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NIEHS Worker Training Program (WTP) Infectious Disease Response Training (IDRT) Program Needs Assessment & Gap Analysis: Overview

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Objective NIEHS WTP IDRT Program

- NIEHS WTP IDRT Needs Assessment & Gap Analysis Themes
- Addressing Gaps
- IDRT Preparedness Efforts
- Current Pandemic Therapeutic Updates



NIEHS WTP IDRT Program

HAZMAT & Biological Safety Training:

- Anthrax attacks (2001)
- Mold remediation from Hurricane Katrina (2005)
- Avian Influenza H5N1 Pandemic (2007)
- H1N1 Pandemic (2009)
- Mold remediation from Hurricane Sandy (2012)
- Ebola virus disease preparedness (2013/2014)
- Infectious Disease Response Training (IDRT) Program (2015-2019)
- COVID-19 (2019-2020)

Training Standards (TTT & Direct Training)

- Bloodborne Pathogens and Respiratory standards
- Personal Protective Equipment (PPE) standard
- General Duty Clause
- ³ Pathogen safety data guidelines



- No current mechanism to integrate public health, medical, occupational health and worker safety activities in a comprehensive and all-encompassing approach
- Lack of synergistic perspectives of key stakeholders for riskbased protective guidance that informs the full spectrum of workers



- Disconnect between infection control, occupational health, worker safety, and emergency management at the healthcare level
- No platform for workers to provide input on needs
- Guidance issued by federal authorities at times delayed or inconsistent
- Resources on infectious diseases from trusted sources can be conflicting or lacking specificity
- No incentive for labor and management to work collaboratively on policies, protocols and practices in the workplace
- Resiliency training was rarely offered in any training



- Sustaining a high level of readiness is difficult
- Multi-factorial: complacency, inadequate funding, loss of interest as outbreak resolves
- Pathogen-specific training and emphasis on technical aspects of personal protective equipment (PPE) can limit competency necessary to perform one's job duties safely



- Timely and consistent guidelines based on worker risk are essential
- Complacency and funding interfere with sustainment of existing programs and development of new programs
- Workers need basic preparedness training to enhance generalized worker safety and health
- No clearly defined and agree-upon core competencies for worker safety and biothreats
- Stigma of the infectious disease du jour



- Partner with awardees to disseminate infection control and hazard recognition education/training programs for a broad spectrum of workers to empower risk-exposure understanding in the workplace
- Coordinated efforts with federal partners for enhanced shared voice
- Awareness-and-Operations level training tools
- Pathogen safety data training module & guidebook
- Support multi-state consortiums of biosafety professionals
- Support HHS ASPR/NETEC preparedness strategies
- Evaluate the efficacy of preparedness training and capabilities
 ⁸ foodback loop integration
- ⁸ feedback loop integration

Addressing Gaps NIESH WTP IDRT Program

High Risk Categories, Grouped

Target Population Category by Applicant												
Population Category	ICWU	SCEO	DUKE	IUB	EMORY	LIUNA	UAB	RUTGERS				
	Cyphers	Frederick	Frothinghom	Gibbs	Isakov	LeConche	McCormack	Rosen				
Airline/Airport Workers	х	x	x			x						
Border Control Workers		X	X									
Cleaning Professional (excluding airline)		X				x						
Community Volunteers/Workers		X			Х			X				
Construction Workers						X						
Correctional Officers	x											
Custodial/Environmental Service Workers	Х		X	Х	Х	X	x					
Daycare Workers	x					·						
First Responders	x	X	x	х	X	х	x	x				
Handling Dead Bodies		х		х								
Healthcare Facility Workers (clinical)	x	X	x		Х		x					
Healthcare Facility Workers (non-clinical)		х	X		Х	х		x				
Healthcare Laboratory Workers	X	X	X		х	-	x					
Healthcare Professionals	x	x	x		х		x	x				
Maintenance Professional	x	X						X				
Nail Salon Workers								х				
Public Health Professionals	х		x		х			х				
Occupational Health & Safety Activists	x	-		x	х	x		x				
Security Workers			x									
Teachers/Students	х											
Transport Workers		х	x	х	5			x				
Vulnerable Populations			x	х		x		x				
Waste Handlers		х	x	х			x					
Total high risk categories, grouped	12	13	13	7	9	8	6	10				

