

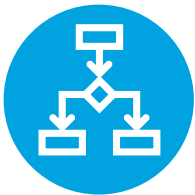
# NICHD AND NIEHS PRESENT:

## TRAINING AND REDCAP DEMONSTRATION FOR THE IMPLEMENTATION OF NICHD'S COMMON DATA ELEMENT (CDE) RECOMMENDATIONS FOR COVID-19 RESEARCH IN PEDIATRIC, PREGNANT, AND LACTATING POPULATIONS PUBLISHED THROUGH THE NIEHS DISASTER RESEARCH RESPONSE (DR2) PORTAL

NOVEMBER 1<sup>ST</sup>, 2022

2:30 – 3:30 PM EST

### PURPOSE



Understand the aim of **NIH's Pregnancy and Pediatric CDEs** related to COVID-19/Post-Acute Sequelae of SARS-CoV-2 Infection (PASC) and how they were developed



Become familiar with **accessing CDEs** via the Disaster Research Response Program (DR2) Website and REDCap



**Call to action** for future use

### LOGISTICS



#### Activities Include:

- Live demonstration on DR2 and REDCap
- Q&A with DR2 and CDE representatives



#### Registration:

- Click [Here](#) for the Zoom Registration Attendee Link
- **Webinar ID:** 960 3266 2934
- **Passcode:** 440012



#### Inquiries To:

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**Training and REDCap Demonstration for the Implementation of NICHD's CDE Recommendations for COVID-19 Research in Pediatric, Pregnant, and Lactating Populations Published Through the NIEHS Disaster Research Response (DR2) Portal**

# Agenda

- 1 Development of Pregnancy and Pediatric CDEs for COVID-19 and Post-Acute Sequelae of SARS-CoV-2 Infection (PASC)
- 2 Overview of NIH CDE Report Structure and Modifications
- 3 Accessing CDEs via the Disaster Research Response Program (DR2) Website and REDCap
- 4 Call to Action, Q&A, and Closing

# Today's Learning Objectives



Review the importance of data harmonization and the critical role of CDEs



Understand the aim of the NIH's recommended Pregnancy and Pediatric COVID-19 and PASC CDE initiatives and how recommendations were developed



Become familiar with accessing the recommended CDEs on the DR2 platform

*“Common data elements are critical for providing consistency in the way we collect, describe, and analyze research data. Our hope is that these common elements are central to future COVID-19 studies.”*

**- Diana W. Bianchi, M.D. NICHD Director**



# **Development of Pregnancy and Pediatric CDEs for COVID-19 and Post-Acute Sequelae of SARS-CoV-2 Infection (PASC)**

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# COVID-19 Data Harmonization: NIH's Deliberate Process

*In the 2020-2021 timeframe, NIH led the development of biomedical, psychosocial, and biospecimen CDEs to promote data harmonization in pregnancy and pediatric research.*

Planned for **data harmonization and future analyses combining datasets** to address key research questions

Used a **modified Delphi approach** to build consensus for data harmonization

Engaged in a **deliberate process** from March 2020 to June 2021 that included the refinement and addition of CDEs, which reflect the increased scientific knowledge of SARS-CoV-2 and Post-Acute Sequelae of SARS-CoV-2 Infection disease manifestation, variants, and vaccine efforts

# Assembled Working Groups Comprised of Subject Matter Experts

*NIH's COVID-19 CDEs encompass the collective contributions of NIH ICO representatives, federal partners, NIH extramural and intramural investigators, and non-NIH funded studies from the relevant research community.*



