AGENDA

11:30 a.m. – 11:35 a.m.
Welcome and Introduction
John Petrich, B.S.Pharm., M.S.

11:35 a.m. – 11:55 a.m.
Gene Therapy: Potential Application in Clinical Practice
Michael Storey, Pharm.D., M.S., BCPS

11:55 a.m. – 12:10 p.m.
Science of Gene Therapy: An Overview
Michael Storey, Pharm.D., M.S., BCPS

12:10 p.m. – 12:50 p.m.
Safe Handling of Gene Therapy and Organizational Readiness
John Petrich, B.S.Pharm., M.S.

12:50 p.m. – 1:00 p.m.
Faculty Discussion and Audience Questions
Gene Replacement and Gene Modifying Therapies: Therapeutics and Safety for Pharmacists

Gene Replacement and Gene Modifying Therapies: Therapeutics and Safety for Pharmacists

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- Michael Storey, Pharm.D., M.S., BCPS
  - AveXis, Inc.: advisory board

Products that have not received FDA approval will be discussed during this presentation.

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Gene Replacement and Gene Modifying Therapies: Therapeutics and Safety for Pharmacists

Learning Objectives
At the conclusion of this activity, participants should be able to
• Describe the potential application of gene therapy in cancer and rare diseases
• Explain the scientific principles involved in the development and clinical application of gene therapy
• Review key considerations in handling gene therapy products in all areas of the health system from a risk-management perspective
• Assess your organization’s readiness to provide gene therapy to patients through clinical trials and commercial therapy

Gene Therapy: Potential Application in Clinical Practice

Michael Storey, Pharm.D., M.S., BCPS
Nationwide Children’s Hospital
Columbus, Ohio

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Gene Replacement and Gene Modifying Therapies: Therapeutics and Safety for Pharmacists

Nationwide Children’s Hospital Center for Gene Therapy

• 11 principal investigators from bench to bedside
• 9,000 sq ft cGMP clinical manufacturing facility
• 12 open gene replacement therapy clinical trials
• Focus on neurology and neuromuscular diseases


cGMP = current good manufacturing practices

Definitions

• Gene therapy – Any therapy that acts on or modifies a gene for a therapeutic benefit
• What gene therapy is NOT
  – Genomic medicine
  – Pharmacogenomics
  – Pharmacogenetics
Rare Diseases

- Orphan Drug Act defines an orphan disease as one affecting <200,000 people in the United States
- More than 7,000 rare diseases
- Affect 30 million people
- Fewer than 500 of these 7,000 diseases have an FDA-approved treatment

Source: National Organization for Rare Disorders

Trials for Rare Disease

- May use single trial as pivotal trial for accelerated approval
- “Control” in studies may be natural history rather than placebo-control
- Number of patients may be very few
- May use surrogate endpoints

Gene Replacement and Gene Modifying Therapies: Therapeutics and Safety for Pharmacists

Gene Therapies Currently in Human Trials


Diseases for Which Gene Therapy Is Under Investigation

- Leber's congenital amaurosis
- Hemophilias
- Spinal muscular atrophy (SMA)
- Mucopolysaccharidosis (MPS)
- Muscular dystrophies
- Neuronal ceroid lipofuscinosis (NCLs)
- Amyotrophic lateral sclerosis (ALS)
- Sickle cell disease
- Cerebral adrenoleukodystrophy (ALD)
- Cancers
- Rett syndrome
- Alzheimer’s disease
- Cystic fibrosis
- Huntington’s disease
- Parkinson’s disease
- Glycogen storage diseases
- X-linked myotubular myopathy
- Crigler-Najjar syndrome
- Severe combined immunodeficiency (SCID)
- Infectious diseases
A Note on Cost of Gene Therapies

- Often small patient population
- May treat diseases with high costs already
- High manufacturing costs
- One-time therapy
- Voretigene neparvovec-rzyl - $850,000
- Cellular therapies vary - $373,000 to $475,000
- Hospitals and clinics must approach strategically


Approaching High-Cost Gene Therapies

- Frequent and early engagement with stakeholders
- Identify eligible patients
- Analyze reimbursement pathways for each drug
- Determine organizational channel strategy
  - Buy-and-bill vs. specialty pharmacy
- Follow reimbursement closely
- Identify organizational resources required
Science of Gene Therapy: An Overview

Michael Storey, Pharm.D., M.S., BCPS
Nationwide Children’s Hospital
Columbus, Ohio

Gene Expression: From DNA to Protein
Proteins as Drugs

- Immunoglobulins
- Alteplase
- Insulins
- Collagen
- Some hormones
- Most vaccines
- Albumin
- Interferons
- Enzyme replacement therapies

