



# RADx-rad Updates

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March 23, 2021

DCC Presentation to the SC



2 min: CDE updates + Q&A

20 min: Diagnostics Core updates + Q&A

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March 23, 2021

RADx-rad DCC Presentation to the SC

# RADx All Required (*Tier 1, Minimum*)

Presented at the Feb  
22 Kickoff

Concept	
Identity	
Race & Ethnicity	American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, White, More than one race, Unknown//Hispanic or Latino, Not Hispanic or Latino, Unknown
Age	Date of birth
Sex	Biological sex assigned at birth
Education	Formal years of education
Domicile	Current Address
Employment	Yes/no/temporary
Insurance Status	private/public/none
Disability status	Six-item Standard Disability Questions (CDC; hearing, seeing, making decisions, bathing...)
Medical history	Substance use including vaping; asthma; cancer; cardiovascular disease; chronic kidney disease; chronic lung disease; diabetes; hypertension; immunosuppressive condition; serious mental illness; sickle cell disease; pregnancy status;
Symptoms	Cough, fever, difficulty breathing, headache; muscle ache, loss of taste or smell, chills, excessive fatigue; N/V, diarrhea, abdominal pain, skin rash, conjunctivitis
Health Status	BMI (weight and height), single-question (How good is your health?)

# A report from the field: Survey statistics

- Total: 43 / 49 (88%)
- Human Subjects:
  - No: 17 (40%)
  - Yes: 26 (60%)
    - Prospective: 19
    - Retrospective: 13

\* 6 projects have both prospective and retrospective subjects

# Survey: Non mutually exclusive answers

**No concerns**

☐ We already collect this CDE, no concerns

**Project changes**

☐ We can collect this CDE, but project changes are needed (e.g., amend IRB) (provide details below)

**Not suitable**

☐ We can collect this CDE, but it is not suitable for our project (provide details below)

**Burdensome**

☐ It is difficult to collect this CDE, as it is burdensome to collect (provide details below)