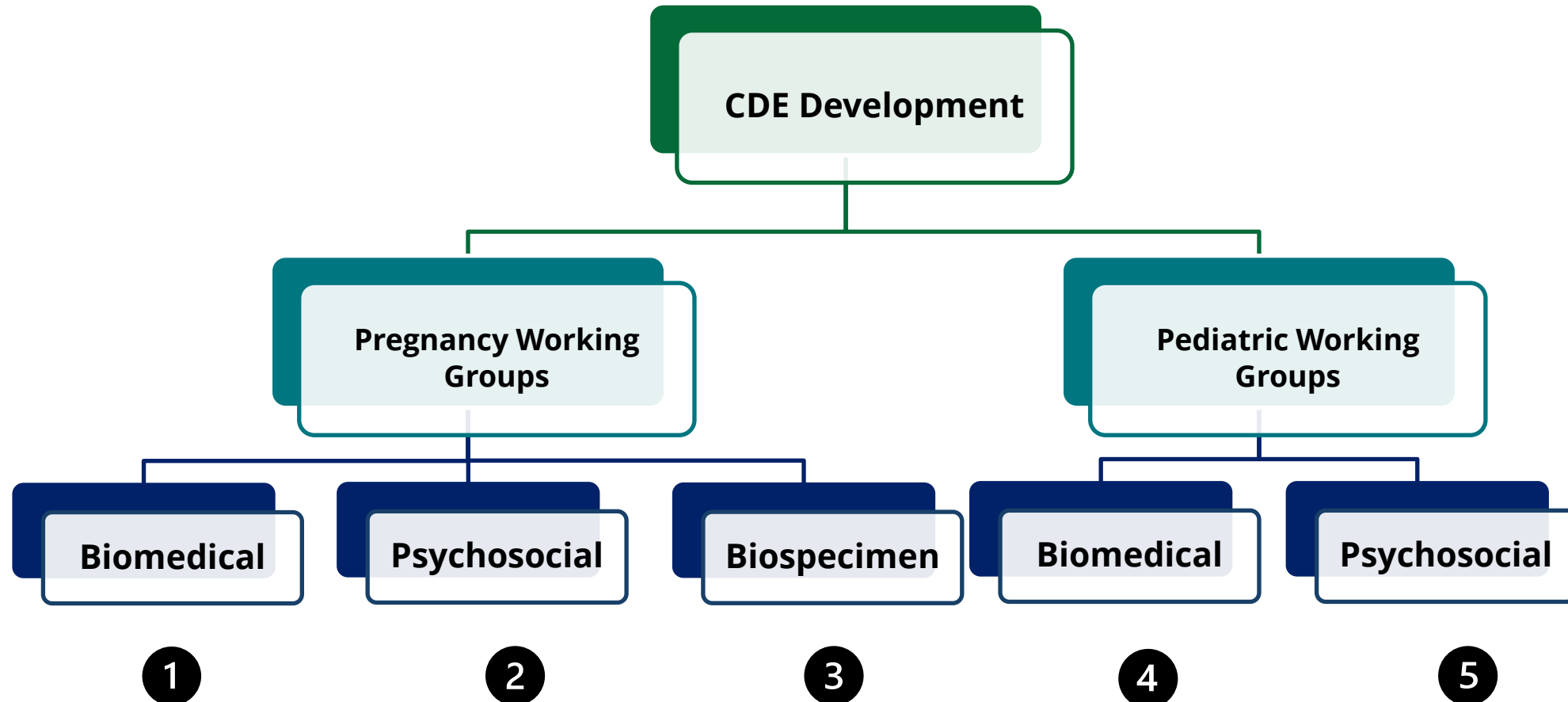
**90+ stakeholders in five working groups (WGs) across NIH, NIH-supported COVID-19 research studies, and three Federal agencies**

Participating NIH Institutes, Centers, and Offices (ICOs) included: **NIEHS, NHLBI, NIAID, NICHD, NIDA, NIDDK, NIMH, NINDS, NLM, and OD**



