Director's Update

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health

Council of Councils
September 17, 2021

NIH

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

Topics for Today

- Changes in Leadership
- NIH and COVID-19
  - State of the pandemic
  - Vaccines – and boosters
  - Therapeutics
  - Diagnostics
- ARPA-H
- UNITE

Changes in Leadership

New Leaders Appointed

Lindsey Criswell, MD, MPH, DSc
Director, NIAMS
February 16, 2021

Marie A. Bernard, MD
Chief Officer for Scientific Workforce Diversity
May 26, 2021

And a farewell....

Christopher P. Austin, MD

Director, National Center for
Advancing Translational Sciences

Detailed to the
White House Office of Science and Technology Policy

Carrie Wolinetz, PhD

Jerry Sheehan, MS

Jackie Ward, PhD

Tara Schwetz, PhD

Julia Segre, PhD

Ursula Koniges, PhD

Office of the Director Acting Positions Filled

Lyric Jorgenson, PhD
Acting Associate Director for Science Policy

Courtney Aklin, PhD
Acting Associate Deputy Director

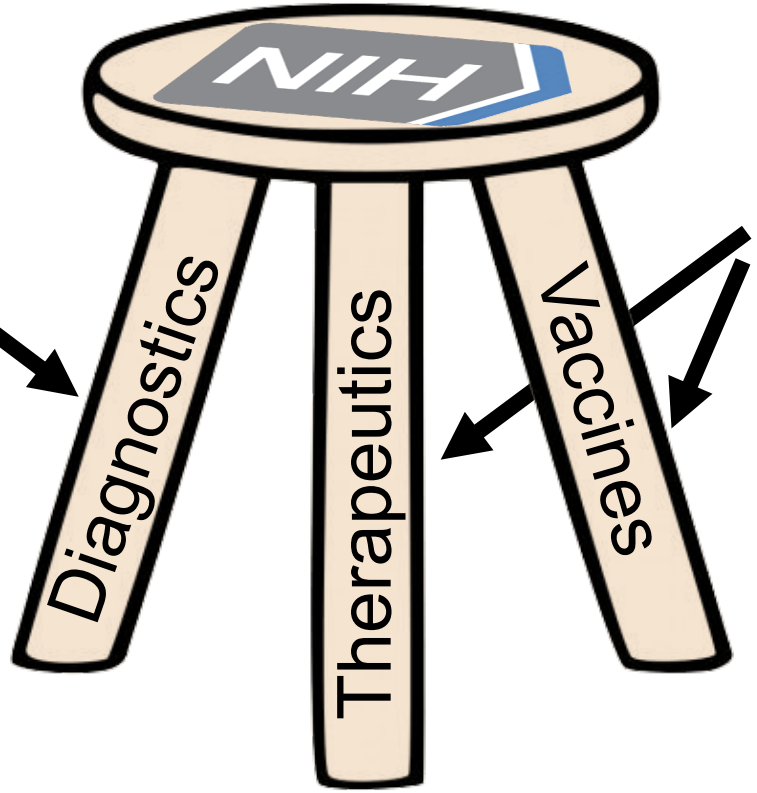
Renate Myles
Acting Associate Director for Communications and Public Liaison and Acting Director, Office of Communications and Public Liaison

John Burklow
Acting Chief of Staff

NIH and COVID-19

NIH's COVID-19 Efforts: Leading the Charge

Rapid Acceleration of Diagnostics
(RADX)



Accelerating COVID-19 Therapeutic Interventions and Vaccines
(ACTIV)

ACTIV Public-Private Partnership

LAUNCH

- On April 17, 2020, NIH announced the launch of a public-private partnership, **Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)**

MISSION

- Develop a coordinated research response to **speed COVID-19 treatment and vaccine options**
  - Establish a collaborative framework for prioritizing therapeutic candidates and accelerating vaccine evaluation
  - Accelerate clinical trials of promising agents and leveraging existing clinical trial networks while maintaining rigorous safety standards
  - Coordinate regulatory processes and leveraging assets among all partners

ACTIV Stakeholders

20 INDUSTRY LEADERS

NOVARTIS
Roche
MERCK
RHYTHM THERAPEUTICS
Pfizer
abbvie
AMGEN
moderna
Lilly
Eisai
Takeda
SANOFI
J&J
evotec
AstraZeneca
Bristol Myers Squibb
gsk
NOVAVAX
VIR
GILEAD

8 GOVERNMENT LEADERS

BARDA
H-CORE
DEPARTMENT OF DEFENSE
EUROPEAN MEDICINES AGENCY
U.S. FOOD & DRUG ADMINISTRATION
NIH
CDC
U.S. ARMY MEDICAL RESEARCH & MATERIEL COMMAND
DEPARTMENT OF VETERANS AFFAIRS

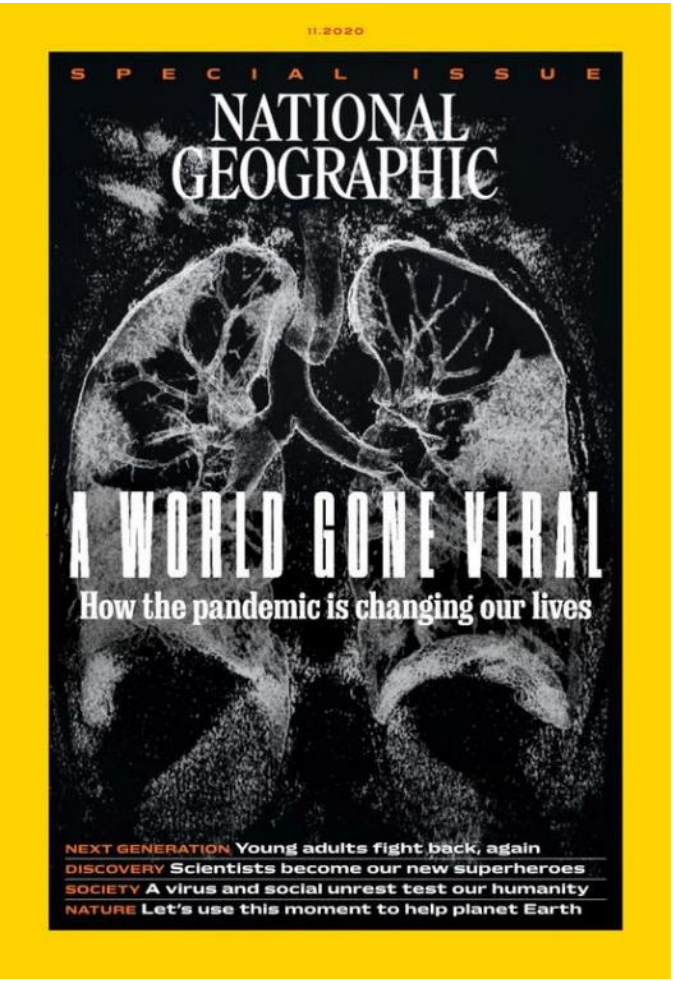
4 NON-PROFIT

FRED HUTCH CURES START HERE
RTI INTERNATIONAL
BILL & MELINDA GATES foundation
FNIH

PROGRAM MANAGEMENT

FNIH
Foundation for the National Institutes of Health

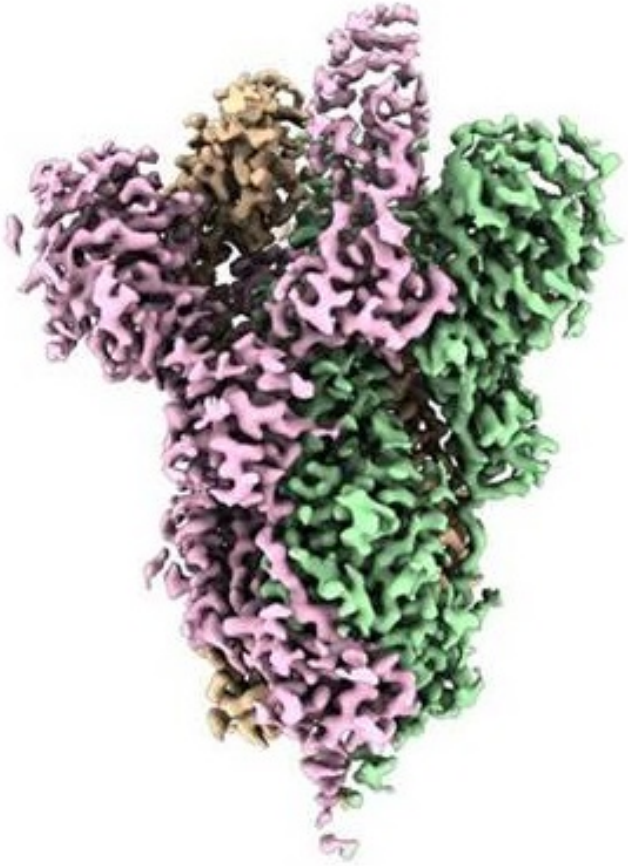
Behind the Scenes: Years of Basic Science Research Led to Rapid COVID-19 Vaccine Development



SCIENCE | CORONAVIRUS COVERAGE

They spent 12 years solving a puzzle. It yielded the first COVID-19 vaccines.

Long before anyone knew of SARS-CoV-2, a small band of government and university scientists uncovered a prototypical key that unlocked life-saving immunizations.