UNOVARTIS

IDRT Preparedness Efforts & COVID-19 Current Events

- Occupational Safety and Health Administration (OSHA) Guidance on Preparing Workplaces for COVID-19: Four Risk Zones
- Social Distancing / Avoid Spread & Exposure
- Use Standard, Contact and Airborne Precautions
- Avoid touching mucus membrane surfaces (eyes, nose, face)
- Hand hygiene with alcohol-based solution before/after contact with infectious material/PPE
- Practice proper don, use and doff of PPE
- Assess and triage for respiratory symptoms and risk factors; face-mask, isolation in Airborne Infection Isolation Room (AIIR) NOVARTIS

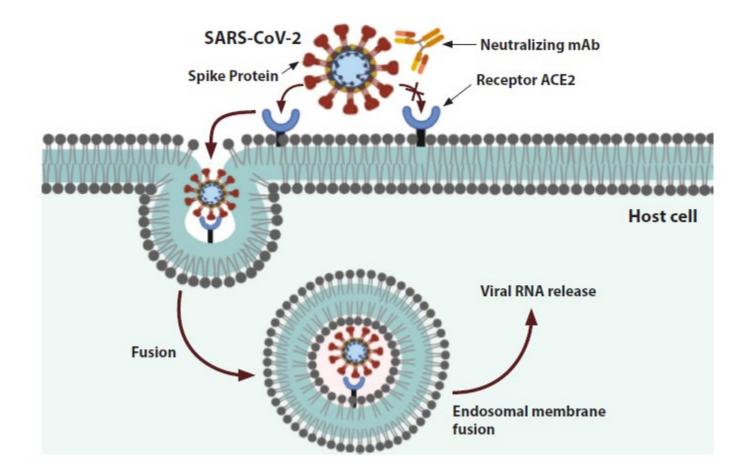
Repurposed treatment

- Viral entry inhibition
- Viral replication inhibition
- Novel approaches using pharmacokinetic and pharmacodynamic data or meta-analyses from existing trials as part of expedited review by the FDA

Small molecule drug development

- New-target, new-chemical compounds
- Biologic therapy development
 - Antibody screening
 - Vaccines
 - siRNA treatments







Repurposed Rx: Remdesivir (ssRNA)

TABLE: CLINICAL TRIALS TESTING REMDESIVIR FOR COVID-19

Remdesivir trials for COVID-19												
Sponsor	Phase	No. of patients	Disease setting	Dose duration	Control	Primary endpoint	Location	Start date				
Gilead	Ph III	600	Mild to moderate	5 or 10 days	Standard of care, open- label	Patients discharged by day 14	Multiple	March				
Gilead	Ph III	400	Severe	5 or 10 days	No control, open-label	Normalization of fever and oxygen saturation for at least 24 hours	Multiple	March				
China-Japan Friendship Hospital	Ph III	308	Mild to moderate	10 days	Placebo	Normalization of fever, respiratory rate, and oxygen saturation, and alleviation of cough for at least 72 hours	Hubei	Feb. 12				
China-Japan Friendship Hospital	Ph III	453	Severe	10 days	Placebo	Time to clinical improvement, measured on 6-point scale from discharge to death	Hubei	Feb. 6				
NIH	Ph II platform	394	Mild to severe	10 days	Placebo	Disease severity on 7-point scale from death to discharged with no	Nebraska	Feb. 21				

limitation on activity

- Repurposed Rx: Lopinavir/Ritonavir
- AbbVie currently collaborating with health authorities (CDC, WHO and NIH) to see if it can be repurposed as treatment for COVID-19

- Repurposed Rx: Sarilumab
- Sanofi on track to test potential use for COVID-19; early stage



- Vaccine Trials:
- Moderna biotech phase 1 testing of developed mRNA vaccine in collaboration with NIAID. Mechanism of action to develop antibodies against spike protein unique to virus.
- Johnson & Johnson investigating development of potential vaccine
- Eli Lilly investigating screening antibody candidate development
- Pfizer is in early development of antiviral therapy and vaccine
- Sanofi development of COVID-19 vaccine
- Novartis development of COVID-19 vaccine





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QUESTIONS?

