- True or False: The absence of clear safe handling guidelines is a barrier to dispensing and administering a high risk biologic medication in the clinic setting.

Answer: True

Self-Assessment Question 2

- True or False: Multidisciplinary collaboration is crucial for designing a successful workflow for the preparation and administration of a high hazard biologic.

Answer: True

Self-Assessment Question 3

- True or False: The development of one workflow for a high risk biologic medication cannot be translated to any other high risk biologic medications.

Answer: False

Key Takeaways

- Key Takeaway #1
  - Developing a workflow for procurement, dispensing, and administration of novel new biologic agents requires identification of the unique obstacles that exist and a multidisciplinary approach.
- Key Takeaway #2
  - A developed workflow should be used to streamline the process for future high hazard biologic agents with similar characteristics.
- Key Takeaway #3
  - Debriefing with key personnel regarding the process to ensure efficacy is crucial.