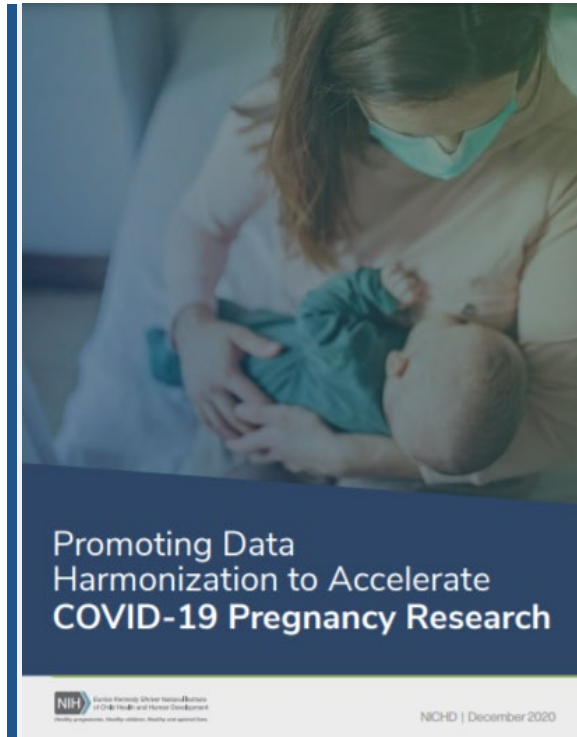


# Five Working Groups Contributed to Pregnancy and Pediatrics COVID-19 and PASC CDE Development

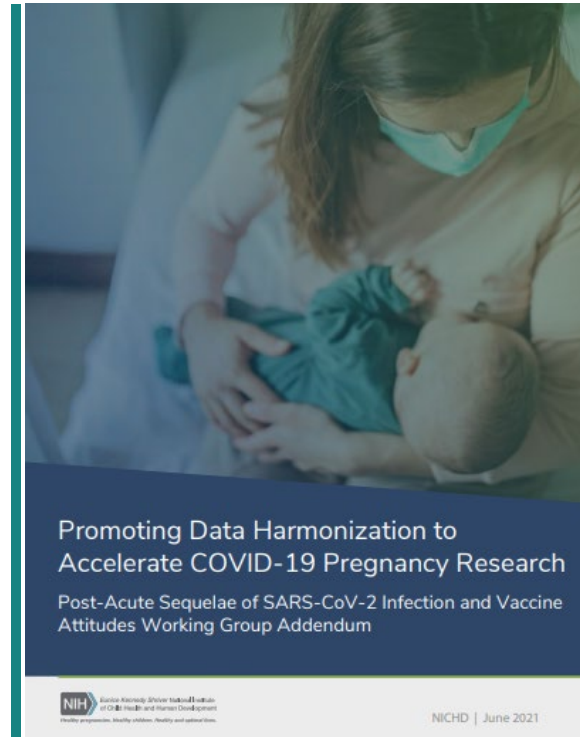


# Pregnancy and Pediatrics CDE Reports

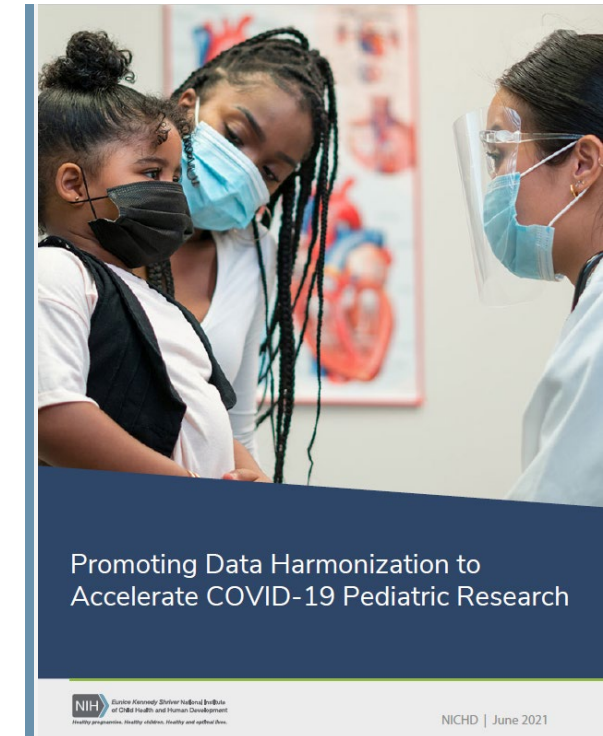
*Recommended biomedical, psychosocial, and biospecimen CDEs are captured in three reports on the Disaster Research Response (DR2) Program website.*



[COVID-19 Pregnancy Research Report](#)



[COVID-19 Pregnancy Research PASC and Vaccine Attitudes Addendum Report](#)



[COVID-19 Pediatrics Research Report](#)

# NICHD Common Data Elements: DR2 Web Analytics

*Combined, our NICHD CDEs have received 1,377 views and 498 downloads since their publish date.*

	Report	Publication Date	Last Updated	Page Views since Publication	Downloads
	COVID-19 Pregnancy Research Report	March 30, 2021	August 2022	497	66
	COVID-19 Pregnancy Research PASC and Vaccine Attitudes Addendum Report	November 29, 2021	August 2022	329	123
	COVID-19 Pediatrics Research Report	November 24, 2021	August 2022	551	309

# Overview of CDE Structure

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# Tier 1 & Tier 2 Recommendations

## TIER 1

### All COVID-19 Studies

Baseline CDEs for any study related to COVID-19 and/or PASC that **may include either:**