**Sensitive**

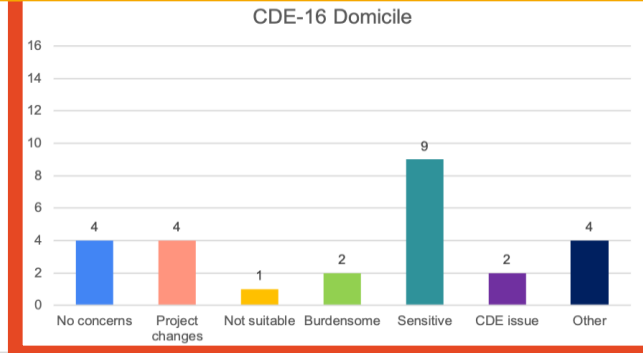
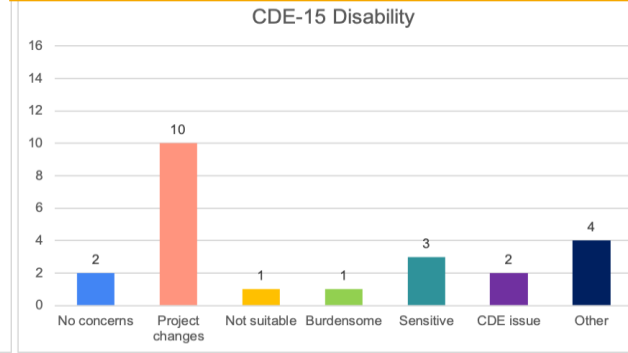
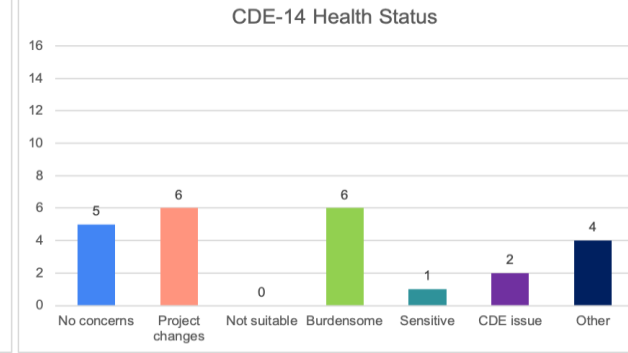
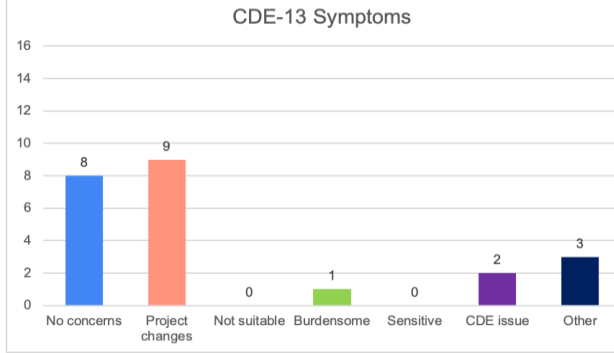
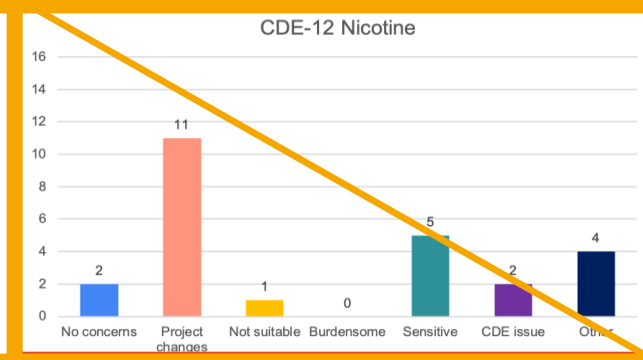
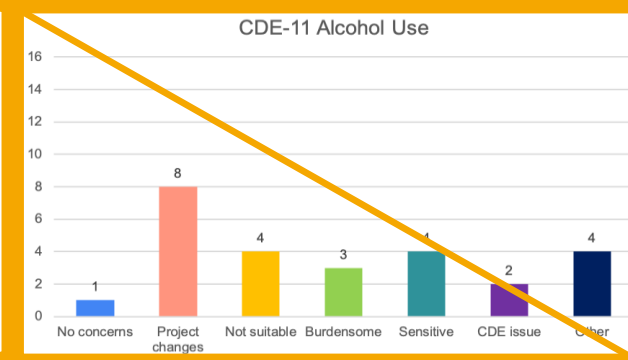
