

Biosafety Challenges with the Use of Viral-Mediated Gene Therapy in a Healthcare Setting



Alex M. Brown, CSP
Research Safety & Injury Management Specialist
Research Safety

Objectives



- 1. Identify the gaps** between the research and the healthcare environments
- 2. Share strategies** to address biosafety challenges

Abigail Wexner Research Institute

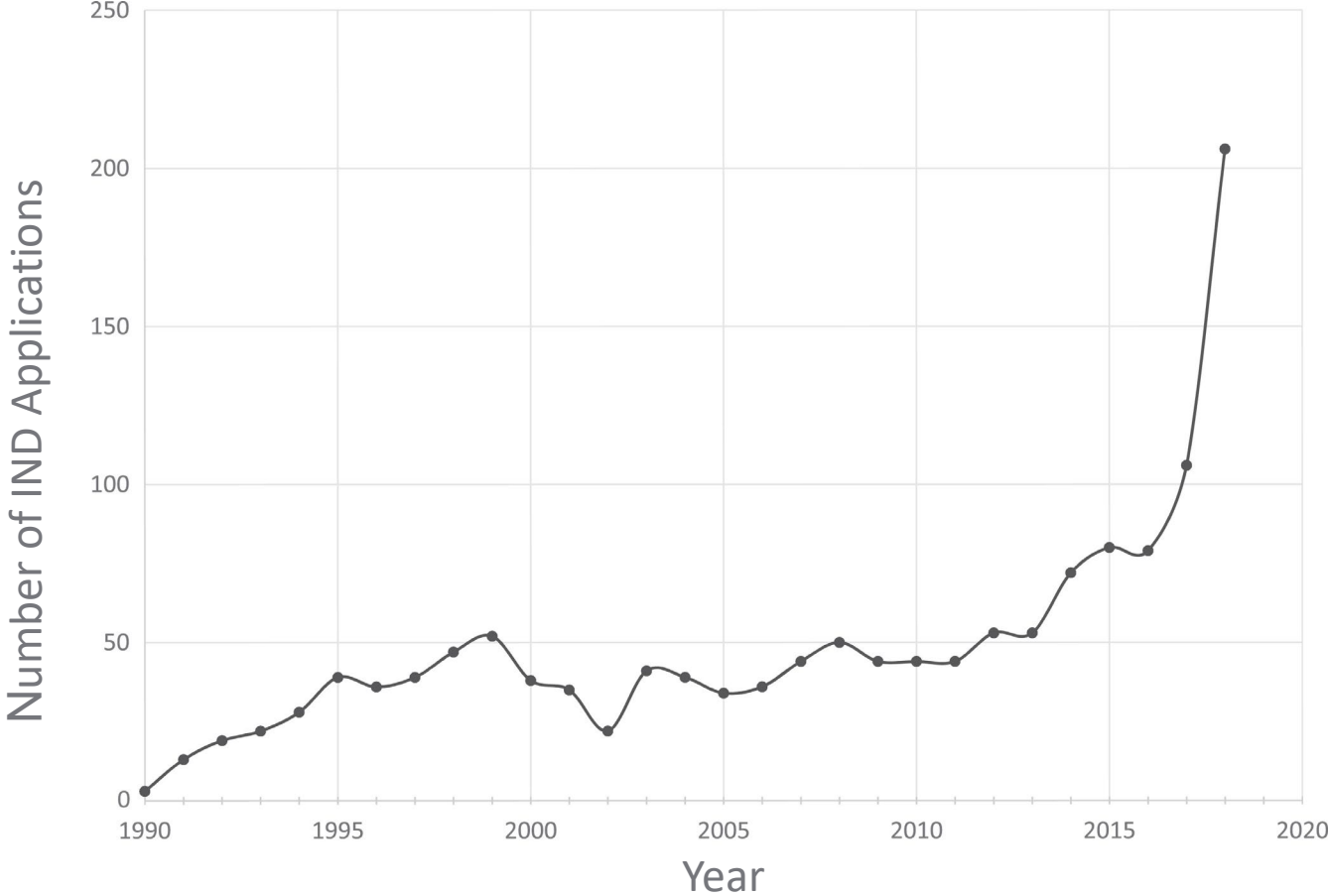


Research dates back to
1941

Top 10 NIH funding
among free-standing
children's hospitals

Over 90 wet labs in 15
Centers

“On The Verge of a Boom”



Language Barrier

Work Environment

Gap Analysis

Training & Education

Policy Development



NATIONWIDE CHILDREN'S

When your child needs a hospital, everything matters.