The New York Times

December 11, 2020

F.D.A. Clears Pfizer Vaccine, and Millions of Doses Will Be Shipped Right Away

Efficacy: 95%

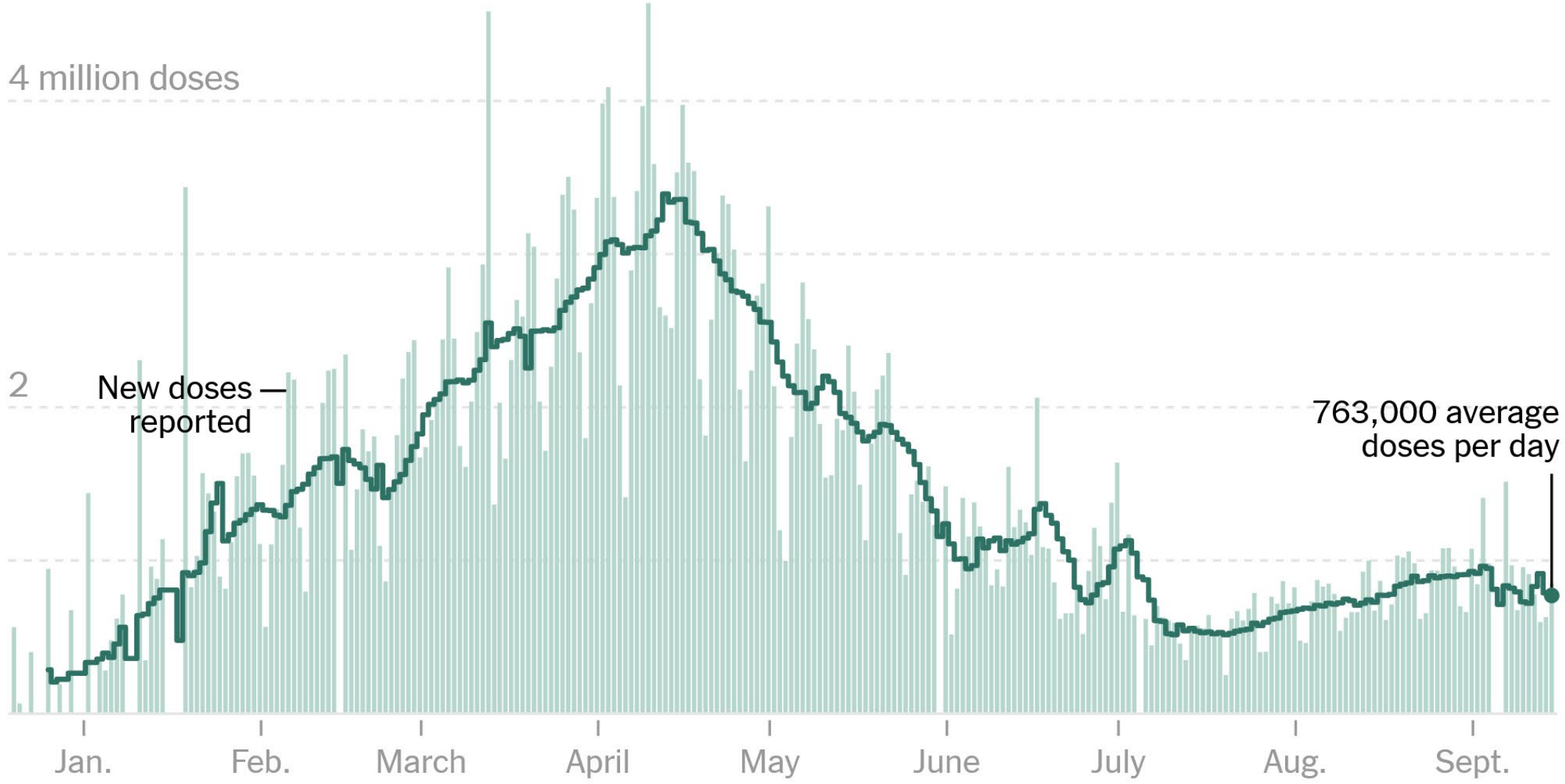
The New York Times

December 19, 2020

COVID-19: F.D.A. Authorizes Moderna Vaccine for Emergency Use, Adding Millions of Doses to U.S. Arsenal

Efficacy: 94%

Total Vaccine Doses Administered in US



NYTimes
CDC

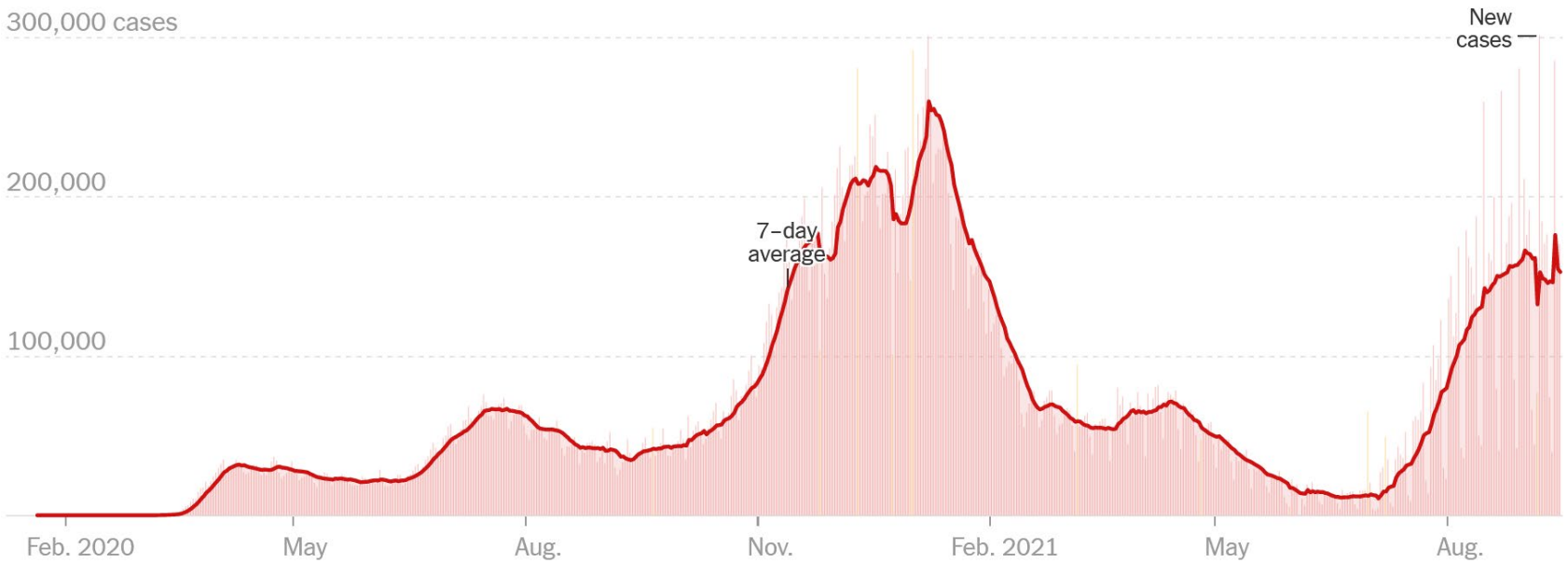
US COVID-19

New Reported Cases

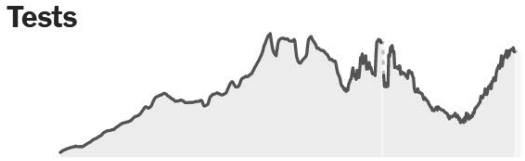
Sept 16, 2021

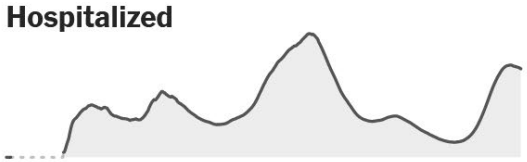
NYTimes/CDC

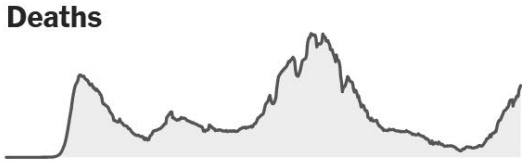
New reported cases



These are days with a reporting anomaly. Read more here.