Cellular Gene Therapy

**CAR-T and TCR-T Immunotherapy**  
*Ex vivo* gene therapy

**FDA-Approved Products**  
Tisagenlecleucel  
Axicabtagene ciloleucel

Leukapheresis of cells  
Cells are re-infused into the patient  
A viral vector is used to genetically modify the T-cells to engage antigens expressed on tumor cells  
Expansion of cells

CAR-T = chimeric antigen receptor-T cell  
TCR-T = T-cell receptor-modified T-cell

Efficacy/Safety - Tisagenlecleucel

- Relapsed/refractory B-cell acute lymphoblastic leukemia
- Phase 2 study of 75 children and young adults
- Efficacy
  - Event-free survival: 73% (6 mo) and 50% (12 mo)
  - Overall survival: 90% (6 mo) and 76% (12 mo)
- Safety
  - Cytokine release syndrome in 77% of patients; 47% admitted to ICU
  - Transient neurotoxicity in 40% of patients
  - B-cell aplasia persisted for >6 mo in 83% of patients


Efficacy/Safety - Axicabtagene Ciloleucel

- Relapsed/refractory diffuse large B-cell lymphoma
- Phase 1 study of 111 adults
- Efficacy
  - Progression-free survival: 49% (6 mo), 44% (12 mo), 41% (15 mo)
  - Overall survival: 78% (6 mo), 59% (12 mo), 52% (18 mo)
- Safety
  - Cytokine release syndrome in 93% of patients; 13% grade 3-4
  - Transient neurotoxicity in 64% of patients; 28% grade 3-4

Gene Replacement and Gene Modifying Therapies: Therapeutics and Safety for Pharmacists

Regulators of Gene Expression

Antisense Oligonucleotides (ASOs) and Double-Stranded RNA (dsRNA)
- Target degradation
- Translational arrest
- Inhibition of RNA binding proteins
- Splicing modulation
- Increased translational activity

FDA-Approved Products
- Fomivirsen*
- Nusinersen
- Mipomersen
- Inotersen
- Eteplirsen
- Patisiran

*Removed from market

CRISPR-Associated Protein 9 (CRISPR-Cas9)

Clustered Regularly Interspaced Short Palindromic Repeats “Gene Editing”

- Enable modification of the cell’s genome at specific sites
- Preclinical and early clinical trials

CRISPR = clustered regularly interspaced short palindromic repeats (CRISPR)


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CRISPR-Cas9


Gene Replacement Therapy

Viral Vector Gene Therapy
Useful for treating monogenic disease

FDA-Approved Products
voretigene neparvovec-rzyl

Efficacy/Safety - Voretigene Neparvovec-rzyl

- RPE65-mediated inherited retinal dystrophy
- 31 patients enrolled in randomized, controlled, crossover trial
- Efficacy
  - Multi-luminance mobility test (MLMT) - 65% of intervention group passed at 1 lux (lowest luminescence level) vs. 0% in control at 1 yr
- Safety
  - Most adverse effects were transient and mild
  - Ongoing adverse effects included cataracts (2), eye pruritus (1), and maculopathy of the epiretinal membrane (1)


Systemic Gene Replacement Therapy:
Adverse Effects

- Transient transaminitis
  - Can be mitigated with corticosteroid prophylaxis
- Arthralgia, headache, myalgia, back pain
- Fatigue
- Insomnia
- Infections


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Concerns with Gene Therapy

- Durability of response
- Adequacy of response
- Unintended effects elsewhere in the genome
- Seroconversion


Serology in Gene Therapy

- Formation of antibodies to viral capsids used for gene therapy
- Some percentage of the population is seropositive to most viruses
- Those who are seropositive to a virus are likely to be excluded from trials with a viral vector
- Risk of seroconversion in caregivers and healthcare professionals from exposure to gene therapy

Seroconversion

Viral vector gene replacement therapy administered

Immune response to virus

Development of antibodies

Immunity to viral vector used to deliver transgene


Key Takeaways

• Gene therapies are now being commercialized
• Cost concerns need to be addressed when introducing gene therapies to your organization
• Gene therapies have various mechanisms of action
• Gene replacement therapies in trials are generally well-tolerated, with transient adverse effects
Gene Replacement and Gene Modifying Therapies: Therapeutics and Safety for Pharmacists

Safe Handling of Gene Therapy and Organizational Readiness

John Petrich, B.S.Pharm., M.S.
Cleveland Clinic
Cleveland, Ohio

Resources

- National Institutes of Health and Centers for Disease Control position paper

- European guidelines

- Hematology/Oncology Pharmacy Association Investigational Drug Service best practice standards

