Welcome!
Thank you for joining us for today’s webinar. The program will begin shortly.
You will not hear the audio until we begin.
If you have technical questions, please email aamc@commpartners.com.
AAMC Research on Care Community (ROCC) Webinar

COVID-19 Research in States with Rural and Underserved Populations: Highlights from the IDeA Program

February 26, 2021
Speakers:

The IDeA Program: Supporting Research and Research Capacity Building Where It Counts the Most

Ming Lei, PhD
Director, Division for Research Capacity Building
National Institute of General Medical Sciences

IDeA State COVID-19 Registries in the National COVID Cohort Collaborative: Ensuring Inclusion of Underserved Populations and Engagement of Investigators

Sally L. Hodder, MD
Director, West Virginia Clinical and Translational Science Institute
Associate Vice President, Clinical and Translational Research
Professor of Medicine, WVU Biomedical Research Center
Speakers:

Protecting Our Communities: COBRE Research Partnerships with Underserved Communities During COVID-19

Alexandra Adams, MD, PhD
Director and Principal Investigator
Center for American Indian and Rural Health Equity (CAIRHE)
Montana State University

SARS-CoV-2 Re-infections Case Study

Subhash C. Verma, PhD
Associate Professor and Director, Cell and Molecular Biology Graduate Program
Department of Microbiology and Immunology
University of Nevada, Reno
IDeA Program: Support Research and Research Capacity Building Where It Counts the Most

Ming Lei, PhD
Director, Division for Research Capacity Building, NIGMS
02/26/2021
Institutional Development Award (IDeA) Program

- Authorized by Congress in 1993
- First IDeA Award funded in 2000 by NCRR
- Moved to NIGMS in 2012
- 23 states and Puerto Rico
Steady Congressional Support for IDeA Program

<table>
<thead>
<tr>
<th>FY</th>
<th>IDeA Appropriations</th>
<th>NIH Appropriations</th>
<th>IDeA/NIH (%)</th>
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<td>2012</td>
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# IDeA Support Critical for Biomedical Research in IDeA States

<table>
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<tr>
<th>State</th>
<th>IDeA awards ($)</th>
<th>All NIH awards ($)</th>
<th>IDeA Funding/NIH Funding</th>
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<td>ID</td>
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<td>KS</td>
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<td>MT</td>
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<td>ND</td>
<td>$ 15,181,788</td>
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<table>
<thead>
<tr>
<th>State</th>
<th>IDeA awards ($)</th>
<th>All NIH awards ($)</th>
<th>IDeA Funding/NIH Funding</th>
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<td>OK</td>
<td>$ 30,247,718</td>
<td>$ 125,084,349</td>
<td>24.2</td>
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<td>PR</td>
<td>$ 9,032,532</td>
<td>$ 49,611,681</td>
<td>18.2</td>
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<td>RI</td>
<td>$ 29,823,324</td>
<td>$ 228,512,973</td>
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<td>SC</td>
<td>$ 25,813,650</td>
<td>$ 212,464,399</td>
<td>12.1</td>
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<td>SD</td>
<td>$ 11,346,121</td>
<td>$ 26,151,628</td>
<td>43.4</td>
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<td>VT</td>
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<td>$ 71,493,061</td>
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<td>WV</td>
<td>$ 16,592,571</td>
<td>$ 45,541,625</td>
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<td>WY</td>
<td>$ 5,884,876</td>
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The NIH RePORTER [https://projectreporter.nih.gov/reporter.cfm](https://projectreporter.nih.gov/reporter.cfm)
An IDeA Dashboard [https://www.nigms.nih.gov/Research/DRCB/Pages/DRCB-IDeA-Interactive-Portfolio-Dashboard.aspx](https://www.nigms.nih.gov/Research/DRCB/Pages/DRCB-IDeA-Interactive-Portfolio-Dashboard.aspx)
IDeA Program Supports Five Funding Initiatives