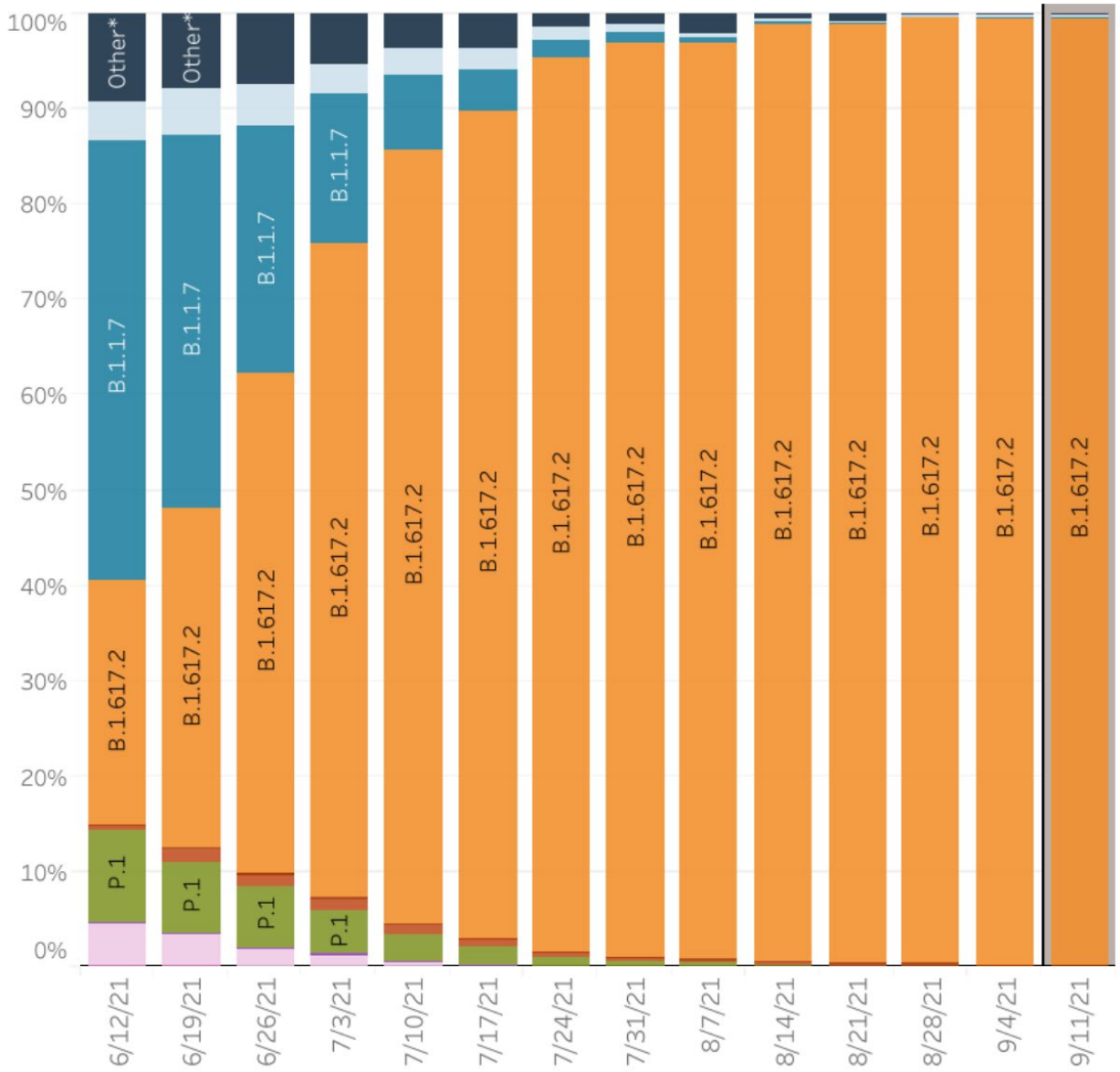






	DAILY AVG. ON SEPT. 15	14-DAY CHANGE	TOTAL REPORTED
Cases	152,605	−8%	41,635,803
Tests	1,583,940	+16%	—
Hospitalized	98,449	−4%	—
Deaths	1,943	+37%	666,816

