



RADx-rad Updates

March 23, 2021

DCC Presentation to the SC



2 min: CDE updates + Q&A

20 min: Diagnostics Core updates + Q&A

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

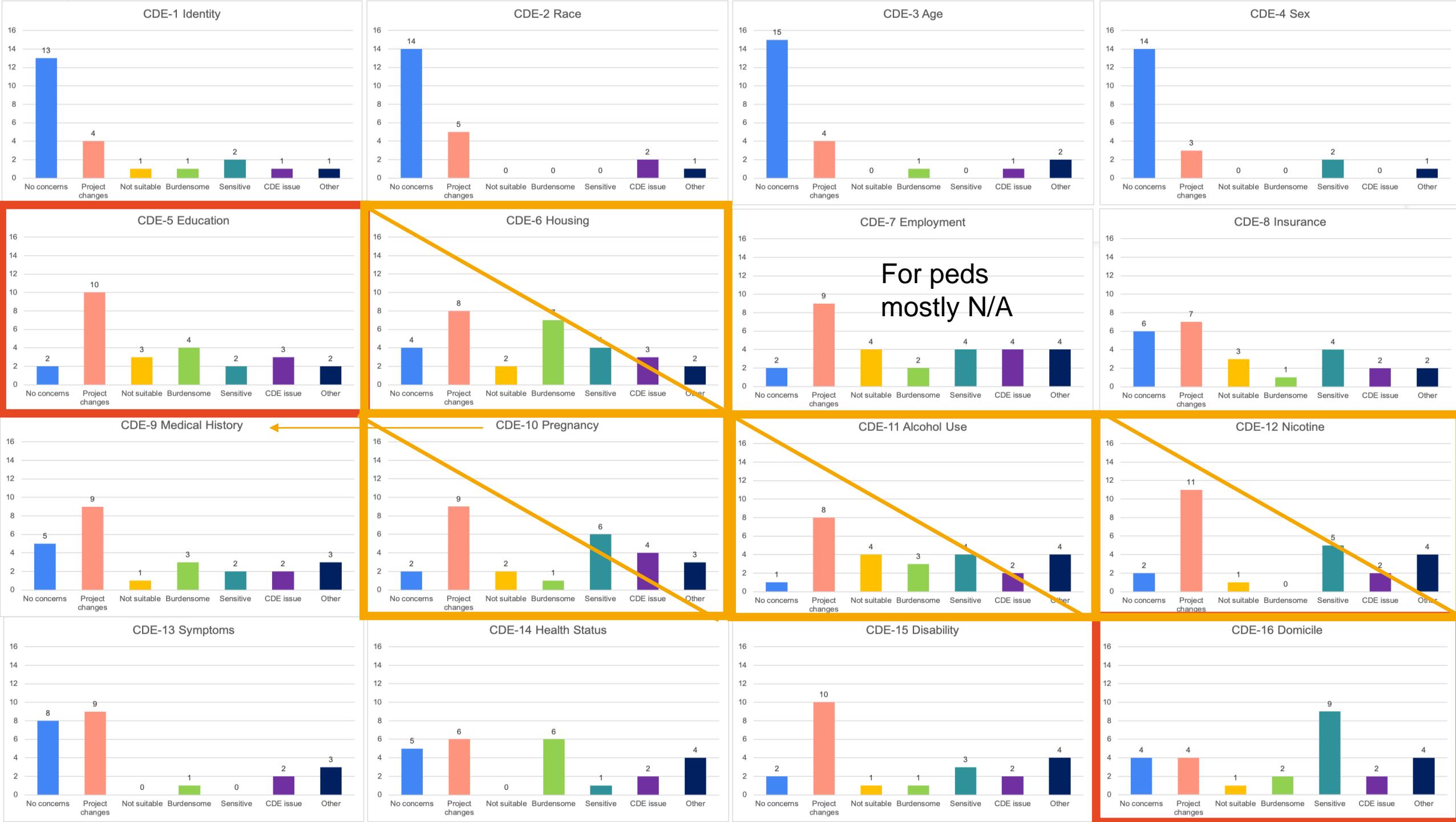
- It is difficult to collect this CDE, as it asks for sensitive data that may affect recruitment (provide details be...

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)



