

NICHD Director's Report

Diana W. Bianchi, M.D.

January 11, 2022



Eunice Kennedy Shriver National Institute
of Child Health and Human Development



Talk Outline

- NICHD 60th Anniversary
- COVID-19 Research Updates
- Decoding Maternal Morbidity and Mortality Challenge
- Bespoke Gene Therapy Consortium
- NCMRR Updates
- NIH and NICHD Staff Updates

NICHD



YEARS OF
INNOVATION



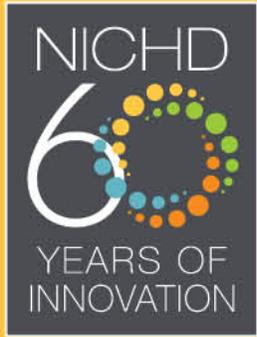
Eunice Kennedy Shriver National Institute
of Child Health and Human Development

Join Us in Celebrating NICHD's 60th Anniversary



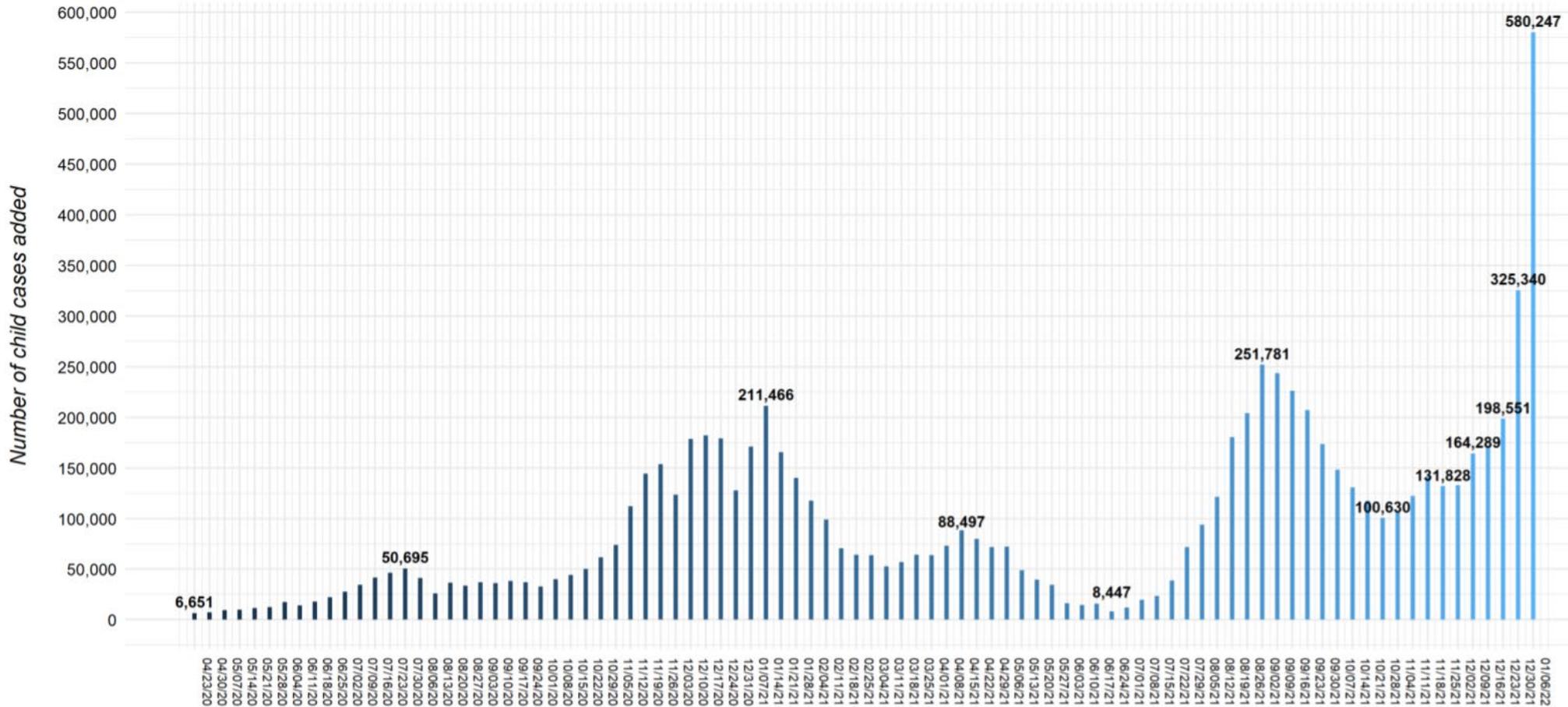
- Visit the NICHD 60th anniversary webpage: <https://www.nichd.nih.gov/60years>
 - Highlights key advances and milestones in NICHD's history
 - Focus on the people who help NICHD achieve its mission
 - Learn about NICHD's future research directions
 - Get updates on anniversary activities and events
- Hold the date!
 - October 17, 2022: 60th Anniversary Symposium: Healthy Pregnancies, Healthy Children, and Healthy and Optimal Lives
 - More details to come