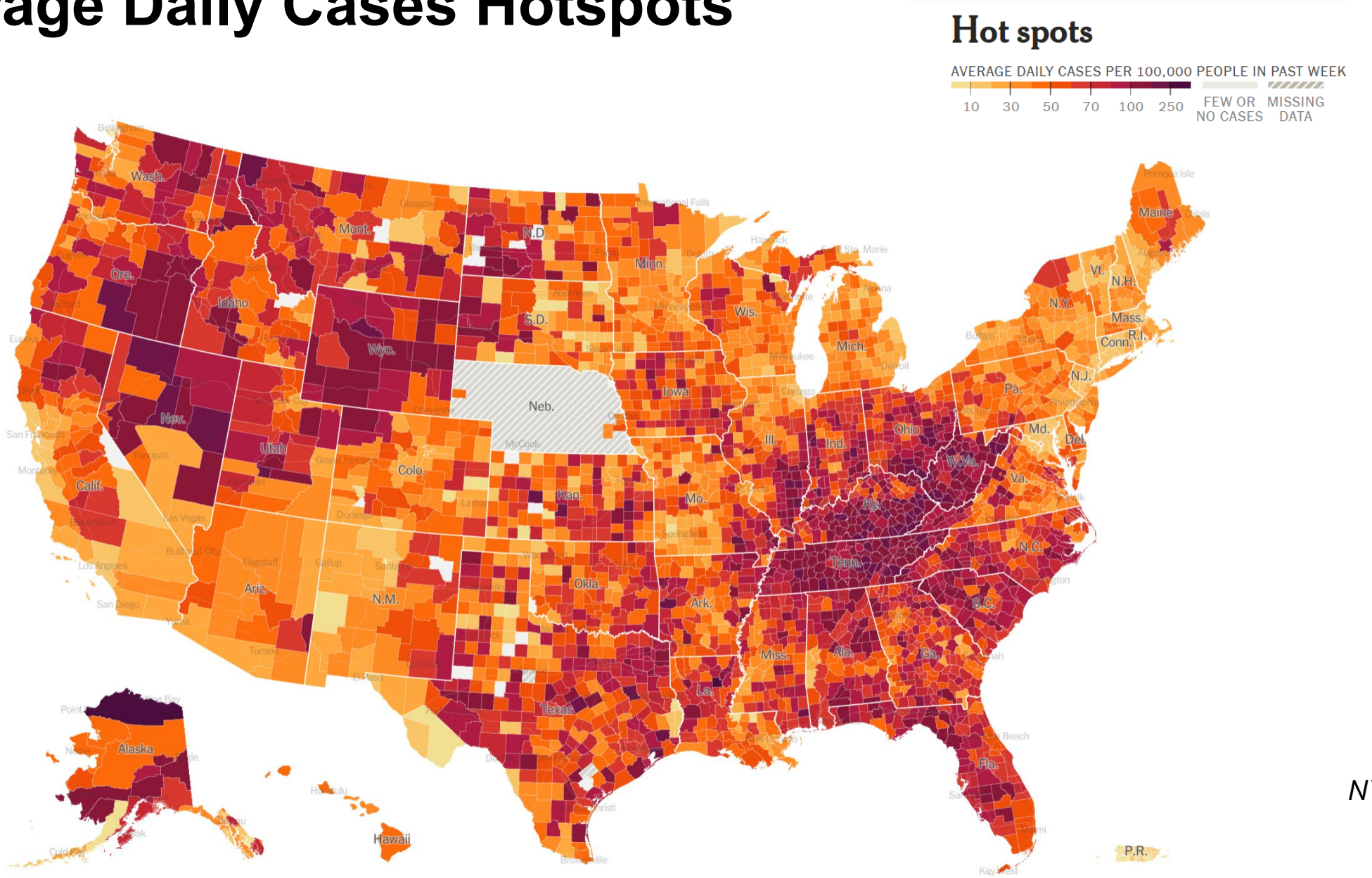
Variants of Concern



Delta variant

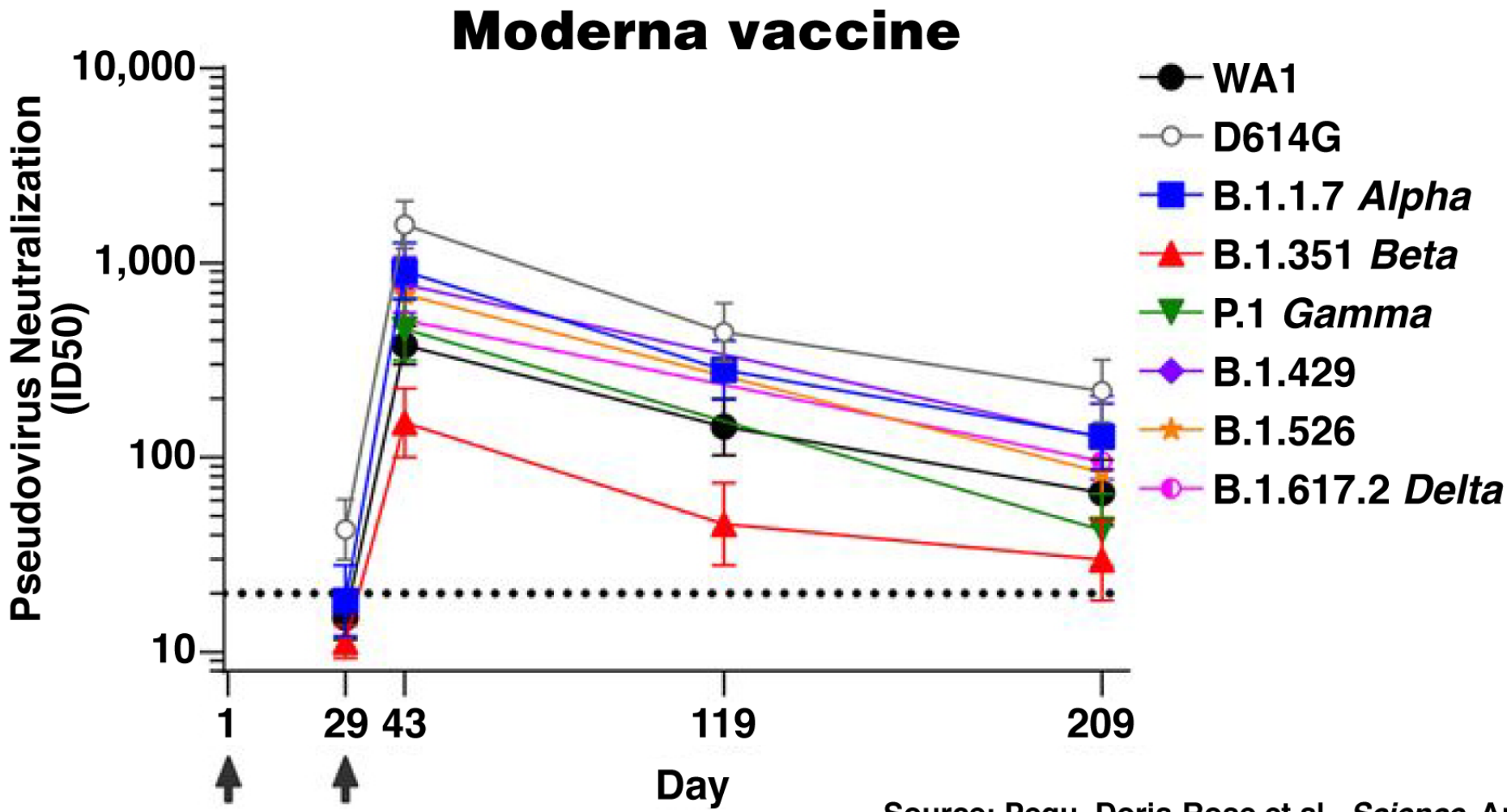
from CDC

Average Daily Cases Hotspots



NYTimes/CDC

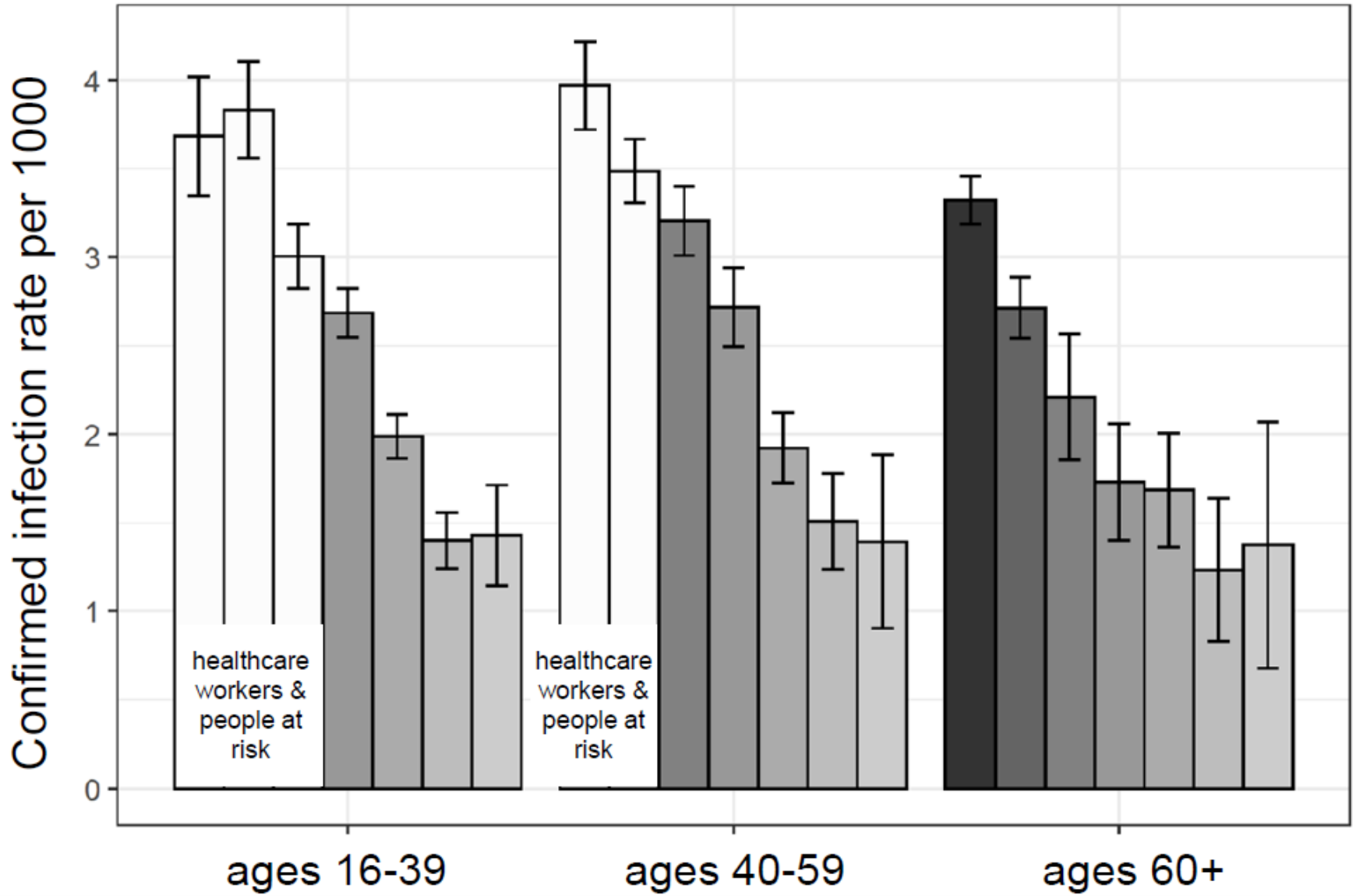
Antibody Levels Decline Over Time Following 2 mRNA Immunizations Regardless of Variant



Source: Pegu, Doria-Rose et al., *Science*, Aug 12, 2021

Waning immunity was observed across age groups

Rate of confirmed **SARS-CoV-2 infections** stratified by vaccination period and age group
Per 1000 persons, during July 11, 2021 and July 31, 2021



Goldberg et al., https://www.medrxiv.org/content/10.1101/2021.08.24.21262423v1

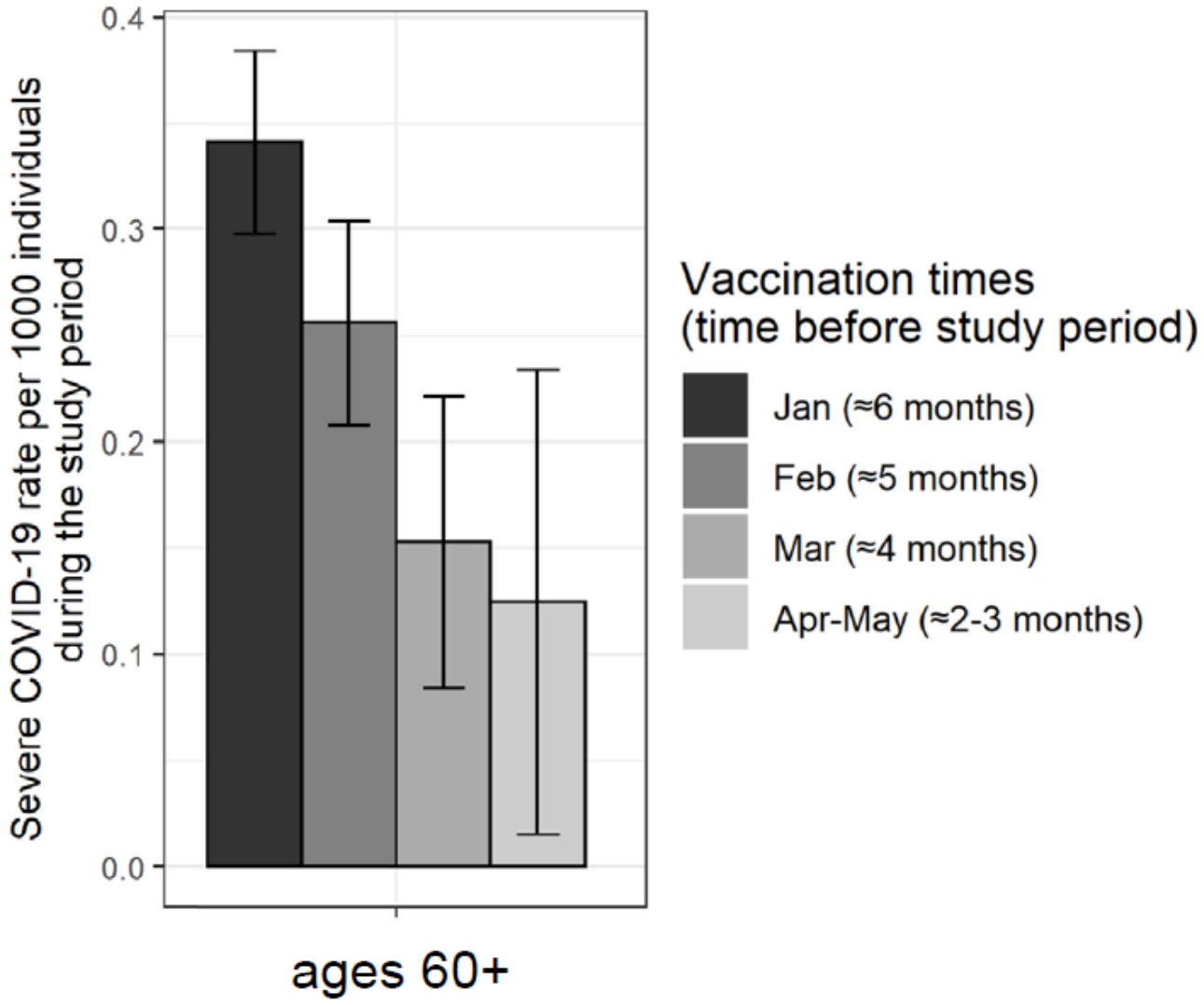
Vaccination times
(time before study period)

- Jan, 16-31 (≈6 months)
- Feb, 1-15 (≈5.5 months)
- Feb, 16-28 (≈5 months)
- Mar, 1-15 (≈4.5 months)
- Mar, 16-31 (≈4 months)
- Apr (≈3 months)
- May (≈2 months)