1. Pregnant participants, postpartum participants, or participants of reproductive age
2. Pediatric populations

## TIER 2

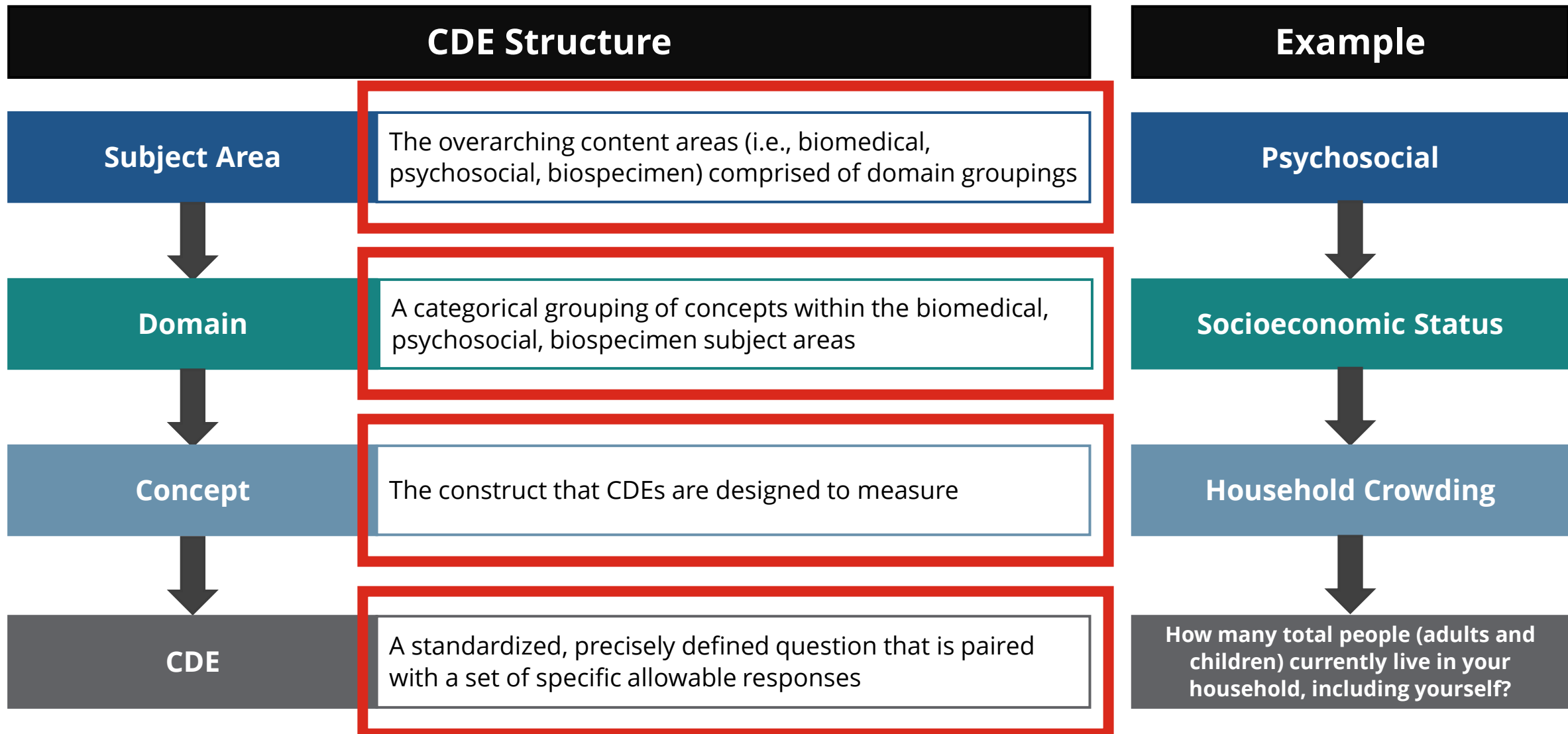
### Population-Specific Studies

More detailed CDEs for any study related to COVID-19 and/or PASC that **focus on either:**

1. Pregnant participants, postpartum participants, or participants of reproductive age
2. Pediatric populations

**Note:** Tier 2 CDEs may pose additional participant or investigator burden that may not be feasible for all studies.

# Subject Area, Domains, Concepts, & Elements



# Pregnancy CDE Domains

*WGs recommended data elements across biomedical, psychosocial, and biospecimen domains.*