Centers of Biomedical Research Excellence (COBRE) (3 5-yr phases; ~$2.3 m/yr for P1&P2)
  o ~114 awards each supports research and infrastructure in a thematic area;
  o For research excellence sustained by a critical mass of faculty securing independent NIH funding
IDeA Networks of Biomedical Research Excellence (INBRE) (5-yr, renewable; ~$4 m/yr)
  o 24 awards each supports a statewide network of PUIs and research-intensive institutions
  o Provides research opportunities to students thus builds pipelines of research workforce
IDeA Networks for Clinical & Translational Research (IDeA-CTR) (5-yr, renewable; ~$4 m/yr)
  o 12 awards each supports a statewide/regional networks of major medical research institutions
  o Engage primary care physicians for research through Practice-Based Research Networks
IDeA Co-Funding: Co-funds R01/R15 and S10 equipment applications submitted to all NIH ICs
IDeA Regional Tech Transfer Accelerator Hubs (STTR Hubs, 4): to build entrepreneurship
Collaborations & Participation in NIH-wide Initiatives

Support collaborations among investigators funded by different IDeA funding programs
  - Supplement to INBREs for collaborations with COBRE, CTR, and IDeA Co-funded R01/R15 investigators

Develop collaborations with non-IDeA NIH programs
  - IDeA State COVID-19 Registries, with CTSA and NIH OD, to address COVID-19 disparities
  - A collaboration with ORWH & NIH ICs for maternal and infant mortality research
  - Collaborations with NIH STRIDES to strengthen cloud computing in IDeA states

Facilitate IDeA grantees’ participation in NIH-wide research initiatives
  - The Rapid Acceleration of Diagnostics-Underserved Populations (RADx-UP)
  - The Community Engagement Alliance Against COVID-19 (CEAL)
  - NIH/Operation Warp Speed-sponsored COVID-19 therapeutics and vaccines trials
Support Research and Research Capacity Building in IDeA States

Collaborations & Participation in NIH-wide Initiatives

- COBREs
- INBREs
- IDeA-CTRs
- IDeA-Co-Funding
- IDeA STTR Hubs

Basic, Translational, & Clinical Research
Thank you!

https://www.nigms.nih.gov/capacity-building
CAIRHE’s Mission

Our mission is to reduce significant health disparities in rural and Native communities in Montana. We work in research partnerships with communities to design and implement health interventions that improve quality of life and, ultimately, save lives.

- Create an effective sustainable center with a critical mass of health equity researchers
- Maintain efficacious and respectful community partnerships
- Promote interdisciplinary approaches to mitigating health disparities in rural Montana
Rapid Acceleration of Diagnostics: Underrepresented Populations (RADx-UP)

$1.4B NIH initiative to speed development, commercialization and implementation of COVID testing technologies

Our project is one of 70+ RADx-UP projects across the United States

Nationwide, RADx-UP aims to help those communities that are most affected by the pandemic
Protecting Our Community: A Pragmatic Randomized Trial of Home-Based COVID Testing with American Indian and Latino Communities

• 2 Year study
• Multidisciplinary partnership
• Why the Flathead Reservation & Yakima Valley?
  • Two communities similar in the rural barriers to testing and experience with health disparities
  • Representation of agricultural migrant communities
  • Many agricultural workers travel between both communities throughout the growing season
Project Organization Chart
Creating culturally grounded solutions to increase SARS-CoV-2 testing

Hypothesis: home-based testing will be feasible, impactful and better accepted using active assistance with test kits by trusted community members vs. passive test distribution.
Study Aims

Aim 1: Determine the cultural, social, behavioral and economic barriers and facilitators to COVID-19 testing

Aim 2: Test the effects of active (via trusted community members) vs. passive (info only) test kit delivery on completion rates

Aim 3: Evaluate the acceptability and feasibility of home self-testing and create community-driven protocols to increase testing in other AI and Latino communities
Aim 1: Conducting Focus Groups and Interviews

Understand cultural, social, behavioral and economic barriers and facilitators of testing

Culturally adapt home-based testing education and outreach materials

Inform development of community-driven models to increase home-testing nationally
Aim 2

Figure 2.
Welcome & Box Contents

Thank you for participating in the “Protecting Our Community” study. This study is being conducted in partnership with:

- Montana State University and Salish Kootenai College in Montana
- Fred Hutchinson Cancer Research Center and the University of Washington in Washington

StudY PurPose

The purpose of this study is to create a community-driven plan for improving testing for COVID-19 in your community, as well as and other American Indian communities.