MINISTRY OF HEALTH

Waning immunity also observed for severe disease in 60+ group

Per 1000 persons, during July 11, 2021 and July 31, 2021

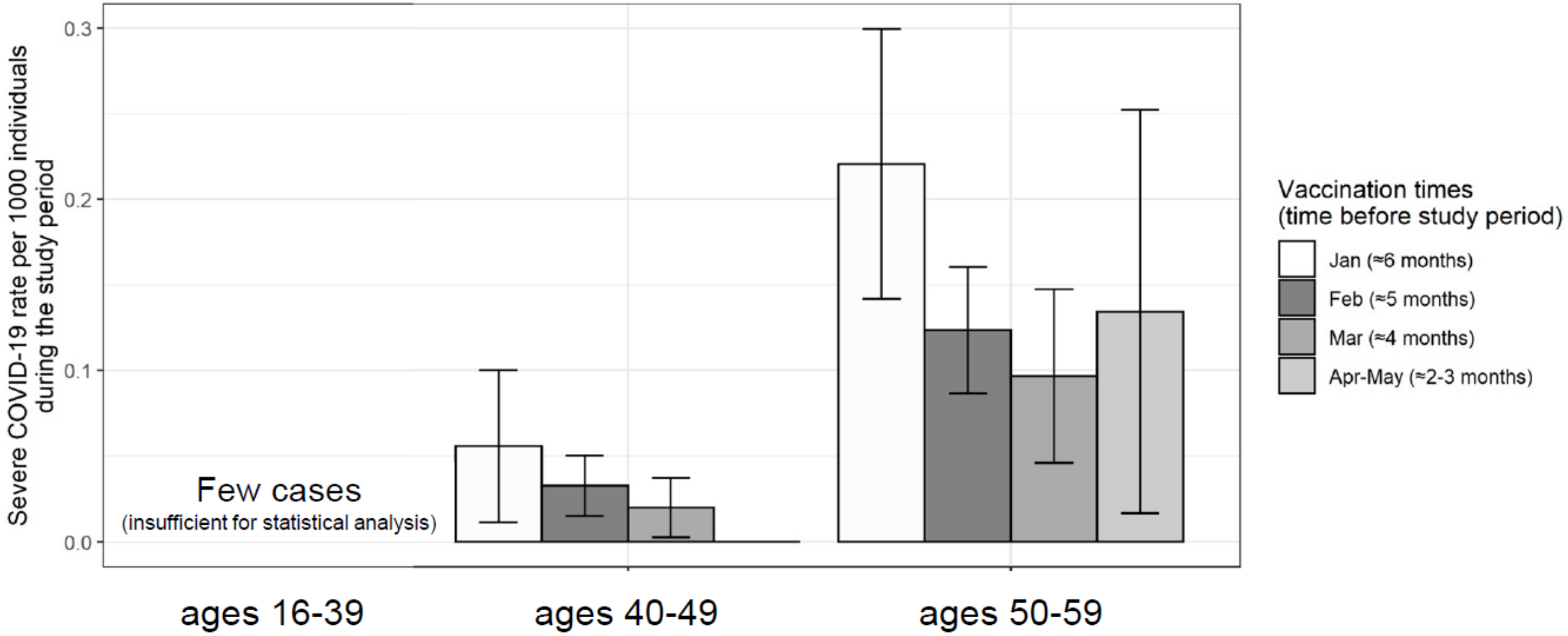


Goldberg et al., https://www.medrxiv.org/content/10.1101/2021.08.24.21262423v1

MINISTRY OF HEALTH

Waning immunity against severe disease may occur also in younger age groups

Rates of severe COVID-19 stratified by vaccination period and age group per 1000 persons, July 11 – Aug 15, 2021



MINISTRY OF HEALTH

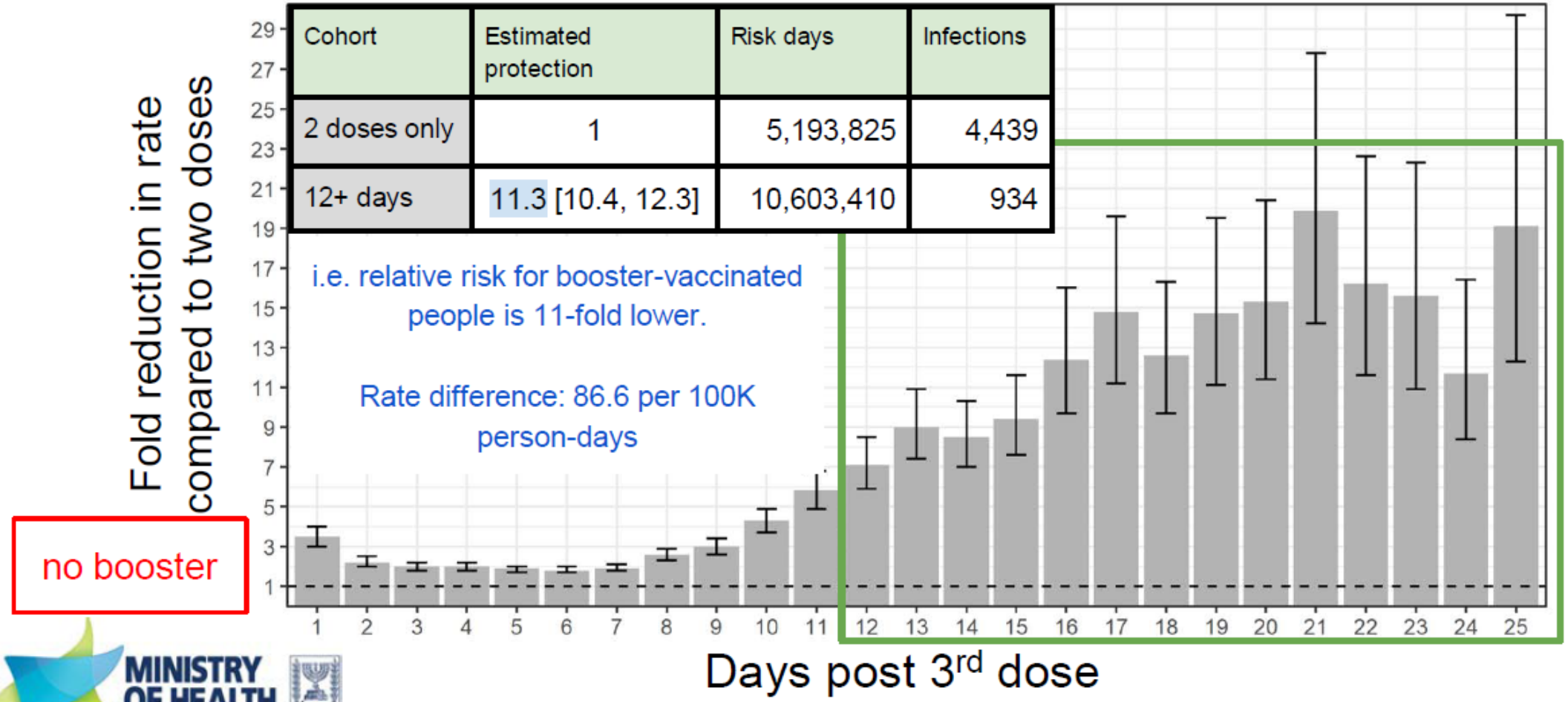
Based on evidence for waning in Israel, and the trajectory towards exceeding national hospitalization capacity given the rapid rise in severe cases, Israel decided to begin a 3rd vaccination campaign on July 30th, starting with the elderly.

MINISTRY OF HEALTH

Relative risk for booster vaccinated is ≈11-fold lower against confirmed infection for ages 60+

Poisson regression adjusted for age, gender, demographic group, 2nd dose period and calendar day.
Based on data from August 10 to August 31

Cohort	Estimated protection	Risk days	Infections
2 doses only	1	5,193,825	4,439
12+ days	11.3 [10.4, 12.3]	10,603,410	934

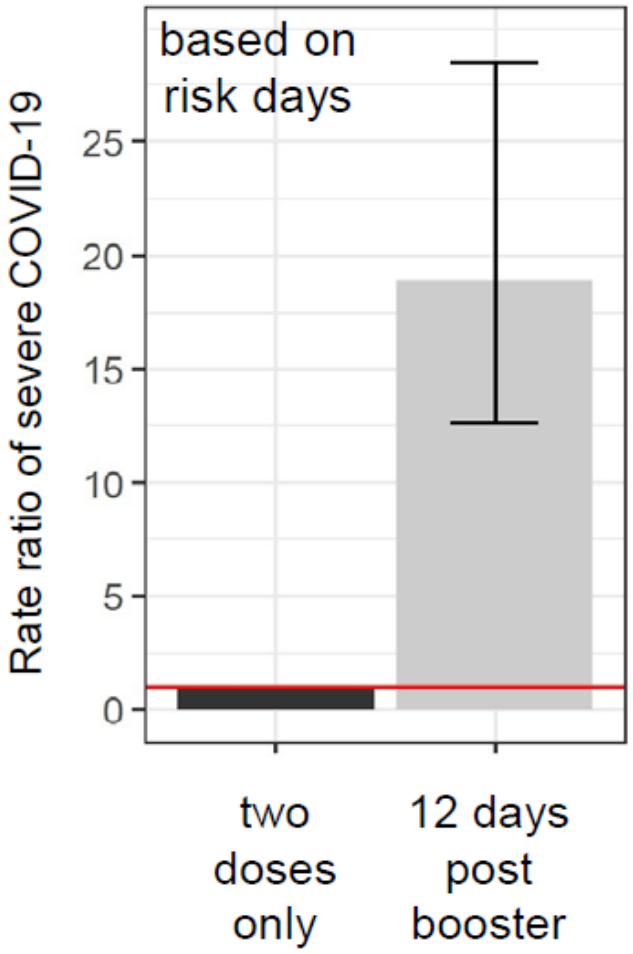


Bar-on et al., https://www.medrxiv.org/content/10.1101/2021.08.27.21262679v1

MINISTRY OF HEALTH

Booster provides >10-fold reduction in relative risk of severe disease in 60+ age group

(**Poisson regression** controlling for age, gender, demographic group, 2nd dose period, and calendar day)