## 13 Biomedical and Psychosocial COVID-19 Domains

### Biomedical

- Baseline Maternal/Pregnancy Characteristics
- Maternal COVID-19 Treatment
- Maternal Outcomes
- Obstetric/Pregnancy Outcomes
- Neonatal Characteristics
- Neonatal COVID-19 Testing
- Early Neonatal Outcomes

### Psychosocial

- Socioeconomic Status, Housing, and Emergent Financial Strain
- Medical Care
- Impact on Parenting
- Stressful Life Events
- Maternal Mental Health
- Health Related Behaviors

## 10 Biomedical and Psychosocial PASC and Vaccine Attitudes Domains

### Biomedical

- COVID-19 Vaccination History
- Vaccine Attitudes
- Postpartum
- Family Planning

### Psychosocial

- Pregnancy and Postpartum Function
- Infant Care Practices
- Childcare and Education
- Attribution of Symptoms
- Domestic Violence
- Access to Care

## 4 Biospecimen COVID-19 and PASC Domains

### Biospecimen

- Biospecimens (Neonate)
- Biospecimens (Maternal)
- Extended Specimen Collection (Maternal)
- Maternal

# Pediatrics CDE Domains

*WGs recommended data elements across biomedical, psychosocial, and biospecimen domains.*

## 8 Biomedical COVID-19 and PASC Domains

### Biomedical

- Baseline Child Health
- Manifestations: Clinical
- Manifestations: Laboratory
- Manifestations: Cardiopulmonary Diagnostic Assessment
- Manifestations: Imaging
- Diagnosis
- Treatment
- Outcomes

## 10 Psychosocial COVID-19 and PASC Domains

### Psychosocial

- Community, Family, and Peer Factors
- Social Media/Screen Time
- Well-being Factors
- COVID-19 Stress and Worry
- COVID-19 Attitudes, Behaviors, and Experiences
- Health-related Behaviors
- Mental and Behavioral Health
- Health Care

## 3 Shared COVID-19 and PASC Domains

### Shared Biomedical and Psychosocial

- Demographics
- Disability/Functional Status
- Underlying Health Conditions/Health History Prior to Pandemic



# Modifications

*As our understanding changes, further CDEs and/or modifications to existing recommended measures may be needed.*



Changing question stem of non-validated CDEs while maintaining the current purpose of the question

Adding in a response item due to increasing knowledge of disease manifestation when answer choices are not formatted in a Likert scale



Changing question stem of CDEs that are part of a validated measure

Making substantive changes to question stem and/or altering the purpose of the question

Changing the timeframe referenced in the question

Removing a specific response item

# Examples of CDE Amendments as our Understanding of the Current Pandemic Continues to Evolve

## Sample Pregnancy Biomedical CDE



Mark Yes/No/Unknown to denote if the patient received any of the following COVID-19 treatments

- ☐ Oseltamivir
- ☐ Hydroxychloroquine/chloroquine therapy
- ☐ Remdesivir
- ☐ Azithromycin
- ☐ Convalescent Plasma
- ☐ [New Treatment Option]

- ✓ Adding a response item as treatment options for COVID-19 evolve
- ✓ Changing the question stem to *"Did the patient receive any of the listed COVID-19 treatments?"*

## Sample Pregnancy Psychosocial CDE



In the past 7 days, I have been able to laugh and see the funny things:

- ☐ As much as I always could
- ☐ Not quite so much now
- ☐ Definitely not so much now
- ☐ *Not at all-Other*

- X Removing the time frame or changing it from **"7 days"** to *"few days," "14 days,"* etc.
- X Removing "Not at all," an existing answer item
- X Adding **"Other"** as a response option when the answers are presented in a Likert Scale
- X Changing the question stem in a way that removes the purpose. For example, *"In the past 7 days, I have connected with family and friends:"*

# **Accessing CDEs via the Disaster Research Response Program (DR2) Website and REDCap**

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# DR2 Hosts NIH COVID-19 Data Collection/Survey Instruments

*The Disaster Research Response (DR2) Program provides training, funding, and a resource portal of tools to empower research in response to disasters and public health emergencies*



## ACCESS

- Access rapidly evolving survey items by researchers
- > 145 COVID-19 surveys currently online
  - New electronic intake processes, search engines, metadata, and comparison tools



## COMPARE

- Compare across datasets and studies, further data integration, and collaborations
- > 15,000 new users