- Standard operating procedures (SOPs) from universities, health systems, Cleveland Clinic
Gene Replacement and Gene Modifying Therapies: Therapeutics and Safety for Pharmacists

Cleveland Clinic Investigational Drug Service (IDS) Pharmacy

- >400 clinical trials, 12 FTEs
- USP-compliant clean room with dedicated negative pressure investigational drug room
- 7 open gene therapy trials

Gene Therapy Risk Groups: RG1

- RG1 agents are not associated with disease in healthy human adults
- Example: adeno-associated virus (AAV)

RG = risk group
Gene Therapy Risk Groups: RG2

- RG2 agents are associated with human disease that is rarely serious and for which preventive or therapeutic interventions are often available
- Example: adenovirus

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3905712/

Gene Therapy Risk Groups: RG3

- RG3 agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available
- High individual risk but low community risk
- Example: poxviruses

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3905712/
Gene Therapy Risk Groups: RG4

- RG4 agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available
- High individual risk and high community risk
- Example: hemorrhagic fever viruses

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3905712/

<table>
<thead>
<tr>
<th>Vector</th>
<th>Vector Replication Ability</th>
<th>Suggested Biosafety Level</th>
<th>Safety Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adenovirus</td>
<td>Deficient</td>
<td>Level 2</td>
<td>Can provoke inflammatory response</td>
</tr>
<tr>
<td>Retrovirus</td>
<td>Deficient</td>
<td>Level 2</td>
<td>Insertional mutagenesis</td>
</tr>
<tr>
<td>Vaccinia virus</td>
<td>Competent</td>
<td>Level 2 with level 3 practices</td>
<td>Can infect weakly; vaccines are available</td>
</tr>
<tr>
<td>Fowlpox, canarypox</td>
<td>Competent</td>
<td>Level 1</td>
<td>Do not infect humans</td>
</tr>
<tr>
<td>Adeno-associated virus</td>
<td>Deficient</td>
<td>Level 1</td>
<td>Could infect if “helper viruses” are present; possible mutational concern</td>
</tr>
<tr>
<td>Herpes simplex virus</td>
<td>Deficient</td>
<td>Level 2</td>
<td>Unknown effect on latent viruses in patients</td>
</tr>
</tbody>
</table>

### Determinant of Biosafety Level? (cont.)

<table>
<thead>
<tr>
<th>Vector</th>
<th>Vector Replication Ability</th>
<th>Suggested Biosafety Level</th>
<th>Safety Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nonviable</strong>&lt;br&gt;Nonviral systems (naked DNA, plasmids, RNA transfer)</td>
<td>None</td>
<td>Level 1</td>
<td></td>
</tr>
<tr>
<td><strong>Other</strong>&lt;br&gt;Lentivirus (HIV)</td>
<td>Deficient</td>
<td>Level 2 with level 3 practices</td>
<td>Very low risk (but not zero) of converting to replication competent</td>
</tr>
<tr>
<td>Bacterial</td>
<td>Competent</td>
<td>Level 1 or 2</td>
<td>Refer to risk group</td>
</tr>
<tr>
<td>Yeast</td>
<td>Competent</td>
<td>Level 1 or 2</td>
<td>Refer to risk group</td>
</tr>
</tbody>
</table>


### Pros and Cons

<table>
<thead>
<tr>
<th>Vector</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adenovirus</strong>&lt;br&gt;High transfection efficiency <em>in vivo</em> and <em>ex vivo</em>&lt;br&gt;Can infect dividing and nondividing cells&lt;br&gt;Wide host cell range</td>
<td></td>
<td>Limited insert size capacity&lt;br&gt;Short duration of expression&lt;br&gt;Immunogenic (repeat dosing therefore ineffective)</td>
</tr>
<tr>
<td><strong>Retrovirus</strong>&lt;br&gt;No immune response&lt;br&gt;Reasonable duration of expression&lt;br&gt;Integrates into host cell genome&lt;br&gt;High transfection efficiency <em>ex vivo</em></td>
<td></td>
<td>Only infects dividing cells&lt;br&gt;Limited insert size capacity&lt;br&gt;Potential safety risk of insertional mutagenesis</td>
</tr>
<tr>
<td><strong>Adeno-associated virus</strong>&lt;br&gt;Can infect dividing and nondividing cells&lt;br&gt;Reasonable duration of expression&lt;br&gt;Low immunogenicity</td>
<td></td>
<td>Inefficient large scale virus production&lt;br&gt;Very limited insert size capacity</td>
</tr>
</tbody>
</table>