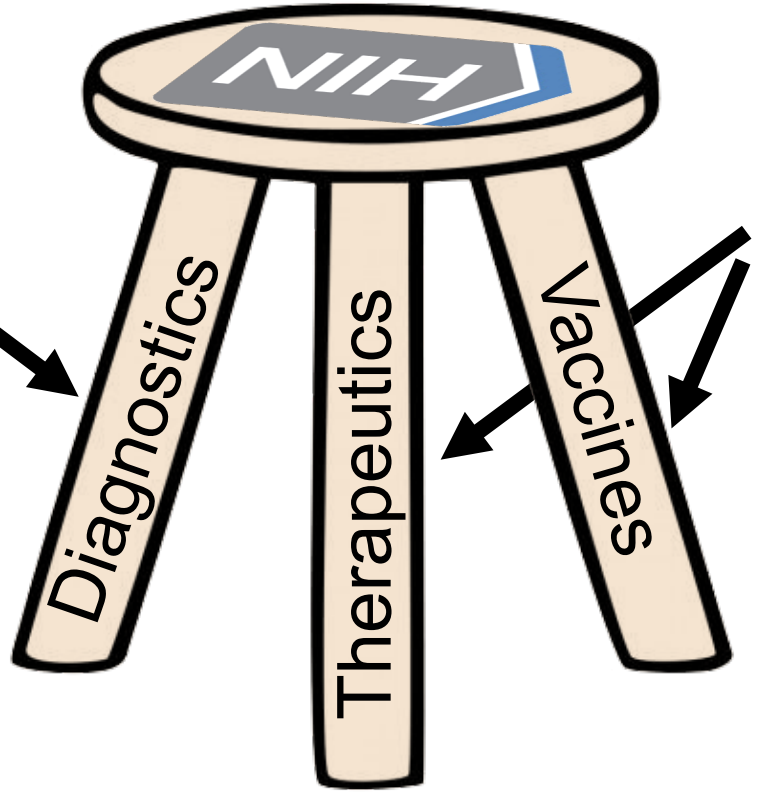


absolute rate difference
of 7.5 severe cases
per 100K person-days

MINISTRY OF HEALTH

NIH's COVID-19 Efforts: Leading the Charge

Rapid Acceleration of Diagnostics
(RADX)



Accelerating COVID-19 Therapeutic Interventions and Vaccines
(ACTIV)

Different Therapies at Different Stages of COVID-19

COVID-19+ Disease Progression

No Symptoms → Outpatient Mild Symptoms → Inpatient No Oxygen → Inpatient Low-flow Oxygen → Inpatient High-flow Oxygen → Mechanical Ventilation

Anti-viral Strategies

Immunomodulatory Strategies

Anti-coagulation Strategies

Antiviral Program for Pandemics (APP)

$3.2B

5-year, $3.2B USG-funded program allocated across 7 virus families of pandemic potential – largest investment supporting pre-pandemic therapeutic development to date

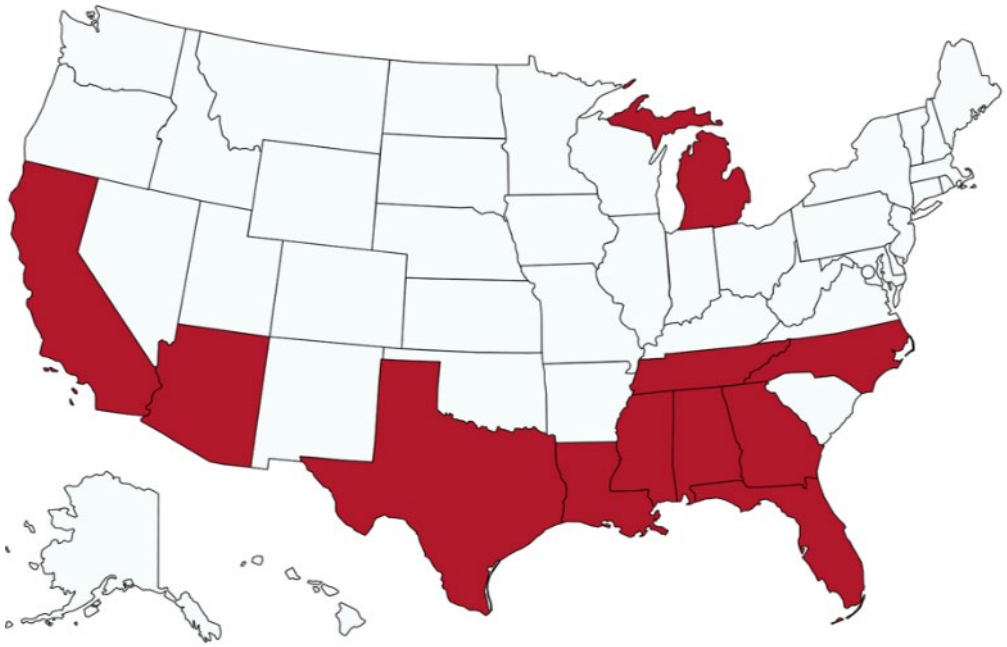
Program objective: accelerate development of direct-acting antivirals from discovery to early development, as a complement to vaccines, neutralizing antibodies, and other therapeutic options

In-kind support and funding opportunities provided by NIAID, NCATS, and BARDA including new Antiviral Drug Discovery (AViDD) Centers and public-private partnerships

United States Government (USG), National Institute of Allergy and Infectious Diseases (NIAID), National Center for Advancing Translational Sciences (NCATS), Biomedical Advanced Research and Development Authority (BARDA)

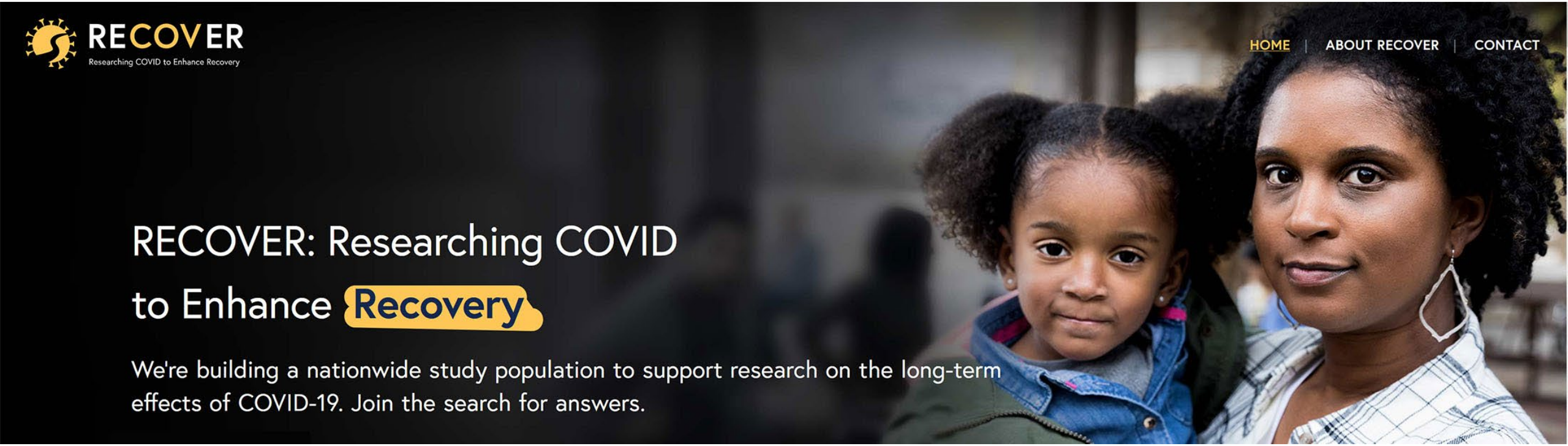
NIH-Wide COVID-19 Community Engagement Effort

- Conduct urgently needed community-engaged research and outreach (30-60-90 day milestones) focused on COVID-19 awareness and education to address misinformation and mistrust
- Promote and facilitate inclusion of diverse racial and ethnic populations in clinical trials (prevention, vaccine, therapeutics), reflective of the populations disproportionately affected by the pandemic
- Creating State CEAL Teams
  - Community Engagement ALliance Against COVID-19 in Disproportionately Affected Communities (CEAL)
  - 11 states identified as potential CEAL Team states



RECOVER: Researching COVID to Enhance Recovery

https://recovercovid.org/



NIH Initiative to understand, prevent, and treat post-acute sequelae of SARS-CoV-2 (PASC), including Long COVID

- To build national study population of diverse research volunteers; support large-scale studies
- New York University Langone Health just received ~$470M parent award, will include sub-awards to >100 researchers at >30 institutions