Box Contents

1. **Supplemental Study Documents**: This box contains a series of documents that were designed by the study team to complement the materials provided by the Everlywell COVID-19 Kit. All of the specially-designed study materials have the “Protecting Our Community” study logo including the following:
   - Self-Swab Instructions
   - Shipping Instructions
   - Receiving your COVID-19 Test Results
   - Interpreting Test Results

2. **Everylywell COVID-19 Test Home Collection Kit Contents**:
   - Nasal swab
   - Protective biohazard bag (plastic)
   - Test tube
   - Kit ID sticker
   - Shipping box
   - Return label
   - Absorbent sheet
   - Alcohol prep pad
   - Prepaid mailer

Completion of your Home Collection Kit

The study team has sent you an email with video instructions to complete the kit. If you have any questions or need assistance with completing your test, call the research team:

- Marissa Basler
  - marissa_basler@skc.edu
  - 406-275-4881

- Ashley Gervais
  - ashley_gervais@skc.edu
  - 406-275-4051

Our staff is available to answer questions between on Monday - Friday from 8am to 4pm.

Sample Processing

In order for your swab sample to be analyzed for COVID-19, you must:

1. Fill out the Kit ID sticker and affix to your sample tube
2. Mail your sample on the same day you collect your sample
3. Mail your sample on a weekday between Monday through Thursday (not on a Friday) by either:
   - Dropping at a UPS Drop Box location before 2pm or the last scheduled pick-up
   - Drop off at [site location] no later between 9am and 12pm.

Questions & Contact

Please contact the study team with any questions or clarifications you may need. We are here to support you.

- Marissa Basler
  - marissa_basler@skc.edu
  - 406-275-4881

- Ashley Gervais
  - ashley_gervais@skc.edu
  - 406-275-4051

Salish Kootenai College
- 406-275-4800

Thank you for your participation in the “Protecting My Community” study.
Aim 3: Developing Generalizable Models for American Indian & Latino Communities

- Post-testing survey
  - Gather feedback about testing experience
  - What worked/didn't work

- In-depth interviews
  - Assess differences between people who completed or didn't complete the test

- Model development
  - Incorporate cultural and social context from key informant interviews & focus groups
  - Adapt existing testing materials
  - Create adaptable testing frameworks to be tailored by new communities
THANK YOU! QUESTIONS?
Center for American Indian and Rural Health Equity (CAIRHE)
www.montana.edu/cairhe
Clinical and Translational Research Centers’ Participation in the National COVID Cohort Collaborative: Ensuring Inclusion of Underserved Populations and Engagement of Investigators

Sally L. Hodder M.D.
West Virginia University

February 26, 2021
IDeA Networks for Clinical and Translational Research (IDeA-CTR)

• IDeA-CTRs support research infrastructure and investigator development to address health challenges in IDeA states

• This mission is critically important as:
  • IDeA states rank lowest in health outcomes
  • CTRs serve mostly rural and/or economically disadvantaged populations
  • Investigators are engaged in addressing regional health issues
  • Community members’ perspective and input actively sought

<table>
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<tr>
<th>Health Challenge</th>
<th>Lowest Ranked State</th>
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</thead>
<tbody>
<tr>
<td>Cancer</td>
<td>West Virginia</td>
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<tr>
<td>Cardiovascular Disease</td>
<td>West Virginia</td>
</tr>
<tr>
<td>COPD</td>
<td>West Virginia</td>
</tr>
<tr>
<td>COVID-19 Case Rate</td>
<td>North Dakota</td>
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<tr>
<td>Diabetes</td>
<td>West Virginia</td>
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<tr>
<td>Drug Deaths</td>
<td>West Virginia</td>
</tr>
<tr>
<td>Obesity</td>
<td>Mississippi</td>
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<tr>
<td>Smoking</td>
<td>West Virginia</td>
</tr>
<tr>
<td>Multiple Chronic Conditions</td>
<td>West Virginia</td>
</tr>
<tr>
<td>Overall Health Outcomes</td>
<td>Louisiana</td>
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</table>

Source: America’s Health Rankings
# IDeA Contributes Data on Underserved Populations Nationwide