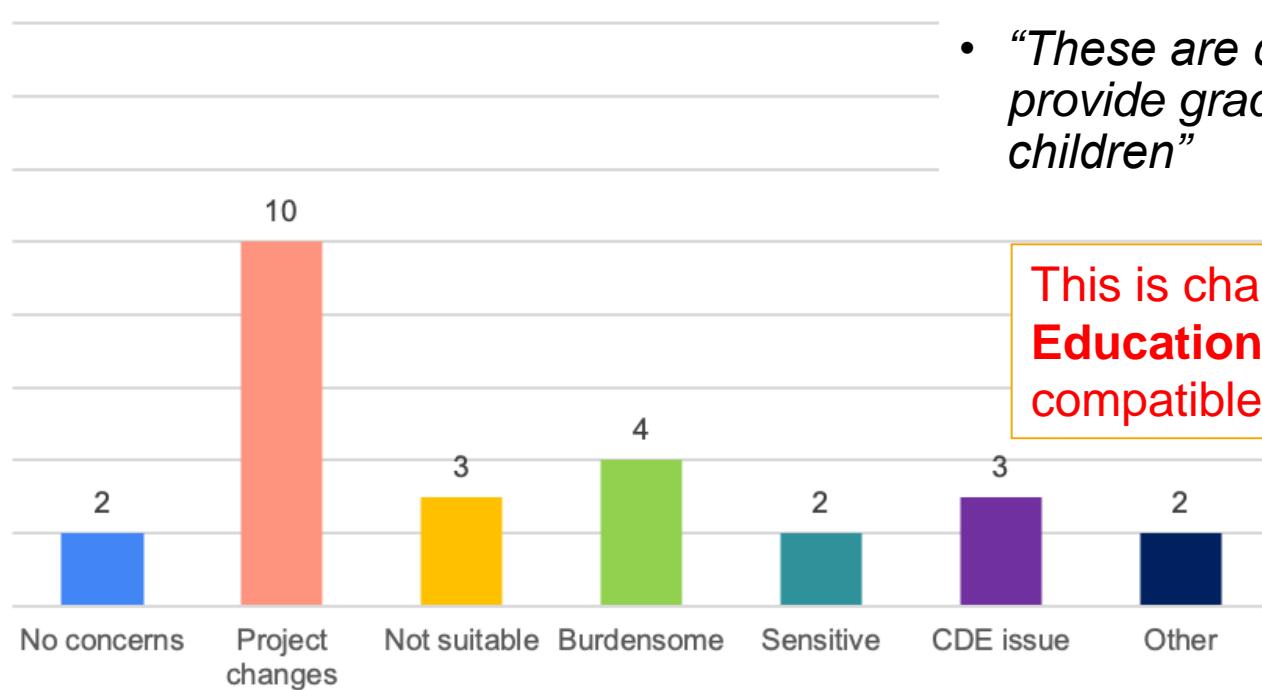
EDUCATION

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>)

- “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”

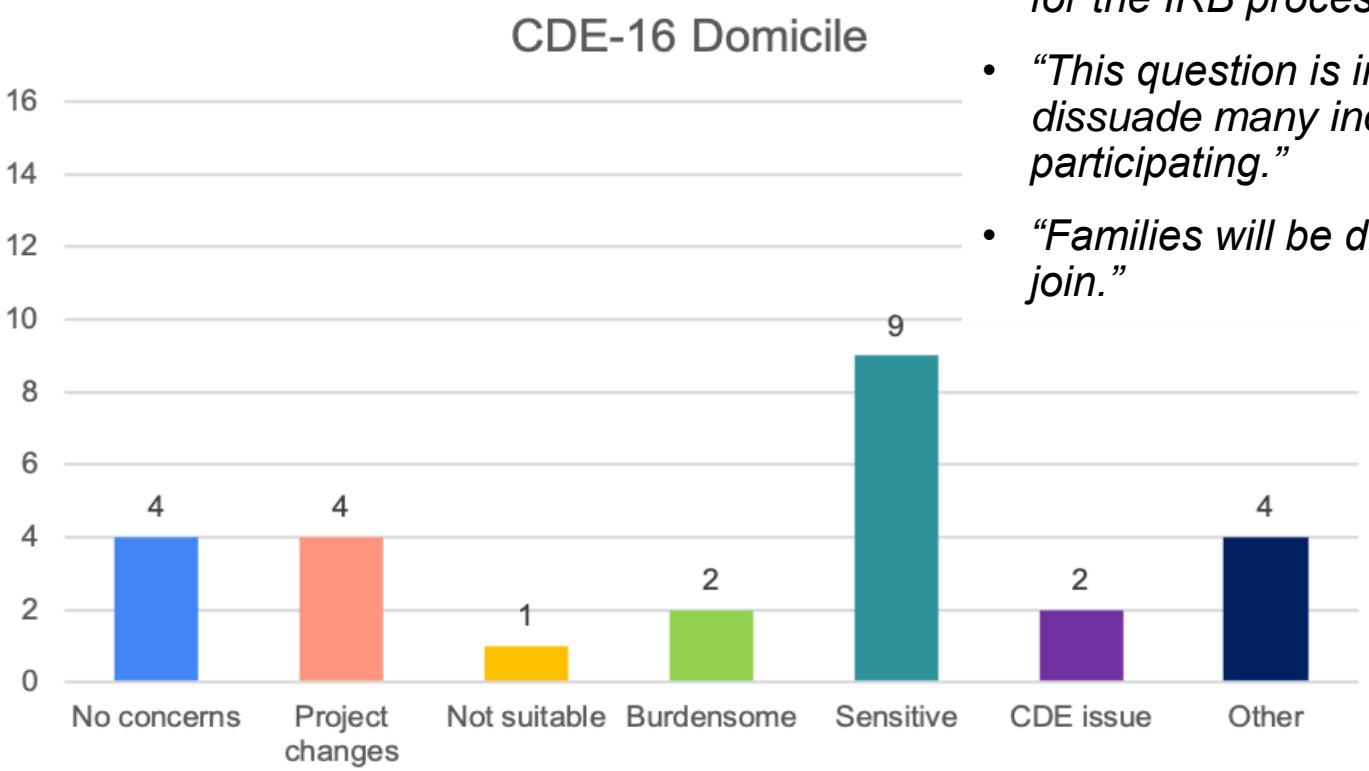
CDE-5 Education



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

- NEVER ATTENDED/KINDERGARTEN ONLY
1() 1ST GRADE
2() 2ND GRADE
3() 3RD GRADE
4() 4TH GRADE
5() 5TH GRADE
6() 6TH GRADE
7() 7TH GRADE
8() 8TH GRADE
9() 9TH GRADE
10() 10TH GRADE
11() 11TH GRADE
12() 12TH GRADE, NO DIPLOMA
13() HIGH SCHOOL GRADUATE
14() GED OR EQUIVALENT
15() SOME COLLEGE, NO DEGR
16() ASSOCIATE DEGREE: OCCUPATIONAL, 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