COVID-19 Research Updates

Number of Child COVID-19 Cases Added Each Week (Week of 1/6/2022)

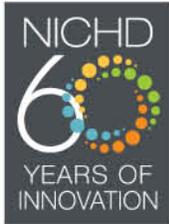


- Children represented 17.4% of all cases
- Seventeen states reported 20% or more of cumulated cases were children





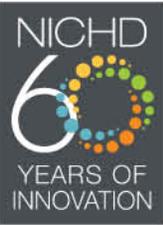
Post-Acute Sequelae of COVID (PASC)



- Comprehensive research effort to understand, prevent, and treat long COVID
- Infrastructure: Administrative, Clinical, and Data coordinating centers and a Biorepository
- Infrastructure will support adult, pregnancy, pediatric, and autopsy clinical cohorts, along with real-world data from EHRs
- Up to 20,000 pediatric participants will be enrolled, with enrollment targets balanced to reflect the impact of COVID-19 in racial and ethnic minorities
 - Will address epidemiology, risk factors, pathobiology, and outcomes in children and adolescents
- Participants with MIS-C (a form of PASC) will be included in RECOVER



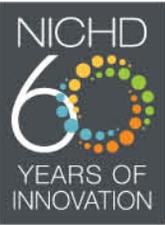
National COVID Cohort Collaborative: Pediatric COVID-19 Severity Dashboard



- PI Tell Bennett is funded by NIH's RECOVER program
- Interactive pediatric COVID-19 severity dashboard for near-real-time tracking
- Analyzes the trajectories of pediatric COVID-19 hospitalization rates
- Leverages the National COVID Cohort Collaborative (N3C), a resource developed with funding from the National Center for Advancing Translational Sciences (NCATS)
- N3C aggregates electronic health record data from over 50 U.S. pediatric centers
 - 1,457,888 pediatric patients in the N3C were tested for SARS-CoV-2
 - 220,177 (15.1%) of those tested were positive
 - Among 13,672 hospitalized children (6.2% of SARS-CoV-2 positive children), 1,989 had severe disease (14.5% of children hospitalized with SARS-CoV-2)

