Pediatric COVID-19 Research Programs
AAP Town Hall

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Active Pediatric COVID-related Research Programs

- CARING for Children with COVID
  - MIS-C Cohorts
  - PReVAIL kIds
- Safe Return to School Diagnostic Testing
- RECOVER
CARING for Children with COVID
CARING for Children with COVID (Collaboration to Assess Risk and Identify Long-term outcomes for Children with COVID)

- Two approaches
- Leverages resources and networks from 3 NIH ICs to capture data from hospitalized patients with MIS-C
- Trans-NIH effort through RADx-Rad to enhance diagnostic and predictive efforts
- CARING4KidswithCOVID.nih.gov
• Observational study, 1232 screened, >750 children with MIS-C enrolled at 27 sites
• Focus on LV dysfunction, coronary artery aneurysms
• Assessing all other organ dysfunction, inflammation, and major medical events
• 5-year follow-up

• Observational study, MIS-C and pediatric COVID, ~100 MIS-C currently at 16 sites
• Focus on inflammatory pathways associated with MIS-C and pediatric COVID
• 1-year follow-up

• Pharmacokinetics of drugs used to treat COVID-19 in children, expanded to study MIS-C
• Observational study, pediatric COVID (~300) and MIS-C (~90) currently enrolled at 27 sites
• 58 treated with remdesivir
• Data on 57 MIS-C patients submitted to Kids First Database

https://caring4kidswithcovid.nih.gov/
### NIH Rapid Acceleration of Diagnostics (RADx)℠ Initiative Overview

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<th>Project</th>
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Predicting Viral-Associated Inflammatory disease severity in children with Laboratory diagnostics and artificial Intelligence
(PreVAIL kIds)

**Develop translational tools to understand the spectrum of pediatric SARS-CoV-2 illness, rapidly diagnose and characterize MIS-C associated with SARS-CoV-2, and predict the longitudinal risk of disease severity** after exposure to and/or infection by SARS-CoV-2

- Genetics; Omics; Other biomarkers
- Viral Dynamics and Immune Profiling Studies
- Digital Health Platforms Leveraged for Children
- Artificial Intelligence

- Milestone-driven award (R61/R33); **up to 4 years**
Predicting Viral-Associated Inflammatory disease severity in children with Laboratory diagnostics and artificial Intelligence

Severity predictors integrating salivary transcriptomics and proteomics with neural network intelligence in SARS-CoV-2 infection in children

Usha Sethuraman

COVID-19 Network of networks expanding clinical and translational approaches to predict severe illness in children

Lawrence Kleinman

Artificial Intelligence COVID-19 Risk Assessment for kids

Ananth V. Annapragada

Data science approach to MIS-C identification and management associated with SARS-CoV-2 infection and Kawasaki Disease in children

Cedric Manlihot

Diagnosis of MIS-C in febrile children

Audrey R. Odom John

Identifying biomarker signatures of prognostic value for MIS-C

Juan Salazar

Discovery and clinical validation of host biomarkers of disease severity and MIS-C in children with COVID-19

Charles Chiu

• 8 Teams w/ multi-disciplinary expertise to address Program aims
• Access to diverse patient populations in > 75 sites across 30 US States
• International collaborations in UK, Canada, Asia, & S. America
• Enrolling >16,000 children with substantial racial and ethnic diversity
• Leveraging established biorepositories

<table>
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<th>39 Sites With Participants</th>
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<tr>
<td>Asymptomatic/Mild</td>
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<tr>
<td>Moderate-Severe</td>
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<tr>
<td>MIS-C</td>
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Safe Return to School Diagnostic Testing
Return to School Phase I Projects

- Wide range of school settings
- Children range in age from 3-17 years
- Projects include children with intellectual or developmental disabilities or medical complexity

![Graph showing the number of projects by demographic group.]

- Blacks/African Americans
- Hispanics/Latinos/as
- Asian Americans
- American Indians/Alaska Natives
- Underserved Rural Populations

![Bar chart showing the number of projects by demographic group. The chart displays the number of projects ranging from 0 to 6.]
NIH COVID-19 testing initiative funds additional research projects to safely return children to in-person school

The National Institutes of Health is funding five additional projects to identify ways of safely returning students and staff to in-person school in areas with vulnerable and underserved populations. The awards are the second installment of the Safe Return to School Diagnostic Testing Initiative, launched earlier this year as part of the NIH Rapid Acceleration of Diagnostics Underserved Populations (RADx-UP) program. The new awards will provide up to $15 million over two years for five projects in California, Arizona, Hawaii, Nebraska and Florida. The 8 initial awards, totaling $33 million over two years, were made in April 2021.
Phase II Scientific Goals

- Address the **impact of vaccine availability** including efforts to increase vaccine confidence
- Provide information on **variants** and **infections** following vaccination
- Increase the reach of the research in **racial and ethnic groups** not included in Phase I applications
- Ensure inclusion of **early education or preschool cohorts**
- Increase the geographic distribution to understand **regional variation** in mitigation strategies
- Increase the number of projects in **dense, urban areas or hard to reach rural areas**
Post-Acute Sequelae of SARS-CoV-2 Infection (PASC)

The New York Times

At 12, She’s a Covid ‘Long Hauler’

Although most young people recover quickly, doctors are seeing some children and teens with lingering fatigue and other chronic problems.
REsarching COVid to Enhance Recovery (RECOVER)

RECOVER Website: https://www.recovercovid.org/

Long-term effects of COVID are real. Join the search for answers.

Have questions about the long-term health effects of the virus? Start by learning about PASC.

SHARE TO RAISE AWARENESS
RECOVER – Research Questions

• What are the clinical spectrum of and biology underlying recovery from acute SARS-CoV-2 infection over time?

• For those patients who do not fully recover, what is the incidence/prevalence, natural history, clinical spectrum, and underlying biology of this condition?

• Are there distinct phenotypes of patients who have prolonged symptoms or other sequelae?

• Does SARS-CoV-2 infection initiate or promote the pathogenesis of conditions or findings that evolve over time to cause organ dysfunction or increase the risk of developing other disorders?
RECOVER Awards to Date

RECOVER Organization: Cores and Cohorts

- Clinical cohorts to include children / pregnant people
- MIS-C included as PASC
- Post vaccine myocarditis to potentially be included