## APPLY

Apply to NIH funding opportunities recommending the use of DR2 COVID-19 CDE collections

# CDEs Live on DR2 via REDCap

*Several NIH institutes (including NICHD), CDC, and more than a dozen state health departments in the U.S. are using REDCap for COVID-19 symptom tracking and monitoring*



## ACCESS

REDCap is a web-based data-entry and collection application



## CAPTURE

It is used to capture data for clinical research and create databases and projects

- Databases employ easy-to-use instruments (e.g., surveys, forms) as research capture tools



## SECURE

REDCap is designed to store highly sensitive information

- Health Insurance Portability and Accountability Act (HIPAA) compliant

# DEMO: DR2

## Disaster Research Response (DR2) Program Common Data Elements (CDE)



### Research

Initiatives in Environmental Health Science

Disaster Research Response (DR2) Program

About the Program +

Common Data Elements (CDE)

Community of Practice

Funding & Support

Human Studies & Research Ethics

Training & Education

A Common Data Element (CDE) is a standardized, precisely defined question, paired with a set of allowable responses, used systematically across different sites, studies, or clinical trials to ensure consistent data collection. Each set of agreed upon CDEs produces a data dictionary (derived from the metadata) that can facilitate the discussion, harmonization, and analysis of data. We encourage use of CDEs not only to assist with a single study and its associated data capture, analysis, and presentation but to also enhance and assure potential for future data sharing.

The [DR2 Resources Portal](#) hosts several CDEs from various institutions so the broader research community may use similar data collection methods to create larger datasets, across a variety cohorts, to provide a deeper understanding of the uncertainties associated with disasters.

The DR2 COVID-19 Collection contains the [NICHD COVID-19 Pregnancy and Pediatric Common Data Elements](#). The DR2 program team worked in collaboration with the NICHD working groups to produce instructional materials on how to access the NICHD COVID-19 CDEs in the Portal and upload them into a REDCap project for quick and easy implementation.

The video and powerpoint provide step-by-step instructions on the following:

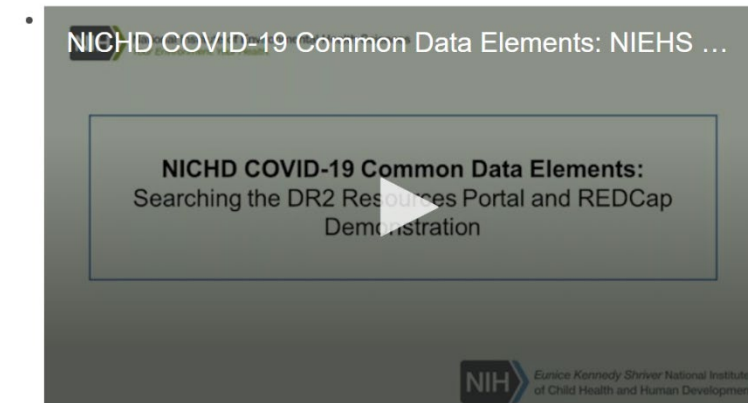
- Searching the DR2 Resources Portal for the NICHD COVID-19 CDEs.
- Accessing and downloading the data dictionary from the NICHD COVID-19 CDE record.
- Uploading the data dictionary into a REDCap project.
- Searching the REDCap Shared Library.
- Importing a survey instrument from the REDCap Shared Library.
- Importing other survey instruments from the DR2 Portal into the NICHD COVID-19 CDEs.

The video and powerpoint provide step-by-step instructions on the following:

- Searching the DR2 Resources Portal for the NICHD COVID-19 CDEs.
- Accessing and downloading the data dictionary from the NICHD COVID-19 CDE record.
- Uploading the data dictionary into a REDCap project.
- Searching the REDCap Shared Library.
- Importing a survey instrument from the REDCap Shared Library.
- Importing other survey instruments from the DR2 Portal into the NICHD COVID-19 CDEs.