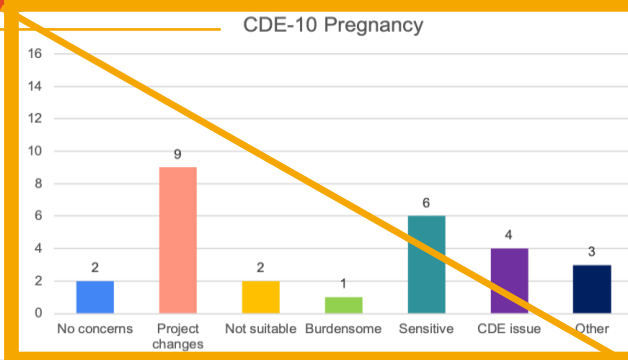
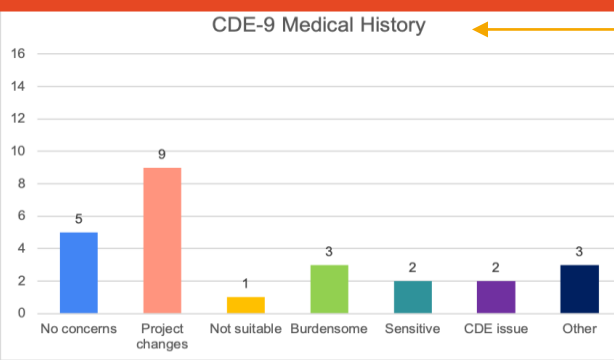
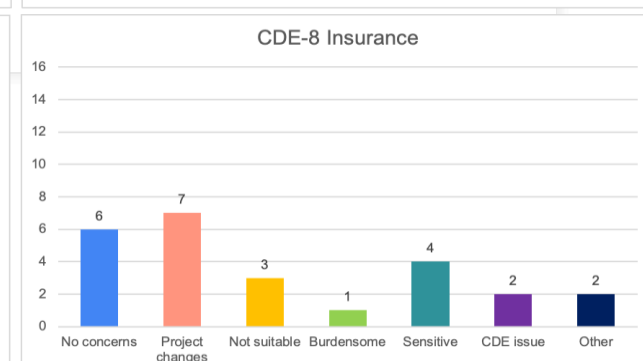
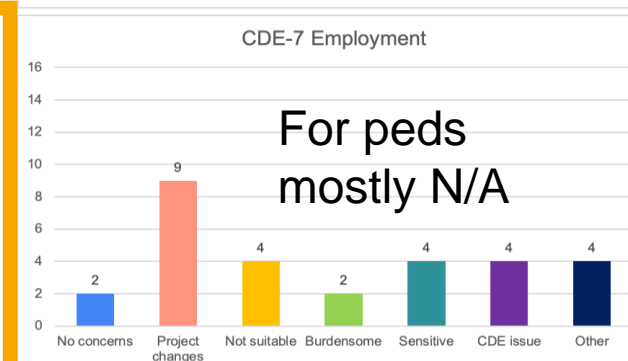
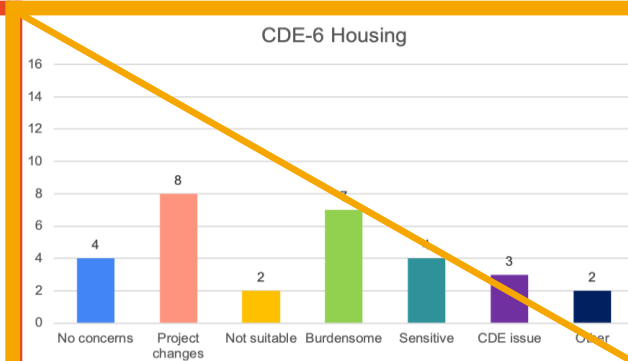
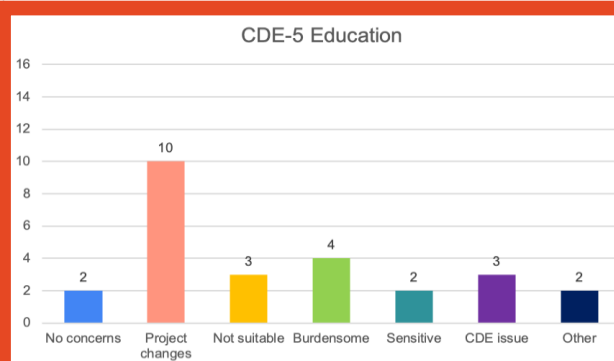
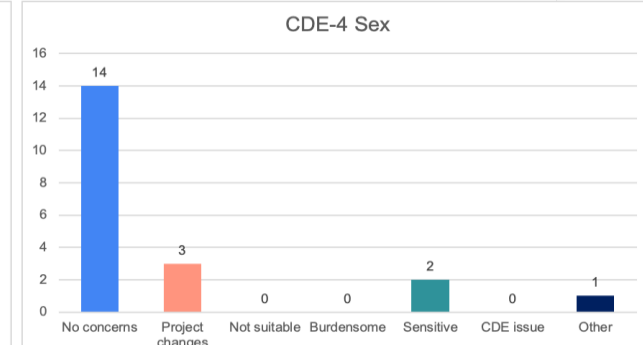