<table>
<thead>
<tr>
<th>IDeA-CTR</th>
<th>Database Demographics</th>
<th>Unique Patients (Million)</th>
<th># Tested for CoV-2</th>
<th># Positive Cases</th>
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</thead>
<tbody>
<tr>
<td>DE</td>
<td>Children: Black 17.5%, Latinx 16.9% (Includes DE &amp; FL)</td>
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<td>40,734</td>
<td>2,374</td>
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<td>NE</td>
<td>Rural and Aging: includes data from KS, ND, SD</td>
<td>1.4m</td>
<td>49,390</td>
<td>4,599</td>
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<tr>
<td>LA</td>
<td>Inner City &amp; Rural: 55% Black</td>
<td>2m</td>
<td>600,000*</td>
<td>80,000*</td>
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<tr>
<td>ME</td>
<td>Rural and Aging: includes data from NH</td>
<td>2m</td>
<td>125,956</td>
<td>5,298</td>
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<tr>
<td>MS</td>
<td>Rural and Obesity: Black 52.8%, Choctaw Indian 6.2%</td>
<td>1m</td>
<td>181,698</td>
<td>21,242</td>
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<td>OK</td>
<td>Rural: 4% American Indian, 14% Black, 12% Latinx</td>
<td>1m</td>
<td>120,693</td>
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<tr>
<td>RI</td>
<td>Longitudinal EHR data for half the state</td>
<td>0.5m</td>
<td>152,347</td>
<td>19,163</td>
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<tr>
<td>WV</td>
<td>Economically Disadvantaged 19%, Rural 39%, Black 3.7%</td>
<td>1.5m</td>
<td>110,061</td>
<td>11,952</td>
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</table>

**Totals as of January 1, 2021**

10.8m | 1,380,879 | 157,201* estimate
IDeA-CTR N3C Accomplishment

June 2020
Proposal for IDeA CTR funding submitted

July 2020
IDeA CTR funded for N3C participation

August 2020
Operations committee formed

Sept-Oct 2020
- CTR investigator engagement events
- CD2H funded to support CTR participation

Nov 2020
All DUAs submitted

Dec 2020
- Rural Health Domain Team created
- CTR Governance committee formed

December 2020
CTR project Approved

February 2021
- Membership on 6/16 Domain Teams
- Subject matter experts
What is the National COVID Cohort Collaborative?

Turning COVID Clinical Data into Knowledge

Clinical Data ➔ Data Harmonization ➔ NCATS Cloud ➔ Investigators
## N3C Enclave Data: Current Stats

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<thead>
<tr>
<th>Category</th>
<th>COVID (N=611183)</th>
<th>Non-COVID (N=2306160)</th>
<th>Overall (N=2917343)</th>
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<td>1010</td>
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<td><strong>Age</strong></td>
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<td><strong>Race</strong></td>
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<td>264735</td>
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Geographic Distribution of N3C Cohort


Bennett, T. XXX
Random Forest Top 10 Predictors

- Age
- AST
- BUN
- Cr
- Glucose
- pH
- RR
- SBP
- SpO2
- WBC

- High confidence.
- Repeatable.
- Clinically relevant.
- Readily deployable.
- Easily refined.

RF Mar-May AUROC: 0.864
RF Jun-Oct AUROC: 0.885
Antimicrobial & Immunomodulatory Medication Use Over Time


Bennett, T. XXX
Key IDeA-CTR Project: Correlate Social Determinants with COVID-19 Treatments and All-Cause Mortality

N3C data: Severity, demographics, drug treatment, comorbidities

Social Deprivation Index
Rural-Urban Commuting Area
US Census Data
FCC Health Maps

IDeA-CTR Sites
Patient Data

Treatments given to Mortality/hospice patients
- Remdesivir: 20%
- Hydroxychloroquine: 15%
- Lopinavir/Ritonavir: 1%
- Chloroquine: 0%
- Any Antibacterial: 79%
- Any Antifungal: 14%
- Any Antiviral: 6%
- Hydrocortisone: 18%
- Methylprednisolone: 16%
- Prednisone: 10%
- Dexamethasone: 9%
- Anakinra: 0%
- Tocilizumab: 6%
- Any systemic steroid: 56%

Evaluate Covid-19 Severity & Mortality
- Effect of various therapeutic agents
- Impact of social determinants of health
- Evaluate treatment disparities
- Inform trials in underserved populations
- Implications for policy to alleviate disparities

IDeA-CTR Cohort Collaborative
Conclusions

• CTRs operate at the intersection of community, health care, public health, and biomedical research