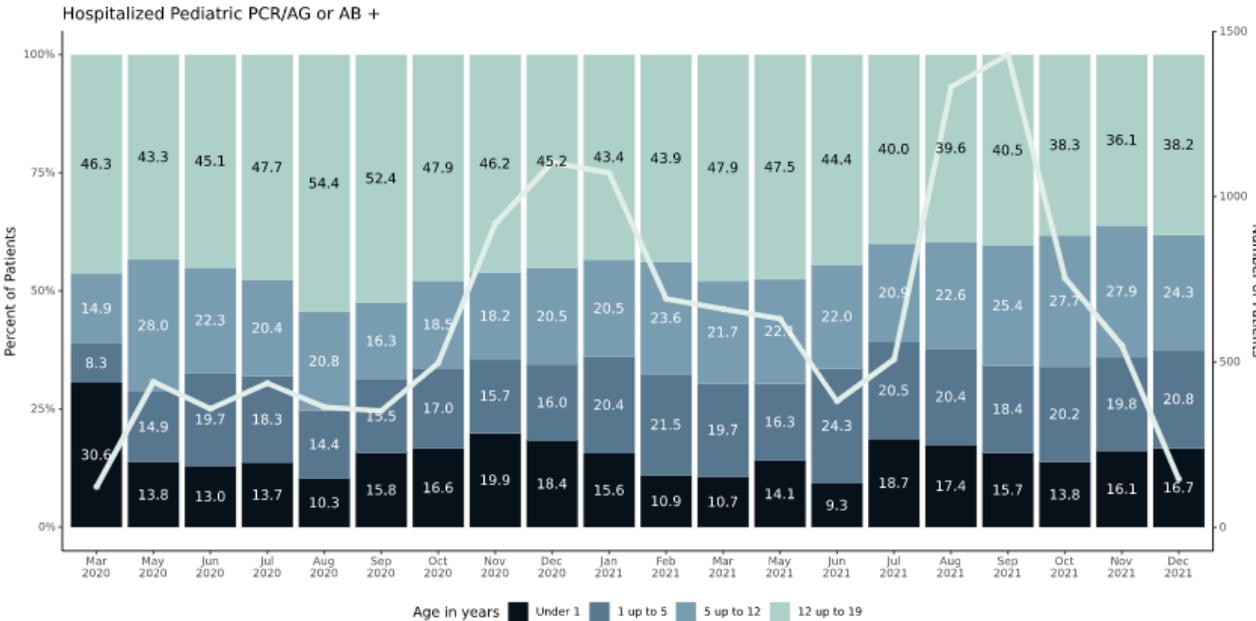
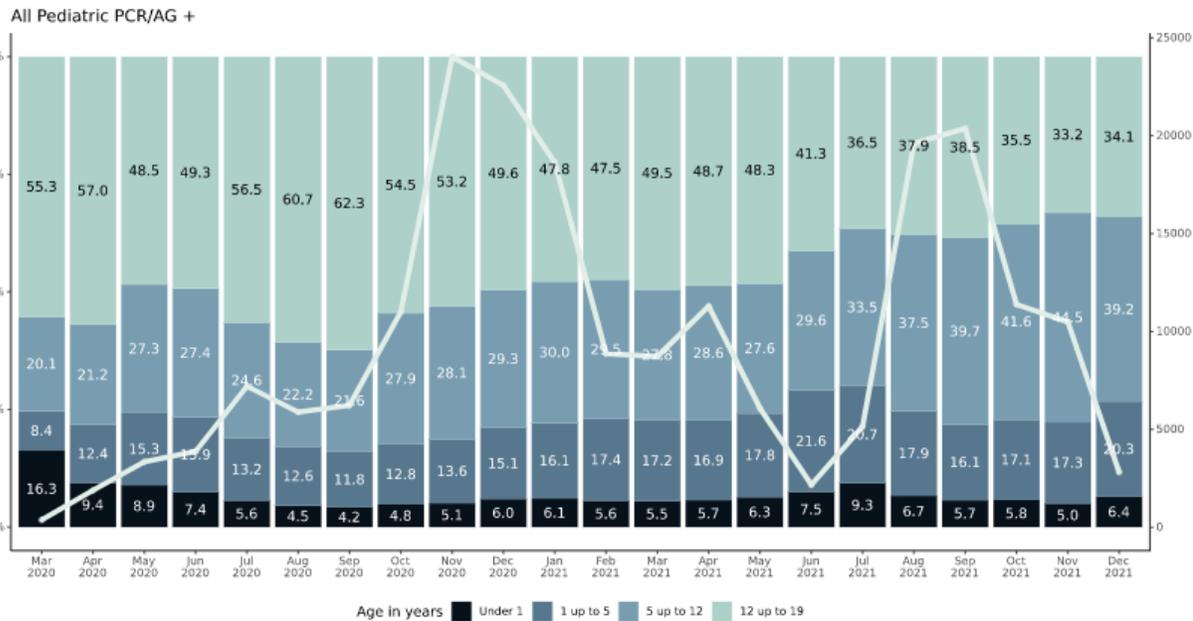


COVID-19 Age Distribution Over Time



All positive COVID-19 cases by age

Hospitalized COVID-19 cases: Positive Test or Antibody



Data updated Dec. 16, 2021

<https://covid.cd2h.org/pediatrics-dashboard/>



COVID-19 Vaccines and Menstruation



- Analyzed de-identified data from nearly 4,000 women via a fertility tracking app
- One dose of a COVID-19 vaccine during a single menstrual cycle increased cycle length by nearly one day compared to unvaccinated women
 - Two vaccine doses in same menstrual cycle increased cycle length by ~ 2 days
 - Increased cycle length not associated with change in the number of days of menses
 - Cycle length returned to normal in subsequent cycles
 - International Federation of Gynecology and Obstetrics classifies a variation in cycle length as normal if the change is less than eight days
- Additional research may determine if COVID-19 vaccination influences associated menstrual symptoms (e.g., pain, mood changes) and characteristics of bleeding (e.g., heaviness of flow)

Edelman, A. et al. *Obstetrics & Gynecology*.
DOI:10.1097/AOG.0000000000004695 (2022)

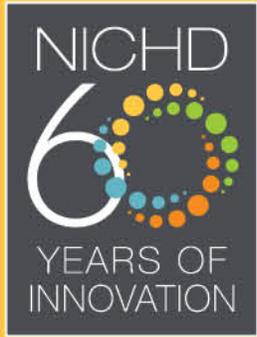


Recent Key Findings: Maternal, Placental and Fetal Immune Response to the COVID-19 Vaccines