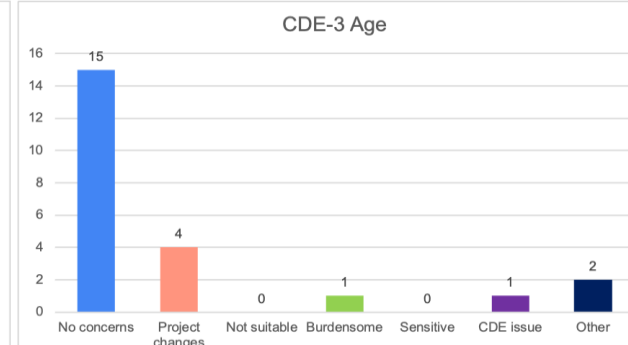
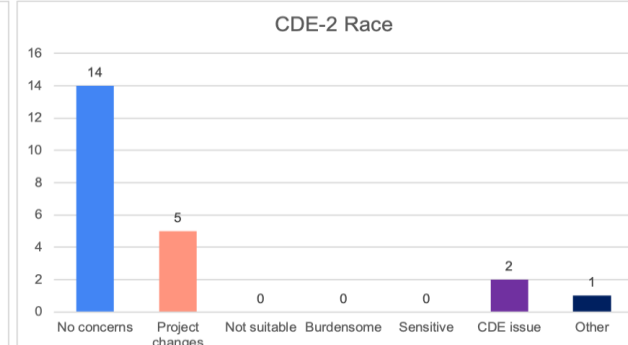
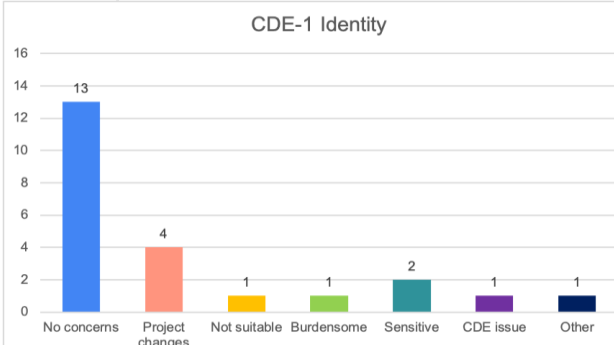
☐ It is difficult to collect this CDE, as it asks for sensitive data that may affect recruitment (provide details below)