Language Barriers



- Biosafety Levels
- Risk Groups
- Viral Shedding
- Specific PPE recommendations



- Infection Control
- Standard Precautions
- Transmission Based Precautions
- Critical thinking based on symptoms/ diagnosis

Work Environment



- Engineering controls
- Limited Access
- Consistent staffing
- SOP Based Work Practices



- Clinical care is not in containment
- Family and visitors
- 24/7 shift based staff
- Varying roles in patient care

Training



- IBC oversight for required training
- Established SOPs and protocols
- Learn processes through apprenticeship
- Training is tracked & documented by PI or designee



- Multidisciplinary work environment
 - Nurse Educators
 - Physicians
 - Unlicensed Staff

Policy Development

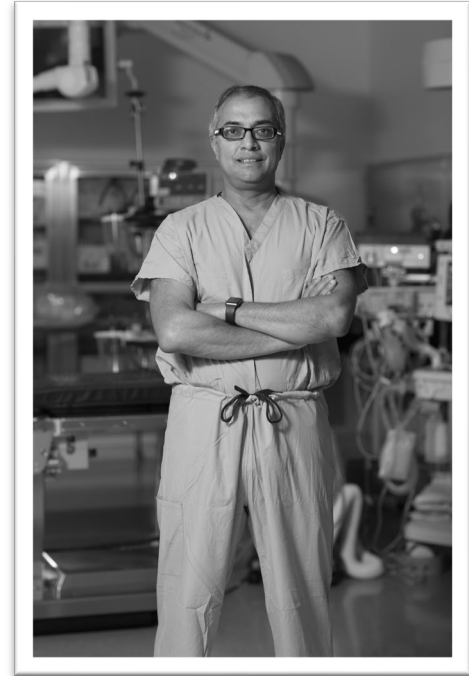


- IBC Oversight
- NIH guidelines
- BMBL 5th Ed.



- Joint Commission / CMS guidelines
- Infection Control Committee/
Epidemiology
- Local and State regulations
- USP 800

What's in place at NCH



Collaboration Across Disciplines

- Pharmacists
- Physicians
- Nurses
- Patient Care Services
- Environmental Services
- Infection Control/ Epidemiology
- Occupational, Physical, Behavioral Therapy
- Administrative Staff



Language Barrier – Hazard Communication

- **Room Signage**
 - Transmission Based Precautions
 - Hand Hygiene
- **Electronic Medical Records**



Language Barrier – Hazard Communication

Epic Banner:

Summary

Asthma Action Plan Complex Patient Report Seizure Action Plan SNAPSHOT VTE Prevention Assessment ALL 5P Handoff Report

GENE THERAPY medications require Hazardous Drug Precautions for 30 Days:

- Place *Hazardous Drug Precautions* door sign after administration
- Consider ALL body fluids hazardous
- Use a single pair of gloves at minimum
 - Additional PPE based on judgment
- Spill of body fluid = hazardous spill

for
1d
on

Contact Precautions, Droplet... C05B, C5B037 Height: 127 cm
HAZARDOUS DRUG PRECA... Current BMI: 23.87 kg/m² (97%)
BSA: None

Policy Development - Infection Control

Table 1 (NCH Approved Disinfectants):

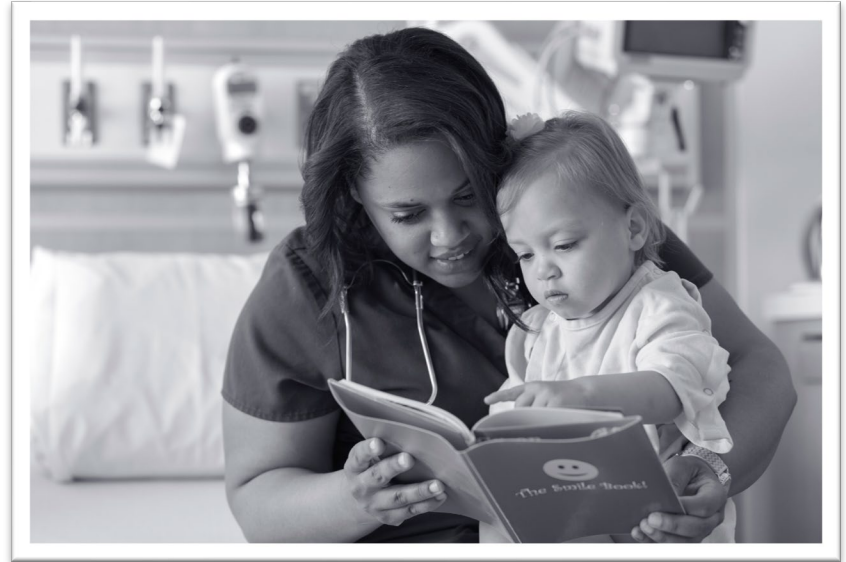
The following intermediate level, and low level disinfectants are approved for hospital use.