- Increased SARS-CoV-2 antibody levels in pregnancy post-vaccination vs. natural infection (Gray KJ et al. *AJOG*, 2021)
- Maternal immune responses were superior in 3rd and 1st trimester vaccination (Atyeo et al., *Medrxiv*, 2021)
 - Maternal cord transfer was highest in 1st trimester vaccination
 - Potential maternal and fetal benefits with earlier vaccination in pregnancy
- Vaccine-induced antibodies in breastmilk samples (Gray KJ et al. *AJOG*, 2021)
- Best protection for an infant is to vaccinate the mother during the 3rd trimester and have the mother breast feed





Decoding Maternal Morbidity and Mortality Challenge

NICHD's First Data Challenge Aims to Identify Risk Factors for First-time Pregnancies



- Proposals analyzed participant data from NICHD's [Nulliparous Pregnancy Outcomes Study: Monitoring Mothers-to-Be \(nuMoM2b\)](#), a racially, ethnically and geographically diverse sample of people who are pregnant for the first time
 - Established in 2010, NuMoM2b has compiled data on more than 10,000 pregnant women, from the sixth week of pregnancy and continuing through delivery
- Twelve prizes totaling \$400,000 were awarded to seven winners
 - Seven prizes of \$50,000 awarded for innovation
 - Five additional prizes of \$10,000 awarded for addressing health disparities
- Winners developed computational methods to analyze data and flag cases that were high-risk for complications
 - These methods can now be used to analyze additional data from other pregnancies

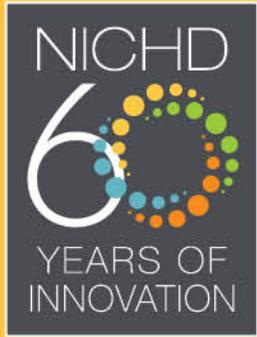


Challenge Award Winners



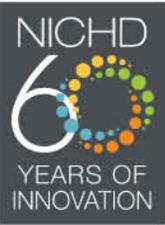
- Sample of award-winning submissions:
 - Multiple approaches to predicting and understanding preeclampsia and hypertensive disorders of pregnancy
 - Developed an inter-sectional social determinants of health (SDoH) phenotype (using 14 indicators) to reveal specific groups who would experience maternal morbidity disproportionately across the sample
 - Understanding the relationship between marginalizing behaviors and postpartum complications for nulliparous women receiving an undesired C-section
 - Tracking changes in health metrics between visits to model adverse pregnancy outcomes





Bespoke Gene Therapy Consortium

Bespoke Gene Therapy Consortium



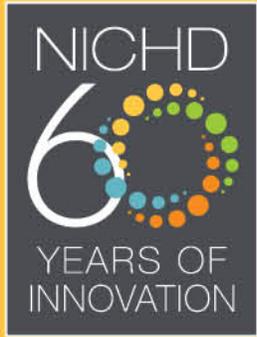
- Part of NIH's Accelerated Medicines Partnership, a public-private partnership with the Foundation for NIH, FDA and private organizations
- NIH-wide participation: NCATS, NICHD, NINDS, NIMH, NHLBI, NIH Clinical Center
- Aims to develop platforms and standards that will speed the development and delivery of customized or 'bespoke' gene therapies that could treat rare diseases
 - Optimize creation of adeno-associated viruses (AAVs) for use in humans
 - Conduct clinical trials using AAVs to treat rare diseases
- De-risks this area for the commercial sector and create a straightforward path for FDA approval



Bespoke Gene Therapy Consortium

- Value to NICHD
 - Strategic Plan Theme 5 – Advancing Safe and Effective Therapeutics
 - Accelerates path to gene therapy for monogenic disorders relevant to NICHD (e.g., Fragile X syndrome, Williams syndrome, Phelan McDermid syndrome)
 - 9 of 12 extramural research branches support research on genetic disorders
- NICHD role
 - Help develop FOAs; provide programmatic input during funding discussions; encourage intramural involvement
- Progress to date
 - Released two requests for proposals seeking high-throughput screens or other developments to optimize individual steps of the AAV vector generation and human gene expression pathways
 - Steering Committee seeking information on rare diseases and disorders that could be candidates for future BGTC AAV gene therapy trials