**CDE issue**

☐ We can collect this type of data, but the specified CDE is problematic for our project (provide details below)

**Other**

☐ Other (provide details below)



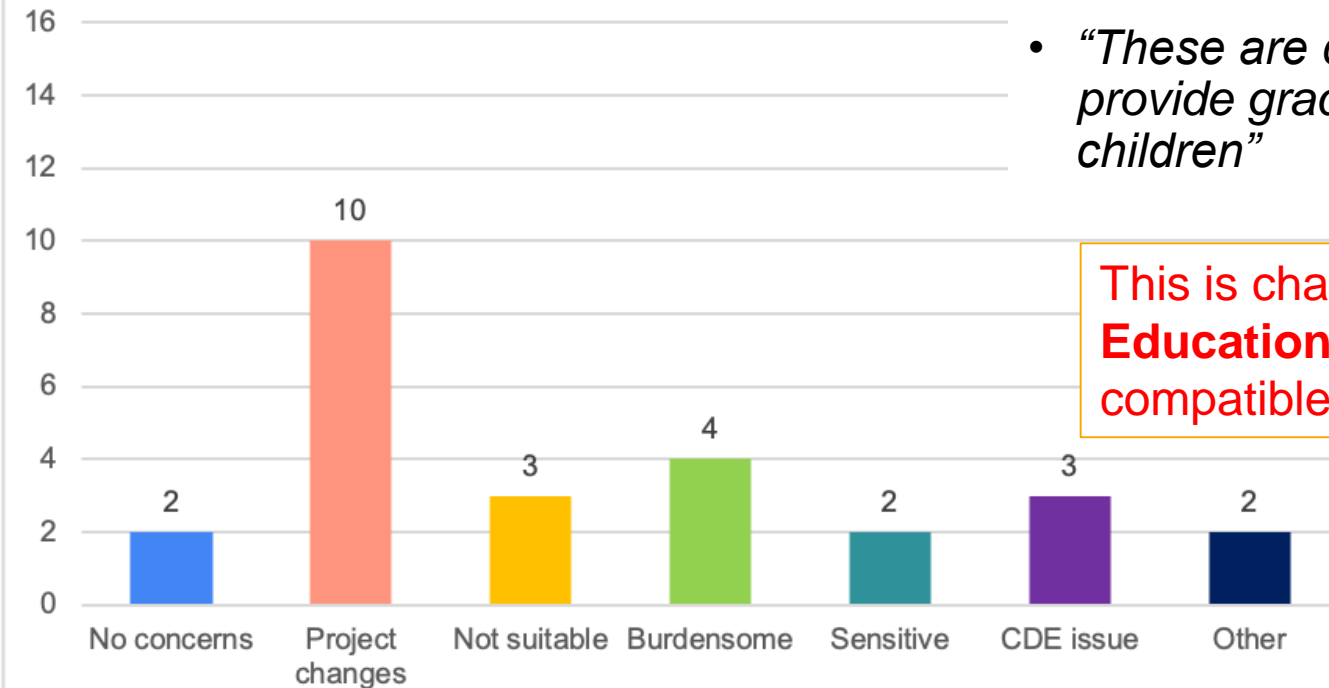
## 5. EDUCATION

What is the highest grade or level of school you have completed or the highest degree you have received? (HAND CARD, READ HAND CARD CATEGORIES IF NECESSARY. ENTER HIGHEST LEVEL OF SCHOOL). (<https://www.phenxtoolkit.org/protocols/view/11002>)

# EDUCATION

- “We plan to collect education data, but we feel that there should many fewer categories to reduce participant burden and recruitment bias.”
- “Pediatric patients, school grade is reported by parents, categories above 14 don't apply”
- “These are children. We can provide grade level for older children”

CDE-5 Education



This is changed to **Years of Education** to be simpler and compatible with other countries

NEVER ATTENDED/KINDERGARTEN ONLY

1( ) 1<sup>ST</sup> GRADE

2( ) 2<sup>ND</sup> GRADE

3( ) 3<sup>RD</sup> GRADE

4( ) 4<sup>TH</sup> GRADE

5( ) 5<sup>TH</sup> GRADE

6( ) 6<sup>TH</sup> GRADE

7( ) 7<sup>TH</sup> GRADE

8( ) 8<sup>TH</sup> GRADE

9( ) 9<sup>TH</sup> GRADE

10( ) 10<sup>TH</sup> GRADE

11( ) 11<sup>TH</sup> GRADE

12( ) 12<sup>TH</sup> GRADE, NO DIPLOMA

13( ) HIGH SCHOOL GRADUATE

14( ) GED OR EQUIVALENT

15( ) SOME COLLEGE, NO DEGR

16( ) ASSOCIATE DEGREE: OCUPATIONAL, TECHNICAL, OR VOCATIONAL PROGRAM

17( ) ASSOCIATE DEGREE: ACADEMIC PROGRAM

18( ) BACHELOR'S DEGREE (EXAMPLE: BA, AB, BS, BBA)

19( ) MASTER'S DEGREE (EXAMPLE: MA, MS, Meng, Med, MBA)