Gene Replacement and Gene Modifying Therapies: Therapeutics and Safety for Pharmacists

Biosafety Levels

• Biosafety levels 1, 2, 3, and 4
• Knowing the difference among biosafety levels and their corresponding safety requirements is imperative for anyone handling gene therapy


Biosafety Level 1 (BSL1)

• Work practices
  – Standard
    • Hand washing
    • Do not pipette by mouth
    • Proper sharps disposal
    • PPE as needed
    • Minimize aerosols
    • Decontaminate surfaces
    • Worker training

• Room requirements
  – Door to restrict access
  – Biohazard sign
  – Cleanable surfaces (no carpet)
  – Hand-washing sink available

PPE = personal protective equipment

Biosafety Level 2 (BSL2)

- Work practices
  - All for BSL1 plus
  - Demonstrate proficiency
  - Follow written procedures
  - Decontaminate equipment
  - Remove PPE before leaving room
  - Conduct procedures generating aerosols in BSC
  - Personnel provided medical surveillance as appropriate
  - Report and evaluate all incidents of exposure

- Room requirements
  - All for BSL1 plus
  - Self-closing and lockable doors
  - Consider negative airflow into room if new facility
  - BSCs certified at least annually
  - Eyewash station available
  - Method for decontaminating waste available

BSC = biological safety cabinet


Biosafety Level 3 (BSL3)

- Work practices
  - All for BSL1 and BSL2 plus
  - All work must be done in a BSC — no open bench work
  - Solid front gowns worn
  - PPE discarded in biomedical waste or decontaminated before laundering
  - Demonstrate proficiency

- Room requirements
  - Work done in class 2 or 3 BSC
  - Room has 2-door access
  - Hands-free handwashing sink
  - Negative airflow and no recirculation to other areas of the building
  - Room must be capable of being sealed for decontamination

Gene Replacement and Gene Modifying Therapies: Therapeutics and Safety for Pharmacists

Biosafety Level 4 (BSL4)

- As the highest level of biological safety, a BSL4 lab is used for work with highly dangerous microbes
- Infections caused by these types of microbes are frequently fatal, and treatment and vaccines are not available
- Two examples of such microbes are Ebola and Marburg viruses
- Personnel are required to change clothing before entering and shower upon exiting the BSL4 lab
- Materials must be decontaminated before exiting
- Personnel must wear appropriate PPE as for BSL3, as well as a full body, air-supplied, positive pressure suit
- A class III BSC must be used


GT Handling

- Receipt and storage
- Preparation
- Dispensing
- Disposal
- Decontamination of spills
- Accidental exposure

GT = gene therapy

GT Handling: Receipt and Storage

- Receipt and storage
- Preparation
- Dispensing
- Disposal
- Decontamination of spills
- Accidental exposure


GT Handling: Preparation

- Receipt and storage
- Preparation
- Dispensing
- Disposal
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GT Handling: Dispensing

- Receipt and storage
- Preparation
- Dispensing
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GT Handling: Disposal

- Receipt and storage
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GT Handling: Decontamination of Spills

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GT Handling: Accidental Exposure

- Receipt and storage
- Preparation
- Dispensing
- Disposal
- Decontamination of spills
- Accidental exposure

Organizational Readiness

- GT products should enter the pharmacy for safe receipt, storage, accountability, and disposal


Organizational Readiness: PPE

- Develop SOPs/IOPs addressing
  - PPE
  - Equipment
  - Preparation and dispensing
  - Disposal
  - Spillage and exposure
  - Transport

IOPs = internal operating procedures
Organizational Readiness: Equipment

- Develop SOPs/IOPs addressing
  - PPE
  - Equipment
  - Preparation and dispensing
  - Disposal
  - Spillage and exposure
  - Transport

Cleveland Clinic Decision Tree

Gene transfer product

Nonviable rDNA (plasmids, liposomes)

Viable Bacteria, yeasts viruses

Replication competent

Replication deficient

Infected human cells?

Yes
No

Infected human cells?