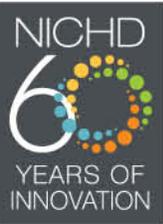




National Center for Medical Rehabilitation Research (NCMRR) Update

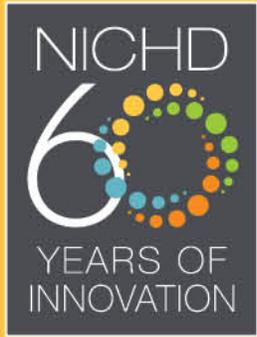
NCMRR Looking Forward

- Published the 2021 NIH Research Plan on Rehabilitation
- Pathways to Prevention Program resulted in a Request for Applications - Home and Community-Based Physical Activity Interventions to Improve the Health of Wheelchair Users
 - [HD-22-017](#)
 - Due date March 30, 2022



NIH Pub. No. 21-HD-8171
October 2021





NIH and NICHD Staff Updates

NIH Director Transition

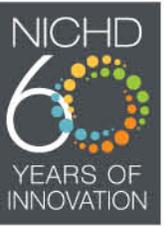


- Dr. Francis Collins stepped down as NIH Director on December 20, 2021
 - Now a tenured senior investigator in NHGRI
- Dr. Larry Tabak is Acting NIH Director
- The White House is conducting the search for the next NIH Director
 - Political appointment requiring Senate confirmation

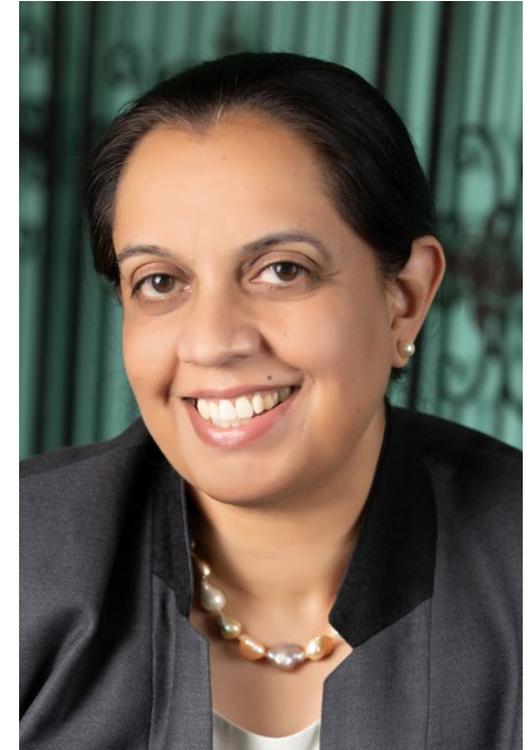


Director, Division of Population Health Research (DiPHR)

Dr. Una Grewal



- Earned MPH and PhD degrees in epidemiology at the University of Michigan School of Public Health
- Joined the DiPHR Epidemiology Branch as a staff scientist in September 2007
- Research focuses on fetal growth and pregnancy outcomes (e.g., labor and delivery, gravid disorders, intrauterine growth restriction, birth defects), especially in relation to maternal nutrition
- Appointed DiPHR Deputy Director in 2013; Acting Director since February 2020



Division of Extramural Research Leadership Positions

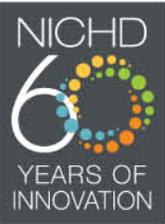


- Associate Director for Extramural Research
 - Oversees NICHD's 12 extramural scientific research branches
 - Selection expected in early 2022; approvals to follow
- Director of Extramural Activities
 - New position
 - Will oversee NICHD's scientific review and grants management branches, as well as the extramural policy and training offices
 - Selection expected in early 2022; approvals to follow



Farewells

- Louis DePaolo, Ph.D., Chief, Fertility and Infertility Branch
 - Retired after 28 years of service



- Charisee Lamar, Ph.D., M.P.H., Director, Office of Health Equity (OHE)
 - To become Deputy Director of Extramural Activities at NIMH

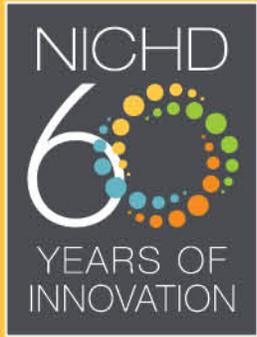


Status Update: Search for New NICHD Scientific Director



- Four finalists completed second round interviews
- Each gave a virtual presentation to DIR
 - Included overview of their science, vision for the DIR, track records in mentoring and in hiring a diverse work force
- Next step:
 - Selection expected in early 2022; approvals to follow
- Additional NICHD intramural and extramural job opportunities: <https://www.nichd.nih.gov/about/jobs>





Thank You!