• CTRs are critically important to ensure that regional health issues, particularly of underserved populations, are addressed

• N3C is providing invaluable data on large numbers of people with COVID-19 as well as matched uninfected persons

• NIGMS ensured inclusion in N3C of COVID-19 clinical data from underserved U.S. populations by providing CTR funding

• Impact of rurality is infrequently assessed in database analyses – inclusion of the CTR consortium ensures that it will be addressed
Acknowledgements

CTR Principal Investigators
Mark Basson         Carlos Luciano
Maria Cruz-Correa   James Padbury
Joey Granger        Stacy Rasmus
Gregory Hicks       Cliff Rosen
Judith James        Gary Stein
John Kirwan         Jovanka Voyich
Parvesh Kumar

Funding
• National Institute of General Medical Sciences Award Number 5U54GM104942-05
• National Institute of General Medical Sciences Award Number 3U54GM104942-05S2
SARS-CoV-2 Re-infections

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Genomic evidence for reinfection with SARS-CoV-2: a case study


Lancet Infect Dis 2020, 21: 52-58
Published Online October 12, 2020

Summary
Background The degree of protective immunity conferred by infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is currently unknown. As such, the possibility of reinfection with SARS-CoV-2 is not well understood. We describe an investigation of two instances of SARS-CoV-2 infection in the same individual.

Immunity and Re-Infection | In the Pipeline
For months now, people have been watching closely to see if it's possible to get re-infected with the coronavirus. It's taken a while for the ...
2 weeks ago

(CNN) — A 25-year-old Nevada man appears to be the first documented case of Covid-19 reinfection in the United States.

Genetic tests indicate the patient was infected with two different varieties of the virus, a team at the University of Nevada Reno School of Medicine and the Nevada State Public Health Laboratory reported.

Analysis | Can You Get Covid Twice? What Reinfection Cases Really Mean
The questions of whether people have immunity to SARS-CoV-2 after getting it, and if so for how long, have become more acute now that ...
1 day ago
Timeline of infection (SARS-CoV-2)

25y old male, no clinically significant underlying conditions, or indications of compromised immunity

Case A:
- Mar. 26: Symptom onset
- Apr. 18: Pos + RT-PCR Ct: 35.24
- Apr. 27: Case A symptom resolution
- May 9: Neg - TMA

Case B:
- May 26: Symptom onset
- May 28: Pos + RT-PCR Ct: 35.31
- June 5: Pos + Ab (IgG, IgM)

Case A: Sore throat, cough, headache, nausea, diarrhea.

Case B:
- Fever, headache, dizziness, cough, nausea, diarrhea.
- Hospitalized 6/5: hypoxic, required oxygen support, shortness of breath.
- Chest x-ray from 5/31 and 6/5 noted new patch bilateral interstitial opacities suggestive of viral or atypical pneumonia.

Tillett, et. al., Genomic evidence for reinfection with SARS-CoV-2: a case study. Lancet Infect Dis 21, 52-58
Unique SNVs in SARS-CoV-2 from the 1st (A) and 2nd (B) infection

Tillett, et. al., Genomic evidence for reinfection with SARS-CoV-2: a case study. Lancet Infect Dis 21, 52-58
Genetic relatedness of SARS-CoV-2 among specimen A and B

Tillett, et. al., Genomic evidence for reinfection with SARS-CoV-2: a case study. Lancet Infect Dis 21, 52-58
Genomic surveillance of SARS-CoV-2 in NV

Unique nsp12 variant

Genomic Surveillance of SARS-CoV-2 variants
SARS-CoV-2 lineages: Re-infections

Specimen collection:
1\textsuperscript{st} infection: 7/22/2020
2\textsuperscript{nd} infection 10/26/2020
Determining SARS-CoV-2 variants among re-infected infected individuals
Acknowledgements:

- Dr. Mark Pandori, Nevada State Public Health Laboratory
- Dr. Cyprian Rossetto, UNR Med
- Dr. Paul Hartley, Nevada Genomics Center, UNR
- Dr. Joel Sevinsky, Bioinformatician
- Southern Nevada State Public Health Laboratory
- Washoe County Health District, Reno, NV

Funding:

- Nevada IDeA Network of Biomedical Research Excellence (GM 103440 and GM 104944): Dr. Baker
- Institutional Funding for SARS-CoV-2 surveillance.