### Informational Materials:

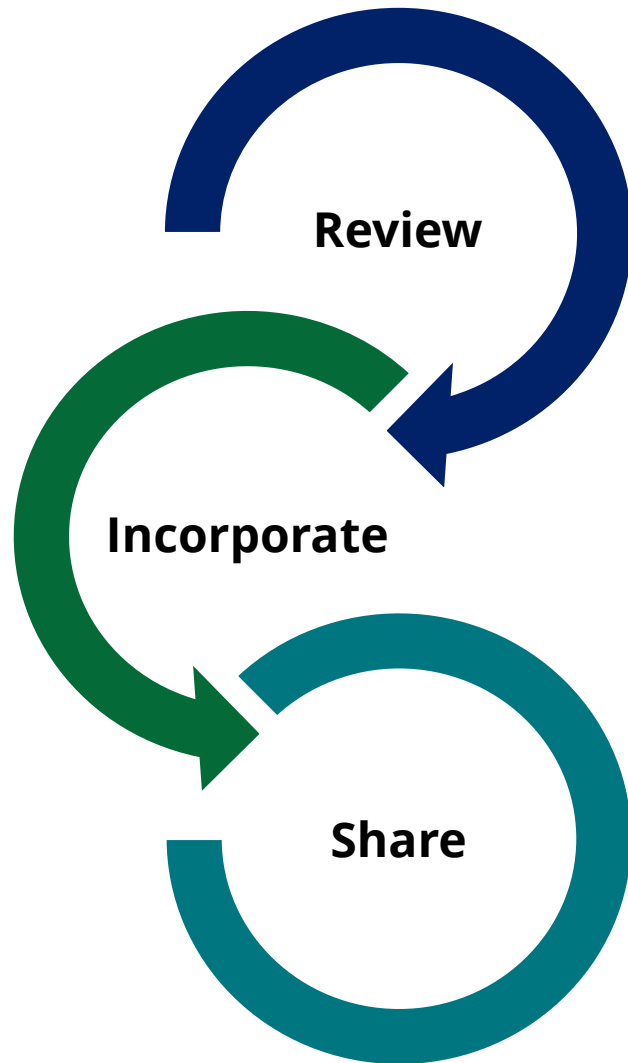
- [NICHD COVID-19 CDE Portal Search and REDCap Stand-alone](#) (6MB)



# **Call to Action**

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# A Call to Action



Review the full set of recommended pregnancy and pediatrics CDEs:

- [Promoting Data Harmonization to Accelerate COVID-19 Pregnancy Research](#)
- [Post-Acute Sequelae of SARS-CoV-2 Infection and Vaccine Attitudes Addendum](#)
- [Promoting Data Harmonization to Accelerate COVID-19 Pediatric Research](#)

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Review the DR2 CDE Webpage including a DR2 and REDCap Demo Video:

- [Disaster Research Response \(DR2\) Program: Common Data Elements \(CDE\)](#)

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Incorporate the recommended CDEs to streamline and harmonize data when planning new studies or continuing ongoing studies

- Use of CDEs is voluntary and not required to receive NIH funding

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Share these recommendations across your research communities to further promote data harmonization



# Contributors

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# Q&A

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# Thank You

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# Appendix

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# Pregnancy CDE Success Stories

## Pregnancy Common Data Elements



### NICHD NOSI Investigating COVID-19 Vaccination and Menstruation

- Extramural [NOSI](#) awardees at Harvard, John's Hopkins, and Michigan State University are using biomedical PASC CDEs to study the effects of COVID-19 vaccinations on menstruation

### NHLBI nuMOM2b Heart Health Studies

- The [nuMOM2b](#) Heart Health Studies are studying first-time pregnant women to understand how pregnancy outcomes are linked to future heart health using recommended pregnancy CDEs

### NYU-NIH NeuroCOVID Project

- The COVID-19 Neuro DataBank Biobank ([The NeuroCOVID Project](#)) is studying neurological complications of COVID-19 using the biomedical pregnancy CDEs

### Researching COVID to Enhance Recovery (RECOVER) Initiative

- [RECOVER](#) seeks to understand, prevent, and treat Post Acute Sequelae of SARS-CoV-2 Infection

# Pediatrics CDE Success Stories

## Pediatric Common Data Elements



### NICHD Post-Intensive Care Syndrome - Pediatrics (PICS-p): Longitudinal Cohort Study

- [PICS-p](#) is a multicentered study of post-intensive care syndrome in children evaluating child and family outcomes over two years post PICU discharge



### NHLBI The PRone and OScillation Pediatric Clinical Trial (PROSpect)

- The [PROSpect Study](#) is a multicentered trial assessing the value of high frequency oscillatory ventilation and prone positioning in children with severe lung disease



### Researching COVID to Enhance Recovery (RECOVER) Initiative

- [RECOVER](#) seeks to understand, prevent, and treat Post Acute Sequelae of SARS-CoV-2 Infection