NIH's COVID-19 Efforts: Leading the Charge

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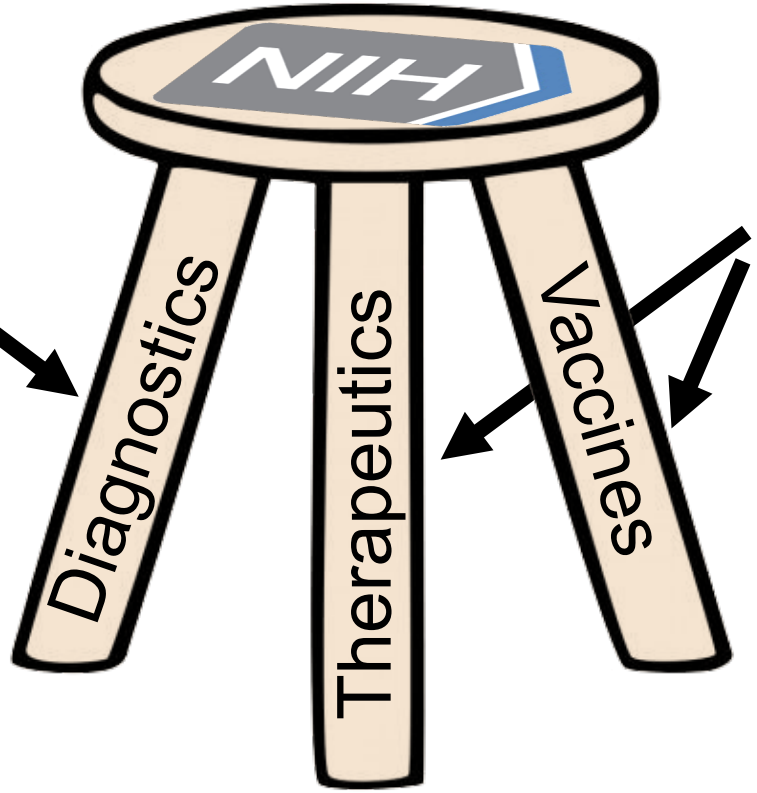


Accelerating COVID-19 Therapeutic Interventions and Vaccines
(ACTIV)

Rapid Acceleration of Diagnostics (RADx) Initiative

- Goal
  - Accelerate innovation in, development and commercialization of, and implementation of COVID-19 testing
- Approach
  - Fund early innovative diagnostic technologies
  - Advance late-stage diagnostic technologies to expand testing infrastructure
  - Identify effective testing implementation strategies in underserved populations
  - Basically turn NIH into a venture capital firm

Rapid Acceleration of Diagnostics (RADx) Initiative

RADx Tech – $908M*

Highly competitive, rapid three-phase challenge to identify the best candidates for at-home or point-of-care tests for COVID-19

RADx Underserved Populations (RADx-UP) – $533M

Interlinked community-engaged research projects focused on implementation strategies to enable and enhance testing of COVID-19 in vulnerable populations

RADx Radical (RADx-rad) – $187M

Develop and advance novel, non-traditional approaches or new applications of existing approaches for testing

RADx Advanced Testing Program (RADx-ATP) – $192M

Rapid scale-up of advanced technologies to increase rapidity and enhance and validate throughput — create ultra-high throughput laboratories and “mega labs”

Data Management Support – $70M

Build an infrastructure for and support coordination of the various data management needs of many of the COVID-19 efforts

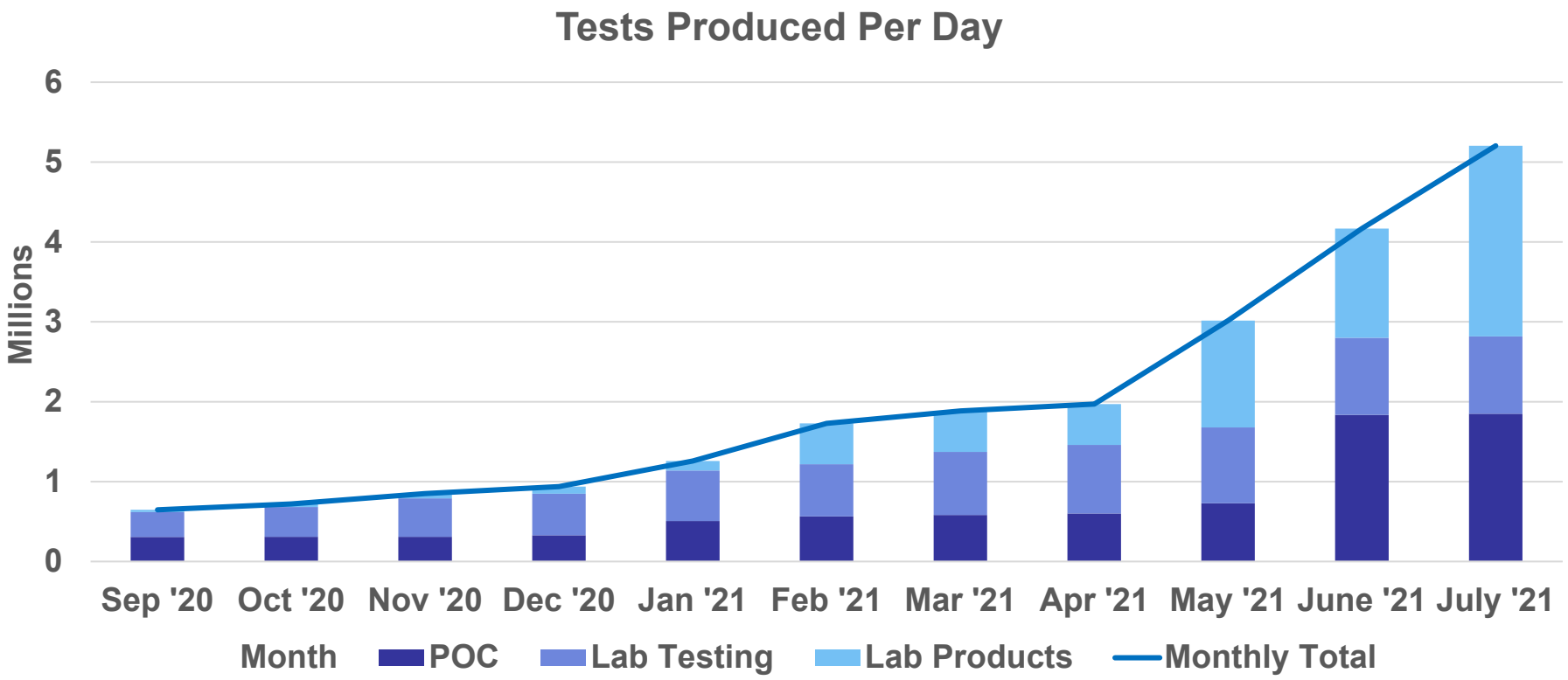
At-Home Diagnostic Testing– $20M

Evaluate the effectiveness of existing diagnostic technologies and platforms in at-home environments

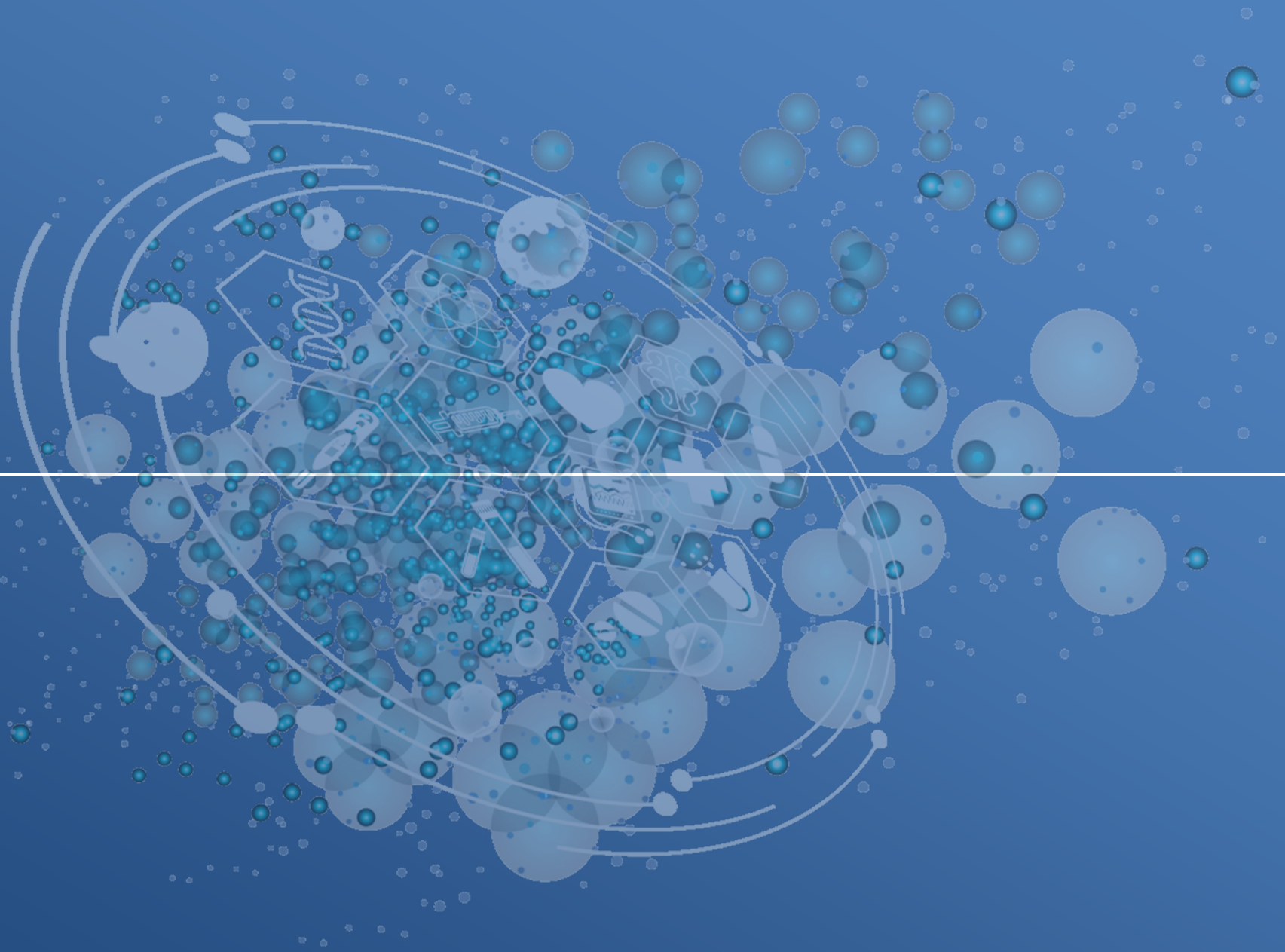
* Includes $185M in BARDA funds for development of RADx tests (funds were not transferred to NIH)

Contribution of RADx to the National Testing Capacity

RADx awards are contributing over 5 million tests per day to the National Testing capacity as of July 2021



ARPA-H



Science

POLICY FORUM

Cite as: F. S. Collins *et al.*, *Science* 10.1126/science.abj8547 (2021).