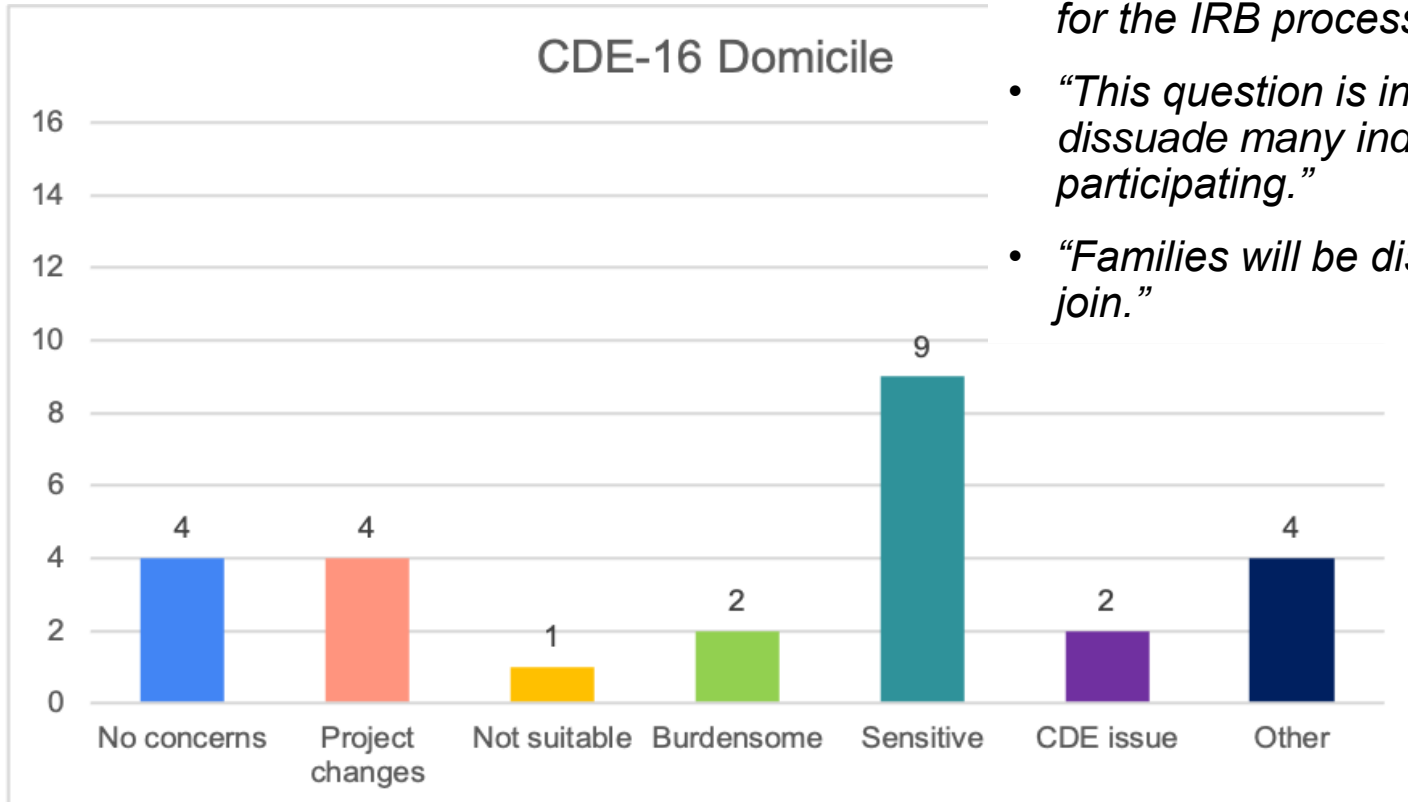
20( ) PROFESSIONAL SCHOOL DEGREE (EXAMPLE: MD, DDS, DVM, JD)

21( ) DOCTORAL DEGREE (EXAMPLE: PhD, EdD)

77( ) REFUSED

99( ) DON'T KNOW

# DOMICILE ADDRESS



- *“The subjects may be particularly hesitant to respond this question (our population subject may include unauthorized immigrants, homeless, etc.), and it will also be problematic for the IRB process.”*
- *“This question is intrusive and could dissuade many individuals from participating.”*
- *“Families will be distrustful and will not join.”*

## DOMICILE ADDRESS

First Name

Last Name

Street Number

Street Name

Street Name 2

Apartment Number

City

State or Territory

Zip Code

Mobile Phone

Home Phone

Work Phone

Personal Email

Work Email

Date of Birth

All this is changed to **Zip Code** to be simpler and less intrusive



# Some Observations about CDEs

- A clear need for a set of revised minimum CDEs for children
- Expected impact on patient recruitment
  - Sensitive information, especially for underserved populations, may result in a biased sample
  - Attrition: Time spent may become excessive, relative to test (e.g., a smell test: 2 minutes test vs. ~20 minutes minimal CDEs collection)
- Over time we will learn which items are consistently skipped and cause the most issues

# Memo to POs

Minimum CDE set for RADx-rad completed

Petition for a waiver for a minimum CDE may be submitted by the institution to the PO with justification

DCC now working on labs and other data elements for each FOA