Yes
No

Consider the risk group of the organism; usually BSL2

BSL1

Consider the risk group of the organism; may be able to decrease level of containment

Organizational Readiness: Preparation and Dispensing

• Develop SOPs/IOPs addressing
  – PPE
  – Equipment
  – Preparation and dispensing
  – Disposal
  – Spillage and exposure
  – Transport

Organizational Readiness: Disposal

• Develop SOPs/IOPs addressing
  – PPE
  – Equipment
  – Preparation and dispensing
  – Disposal
  – Spillage and exposure
  – Transport
Organizational Readiness: Spillage/Exposure

- Develop SOPs/IOPs addressing
  - PPE
  - Equipment
  - Preparation and dispensing
  - Disposal
  - Spillage and exposure
  - Transport

Organizational Readiness: Transport

- Develop SOPs/IOPs addressing
  - PPE
  - Equipment
  - Preparation and dispensing
  - Disposal
  - Spillage and exposure
  - Transport


Education and Training

- Training and education
  - Fill education gaps resulting from additional and changing roles and responsibilities
    - Should be specific for each group, including nurses, physicians, and pharmacists

- Caregiver education
  - Pharmacists have a role in educating patients and caregivers about administration issues, waste handling
Gene Replacement and Gene Modifying Therapies: Therapeutics and Safety for Pharmacists

Planning for the Future

• Standardize gene therapy within your institution to reflect a scientifically valid, rational balance of practice considerations to ensure broad access
  – SOPs or IOPs that are therapy specific
• Consider appointing a pharmacist to assume responsibility for gene therapies once enough are approved and used in your institution

Key Takeaways

• Gene therapy and its handling are unique
  – Requires containment to protect healthcare workers, patients, and the environment by adhering to aseptic principles
  – Can be handled safely with minimal risk once institutional procedures are in place with education and training
• Pharmacists have a key role
  – Identify risk level
  – Establish infrastructure
  – Develop policies and procedures

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Which of these practice changes will you consider making? Select all that apply.

a. Educate colleagues about GTs in the pipeline
b. Be a champion to ensure safe handling of GTs to protect myself, other staff, and patients and their caregivers
c. Develop policies and procedures related to handling GTs
d. Train staff to handle GTs in a controlled environment
e. Involve clinical and administrative representatives in evaluating the capacity of my organization to provide GTs in the future

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ASHP CE Processing
✓ Deadline: January 31
✓ elearning.ashp.org
✓ Code: ____________
✓ Complete evaluation
✓ Additional instructions in handout

Watch for follow-up activities on this topic in 2019
- e-Newsletters
- Engaging the Experts interview
- Ask the Experts webinar
- Archived version of today’s symposium
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Questions? Contact EducServ@ashp.org!
ABOUT THE FACULTY

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John Petrich, B.S.Pharm., M.S., is Manager of the Investigational Drug Service (IDS) at the Cleveland Clinic Health System (CCHS) in Cleveland, Ohio.

Mr. Petrich earned his Bachelor of Science in Pharmacy degree from the University of Toledo and Master of Science in Health Sciences degree from Cleveland State University.

At CCHS, Mr. Petrich oversees medication management for patients in clinical trials at the main campus in Cleveland and in Nevada. His focus is on clinical, regulatory, and financial aspects of trial conduct in both the acute and ambulatory settings. Before assuming the IDS role at CCHS, he was a member of the lung transplant team and pharmacokinetic consult service.

With ASHP, Mr. Petrich has served on several Section Advisory Groups, Education Steering Committee, and as a Network Facilitator. He authored a book chapter on IDS operations and has presented on the topic of clinical research related to medication safety, quality control, and health-system operations. Mr. Petrich is Past President of the Society of Clinical Research Associates (SOCRA), a nonprofit organization committed to providing education and certification opportunities to clinical researchers. He remains a standing member of the SOCRA certification and annual conference poster program committees.

Michael Storey, Pharm.D., M.S., BCPS, is Medication Use and Formulary Coordinator at Nationwide Children’s Hospital in Columbus, Ohio.

Dr. Storey received his Doctor of Pharmacy degree from Ohio Northern University in Ada, Ohio. Following graduation, he completed a PGY1/PGY2 residency in Health-System Pharmacy Administration at The Ohio State University Wexner Medical Center and concurrently completed his Master of Science degree at The Ohio State University College of Pharmacy.

In his current role at Nationwide Children’s Hospital, Dr. Storey coordinates operations of the P&T committee and collaborates across the hospital on cost and quality projects. He also is a leader in implementing complex, high-impact therapies, with expertise in ensuring that operational, financial, and clinical needs are met. Previously he served the hospital in various pharmacy leadership roles, including managing operations, clinical services, and oncology.

Dr. Storey is a member of ASHP, Hematology Oncology Pharmacists Association, Children’s Oncology Group, International Academy of Compounding Pharmacists, Ohio Pharmacists Association, and Ohio Society of Health-System Pharmacists. He serves on the Raabe College of Pharmacy Advisory Board at Ohio Northern University.

Additional Activities on Gene Therapy Coming in 2019

- On-demand activity of today’s live symposium
- Engaging the Experts interview and e-newsletters
- Ask the Experts webinar based on questions from today’s activity

www.ashpadvantagedmedia.com/genetherapy

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