Intermediate Level Disinfectants		
Product	Description	Contact Time Wet Time
Clorox Healthcare® Bleach Germicidal Cleaner Spray or Wipe	<ul style="list-style-type: none"> - Active Ingredient: 0.55% Sodium Hypochlorite (equivalent to a 1:10 bleach solution) - Only hospital approved product effective against <i>Candida auris</i>, <i>Clostridioides difficile</i>, cryptosporidium, and <i>Macacine herpesvirus</i> (i.e. herpes B, monkey B virus). In addition, to be used when norovirus or sapovirus is suspected or confirmed. 	3 minutes
PDI Sani-Cloth® AF3 Germicidal Disposable Wipe	<ul style="list-style-type: none"> - Active Ingredients: Quaternary Ammonium Compounds - Does not contain fragrance, alcohol, bleach, acid, phenol, acetone, or ammonia. - Only available in a wipe, if a Quaternary Ammonium spray is needed, the approved product is Virex™ Tb RTU 	3 minutes
Metrex CaviCide™ Spray or CaviWipes™	<ul style="list-style-type: none"> - Active ingredients: Isopropyl Alcohol (17.2%) and Ammonium Chloride. - Only approved for hospital use if equipment IFU requires it - Bleach free 	3 minutes
Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Spray or Wipe	<ul style="list-style-type: none"> - Active Ingredient: 1.4% Hydrogen Peroxide 	Wipes: 5 minutes Spray: 4 minutes
Diversity Virex® Tb Ready-To-Use Disinfectant Cleaner Spray	<ul style="list-style-type: none"> - Active Ingredients: Quaternary Ammonium Compounds 	10 minutes

Training & Education







Clinical Staff

- Nurse Educators
- Learning Management Systems



NATIONWIDE CHILDREN'S
When your child needs a hospital, everything matters.

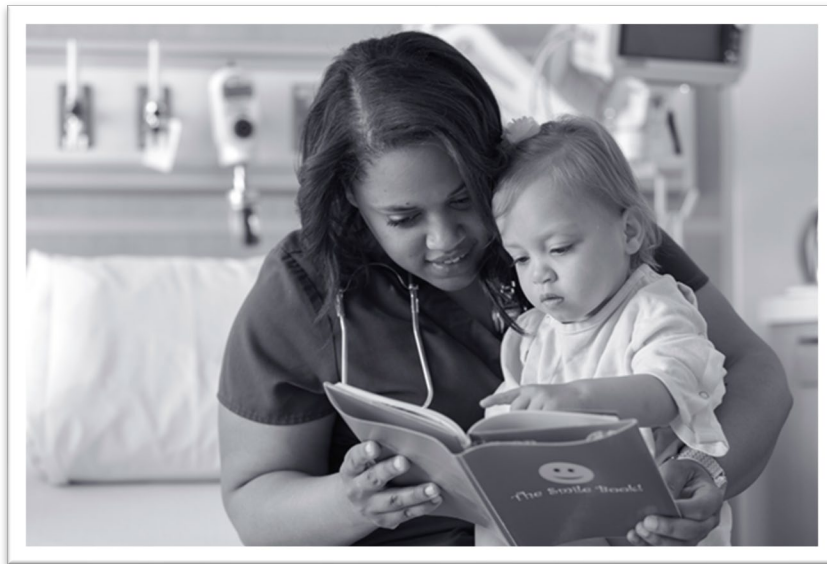
Training for Clinical Staff

	NCH 2020 General + Research (C21) Due: 8/26/2020 Status: Registered	Open Curriculum ▾
	NCH 2018 POCT NOVA STATSTRIP GLUCOSE TRAINING Due: 11/30/2018 Status: Registered / Past Due	Open Curriculum ▾
	New Employee: Department Orientation Checklist Due: 1/19/2018 Status: In Progress / Past Due	Inactive ▾
	Open Enrollment Information for the 2019 Plan Year Due: No Due Date Status: In Progress	Launch ▾
	NCH One Team: Culture Shaping Workshop (Starts 8/19/2016) Due: No Due Date Status: Registered	View Training D... ▾
	NCH 2018 Human Gene Therapy Biosafety Training Due: No Due Date Status: In Progress	Launch ▾

Training & Education

Clinical Staff

- Nurse Educators
- Learning Management Systems
- Just-in-time Documents



Training & Education at NCH

Patient Families

- Risk Communicated Through Informed Consent
- Take Home Letter
 - Contact precautions
- Carry Card
- Helping Hands



Ongoing Challenges at NCH

- Tracking of training
 - Physicians
 - Rotating Staff/ Float Staff
- FDA approved products



Questions?

Contact Information:

Alex M. Brown

575 Children's Crossroads

Columbus, OH 43215

(614) 355-3574

alex.brown@nationwidechildrens.org