ARPA-H: Accelerating biomedical breakthroughs

Francis S. Collins[1], Tara A. Schwetz[1,2], Lawrence A. Tabak[1], Eric S. Lander[2]

[1]National Institutes of Health; Bethesda, MD 20892, USA. [2]Office of Science and Technology Policy, Executive Office of the President; Washington, DC 20502, USA. Email: eric.s.lander@ostp.eop.gov

A DARPA-like culture at NIH can drive biomedical and health advances

The biomedical research ecosystem has delivered advances that not long ago would have been inconceivable, exemplified by highly effective COVID-19 vaccines developed by global partners and approved in less than a year. The United States stands at a moment of unprecedented scientific promise and is challenged to ask: What more can we do to accelerate the pace of breakthroughs to transform medicine and health? Toward that end, President Biden recently proposed to create a new entity, the Advanced Research Projects Agency for Health (ARPA-H), within the National Institutes of Health (NIH) "to develop breakthroughs—to prevent, detect, and treat diseases like Alzheimer's, diabetes, and cancer," requesting $6.5 billion in the fiscal year 2022 budget (*1*). The idea is inspired by the Defense Advanced Research Projects Agency (DARPA), which follows a flexible and nimble strat-

sophisticated therapies and devices to patients. Biotechnology companies have access to abundant capital to develop products—provided they can protect their intellectual property and recoup the costs by generating sufficient profit in a short enough period of time. Currently, more than 8000 medicines are in development, including 1300 for cancer (*4*, *5*).

In many cases, these two components are all that's needed to drive progress toward clinical benefit—though subsequent regulatory approvals, reimbursement, and adoption in health care systems can also be optimized. It's becoming clear, though, that some of the most innovative project ideas, which could yield breakthroughs, don't always fit existing support mechanisms: NIH support for science traditionally favors incremental, hypothesis-driven research, whereas business plans require an expected re-

ARPA-H

Goals

- Build **capabilities and platforms** to revolutionize prevention, treatment, and cures in a **range of diseases**
- Convert **use-driven ideas** into tangible solutions for patients far more rapidly than previously believed possible
- Speed application and implementation of **health breakthroughs** to serve all patients
- Foster breakthroughs across various levels – from **the molecular to the societal**
- Overcome market failures through **critical solutions or incentives**

UNITE

The NIH UNITE Initiative

Strengthen Diversity, Equity, and Inclusion

U Understanding stakeholder experiences through listening and learning

N New research on health disparities/minority health/health equity

I Improving the NIH Culture and Structure for Equity, Inclusion, and Excellence

T Transparency, communication, and accountability with our internal and external stakeholders

E Extramural Research Ecosystem: Changing Policy, Culture, and Structure to Promote Workforce Diversity

Cell
Leading Edge

CellPress

184, June 10, 2021

Commentary

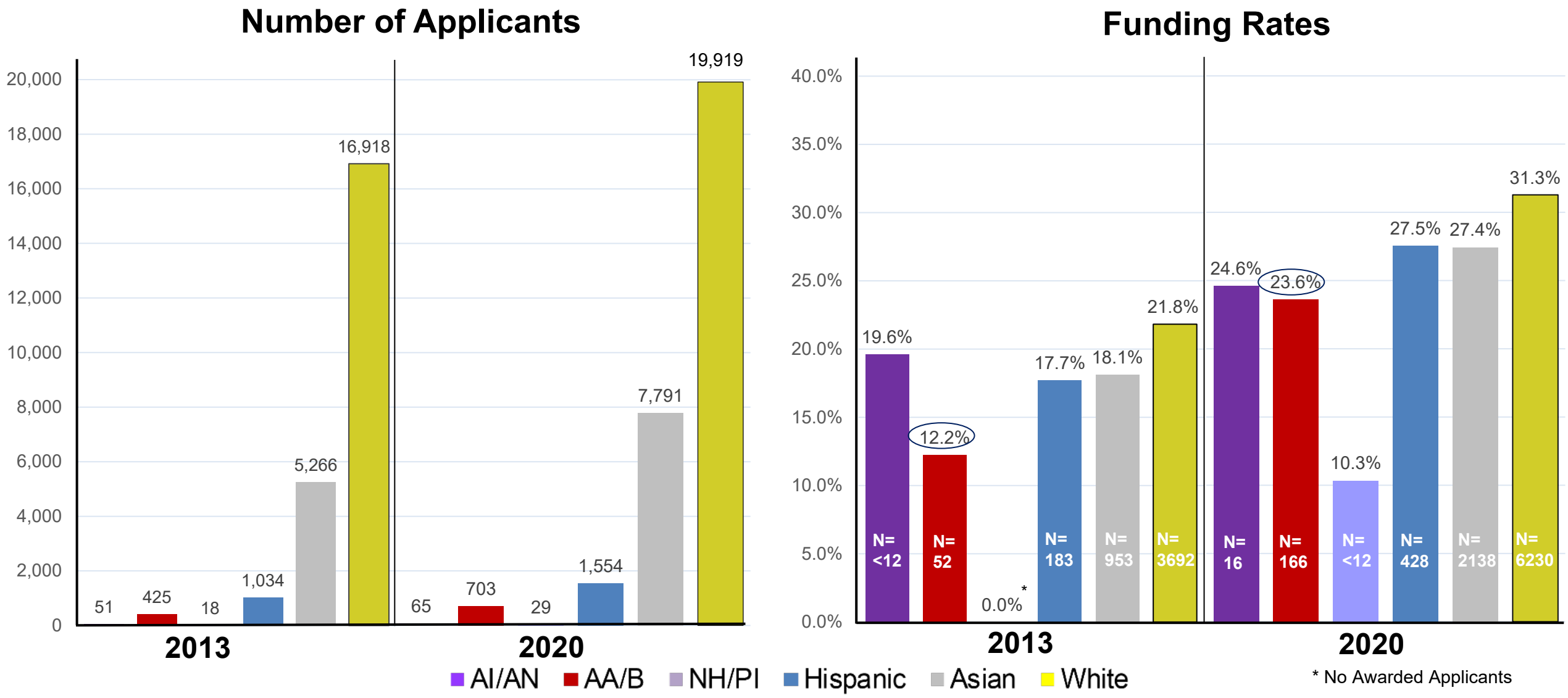
Affirming NIH's commitment to addressing structural racism in the biomedical research enterprise

Francis S. Collins,[1,*] Amy Bany Adams,[2] Courtney Aklin,[3] Trevor K. Archer,[4] Marie A. Bernard,[5,6] Ericka Boone,[7] John Burklow,[8] Michele K. Evans,[6] Sadhana Jackson,[2,9] Alfred C. Johnson,[10] Jon Lorsch,[11] Mia Rochelle Lowden,[12] Anna María Nápoles,[13] Anna E. Ordóñez,[14] Robert Rivers,[15] Victoria Rucker,[5,16] Tara Schwetz,[3] Julia A. Segre,[17] Lawrence A. Tabak,[3] Monica Webb Hooper,[13] Carrie Wolinetz,[3] and NIH UNITE

Initial UNITE Recommendations and Actions

- **Publicly commit to identifying and correcting any NIH policies or practices that may have helped to perpetuate structural racism – *Published 3/1/21***
- **Continue to aggressively implement approaches to address the "Ginther Gap" and enhance portfolio diversity - *Ongoing***

Disparities in NIH R01 Grant Application and Funding Rates



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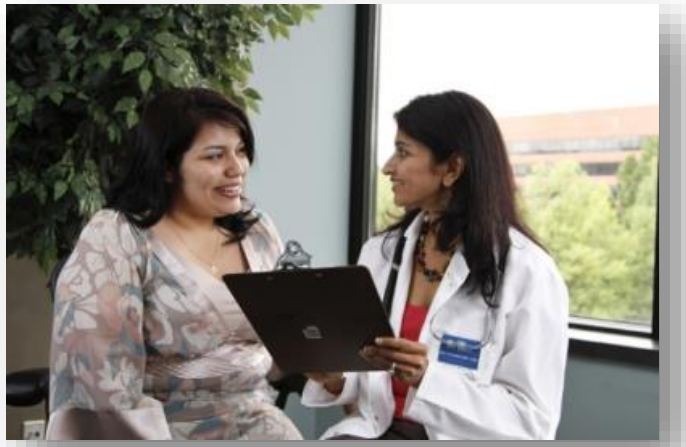
- **Continue to aggressively implement approaches to address the "Ginther Gap" and enhance portfolio diversity - *Ongoing***
- **Launch a multi-phased, -tiered, and -integrated Common Fund Initiative focused on transformative health disparities research initiatives to reduce health disparities/ inequities – *RFAs published 3/26/21***
- **Ensure a robust NIH Enterprise-wide commitment to support a major new funding opportunity announcement, led by NIMHD: focused on the effects of structural racism and discrimination on health disparities/ inequities; encourage funding levels that are commensurate with overall IC resources – *RFA published 3/23/21***
- **Develop a sustainable process to gather and make public the demographics of our internal and external workforce *- Ongoing***

NIH… *Turning Discovery Into Health*

www.nih.gov/hope

directorsblog.nih.gov

@NIHDirector