

1. Background

Environmental influences on Child Health Outcomes ([ECHO](#)) is a nationwide National Institutes of Health (NIH)-funded research program whose mission is to enhance the health of children for generations to come. The program consists of observational and intervention components that will collect data from 83 cohorts based on grants to 35 primary institutions.

As part of developing an ECHO-wide data collection protocol, the ECHO program issued a request for information (RFI) inviting comments on data elements, types of biospecimens, and innovative data collection methodology. The [RFI](#) was posted on the [NIH guide](#) and distributed to identified stakeholders by NIH program staff on Friday, August 11, 2017. Comments responding to the RFI were received until September 13, 2017. The RFI responses are summarized below.

2. Description of Responses Received

The summary of comments provided here is organized according to the six categories included on pages 2 and 3 of the RFI: (1) data elements—unnecessary; (2) data elements—critical, not currently included; (3) biospecimens—unnecessary; (4) biospecimens—essential, not currently included; (5) biospecimens— alternatives that are likely to be easier to collect or to reduce participant burden; and (6) additional data elements critical to address ECHO research questions. We have also included a seventh category, “other,” for responses that do not fit neatly within one of the six original categories.

a. Category 1—Unnecessary elements currently included in the protocol

- “In pregnancy-related data elements, the protocol requires information on the first full feed and first full *per os*, or PO, feeding. However, determining a full feed may be difficult, especially if this measure is reported by a parent, and may not be relevant to any research question.”
- “The protocol appears to require the duration of an infant’s NICU stay to be measured prenatally ...this is impossible... it should be measured in the perinatal period.”
- “The NICU Network Neurobehavioral Scale is not standardized across all NICUs... including it without standardization could lead to inaccurate conclusions.”
- “Some data elements may be covered in other measures, including infant cerebrospinal fluid culture results, which is covered by the infant meningitis measure, and Patent Ductus Arteriosus surgery, which is included in the larger infant surgery measure.”
- “Replace ambiguous NICU pain/withdrawal measurements with a report of the medications used to treat these symptoms...”
- “Replace infant temperature at birth for all infants with temperature at admission for NICU patients only.”

b. Category 2—Critical elements currently not included in the protocol

Suggestions for critical elements not in the current protocol included the data element itself, the research question(s) that require it, and the life stage at which it should be measured. This report also adds available information about the source of the suggested additional data

element. To facilitate readability, this information is summarized in a table in Appendix 1.

Responses related to biospecimens spanned several data collection elements. Several respondents commented that data element concepts currently included in the protocol should be collected at additional life stages. We included those responses in Appendix 1.

c. [Category 3—Currently included biospecimens unnecessary to address high- impact questions relevant to ECHO’s scientific goals](#)

- Placenta and cord blood. “These two biospecimens can be difficult to collect at time of delivery.”

d. [Category 4—Additional biospecimens critical to address high-impact questions relevant to ECHO’s scientific goals](#)

None of the respondents commented on this issue.

e. [Category 5—Alternative biospecimens to increase likelihood of successful collection or decrease participant burden](#)

- The placenta is an essential biospecimen, but collecting whole placentas will likely exhaust storage capacity. ECHO should clarify that placental samples rather than the whole placenta are adequate for study purposes.

f. [Category 6—Innovative data collection methodologies](#)

- “Consider taking a look at the cycle of engagement work of Christy Bethell and [CAHMI](#) with the [Well-Visit Planner](#) and PHDS, as well as client-level child development and social needs navigation enhancement tools for navigators and families like Dayna Long’s [FINDconnect](#). The powerful data aggregation and insights on a population level that come from tools that automate screenings, referrals, and care coordination (things [we] recommend but appear per HealthySteps’ and others’ experiences too burdensome to collect data on). Perhaps the ECHO cohorts could be introduced to tools like these and consider their use to make data collection on patient experience, child development, and social determinants of health less burdensome across the board.”
 - “[We] suggest NIH investigate the use of the Fast Healthcare Integration Resources (FHIR) standard to extract data from ECHO Cohorts. If unfamiliar with FHIR, a good place to start is the [Argonaut Project](#). Argonaut is a private sector initiative to develop a FHIR-based API and Core Data Services specification to enable sharing of electronic health information.”
 - “In addition to innovation [sic] method of collecting data, considerations must be given to innovative ways to share the data. Sharing data implies broad access to data with robust documentation to enable other researchers to make use of the considerable investment being made in collecting the data...”
 - Delay of access to the data should be avoided as it “undermines the return on investment.”
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g. Category 7—Other Comments and Suggestions

Some respondents provided commentary that did not speak directly to categories 1-6 in the RFI. They span a range of topics including the impact of adverse childhood experiences, requests for more information on standard operating procedures, data storage and information on how data elements link with research questions, definitions of life stage categories, and emphasis on the inclusion of individuals with disabilities. These responses are given below:

- Cohorts should consider tracking adverse childhood experiences (ACEs) and supportive structures (contexts) in the home and community because both may have consequences for the well-being of children and adolescents; they may impact both biological and behavioral functioning and sense of well-being (health = experience of well-being, not just absence of disease) throughout the life course.
- Centralizing massive amounts of personal data from individual ECHO cohorts augments the risk of breach of confidentiality for participants. “Even if explicit identifiers such as names, addresses, medical record numbers are not transmitted and stored by the ECHO-DAC, there are many data elements that could potentially be used to identify research subjects.” These include birthdates and geographic indicators used to identify neighborhoods (e.g., zip code, census tract, latitude and longitude). Such variables are critical to establishing relationships between environment and health outcomes, but could be used to identify individual research subjects, particularly by entities and algorithms developed for mining and linking data from disparate sources.
- Not sure why ECHO defines mid-childhood as going up to age 12; the standard definition of adolescence in developmental science and adolescent medicine (also accepted by WHO) covers ages 10-20. Child pubertal development measures should begin earlier than 11-20 as currently called for in ECHO because puberty often begins much earlier.
- “The research topics and questions, and the list of essential common data elements looks demanding for an individual cohort to maintain along with their own local goals/objectives.”
- “There is an “overabundance of essential data elements to address the research questions...It seems as though some of these elements are collected for the sake of collection and the science behind each element is not being considered.” The respondent suggests the data elements be mapped to each research question.
- “Appropriate specialized expertise [be] available for consultation and that robust quality control procedures are utilized and implemented in all standard operating procedures (SOPs) for data collection.”
- The current protocol lacks detail on how existing data will be standardized. In particular, they questioned how ECHO will address changes in technology, methodology, and diseases in past and current data.
 - ◆ “How will the program deal with differences in case definitions of disease over the data collection period?”
 - ◆ “How will the program account for variances in data collection across different sites, such as standing height and laying height?”
 - ◆ “How will the program account for differences in collection techniques, methodologies, etc.?”
- There is strong emphasis on medical and genetic variables, and recommend these variables be “examined in concert with behavioral and psychological dimensions.” The behavioral measures identified include “sleep, resilience, adverse childhood experiences,

executive functioning, quality of life (e.g., weight-related quality of life for overweight and obese youth), and transition from child medical care to adult medical care.”

- Recommends the use of adaptive techniques and approaches to collect data from individuals with participants who may not “be able to respond using either speech or motor movements, notably individuals with disabilities and other chronic conditions.”

Appendix 1: Suggested Critical Elements for Inclusion in the ECHO-wide Data Collection Protocol

Data Element Concept (as listed in Protocol)	Data Element (as named by respondent)	Research Question(s) that require it	Life Stage(s) to Collect it
Any federal assistance (e.g., WIC, food stamps, housing assistance)	Any federal assistance (e.g., WIC, food stamps, housing assistance)	N/R	All life stages (not just collect once)
Built / Physical Environment	Location of child care / ECE and toxin exposure	To what extent is the location of the out-of-home care environment associated with toxin exposure and link to child health and well- being	Birth through age 5
Built / Physical Environment / Home environment	Food deserts	The extent to which availability of fresh and quality food impacts children’s health and well- being, as well as parents and caregivers	All ages
Built / Physical Environment; Child Health Behaviors / Lifestyle	Child care / ECE nutrition practices and physical health	How the quality of the out-of-home care environment impacts children’s health and well- being	Birth through age 5
Child Health Behaviors / Lifestyle; Home environment	Food insecurity	N/R	N/R
Child neurodevelopmental health	“Child neurodevelopmental health” should include specific measures like motor dysfunction or cerebral palsy	N/R	N/R
Child Social Role Performance & Functioning	Child sexual behavior	N/R	Early childhood / middle childhood (in addition to adolescence)
Child Social Role Performance & Functioning	Child gender identity	N/R	Early childhood / middle childhood (in addition to adolescence)

Data Element Concept (as listed in Protocol)	Data Element (as named by respondent)	Research Question(s) that require it	Life Stage(s) to Collect it
Demographics	Family assets (e.g., home and car ownership, work benefits like 401k, and death benefits)	<p>The extent to which familial assets serve as protective health factors for those experiencing temporary poverty</p> <p>Examining impacts of intergenerational transmission of poverty and wealth on health</p>	All ages
Demographics	Unemployment	“Loss or lack of a job can occur at any time in a child’s life cycle and impact school readiness, parental depression, etc.”	Should be assessed multiple times, not only once
Demographics	Access to skilled system navigation support	N/R	N/R

Data Element Concept (as listed in	Data Element (as named by respondent)	Research Question(s) that require it	Life Stage(s) to Collect it
Demographics	<p>Expand race or ethnicity questions to include whether a subject's mother or father was born outside the United States</p> <p>If the mother or father is a foreign national, ask from which country they immigrated</p>	<p>Many perinatal outcomes are stratified by race or ethnicity, but more can be done to understand specific perinatal outcomes of various racial or ethnic groups in particular. For example, the ethnicity "Hispanic" contains within it several possibilities for country of origin. One may discover different risk stratification for a particular race or ethnicity depending on their country of origin, compared to an individual of the same race or ethnicity [who] is born in the United States. (The value of the information gained may need to be weighed against the possible recruitment challenges for those populations wary of divulging country of origin.)</p>	Preconception period
Demographics / Home environment	Housing insecurity or lack of housing	N/R	N/R
Demographics; Built / Physical Environment	Social environment ("policies, neighborhood safety and poverty, access to healthy foods, parks and other features of the built environment")	N/R	N/R
Home Environment	Family nutrition practices and physical health	How quality of the home environment as it concerns nutrition and physical activity influence child health and well- being	2-8 years old

Data Element Concept (as listed in Protocol)	Data Element (as named by respondent)	Research Question(s) that require it	Life Stage(s) to Collect it
Parent incarceration	Expand parental incarceration measures to include previous incarceration or other involvement with the criminal justice system	N/R	N/R
Pregnancy-Related	Reason for premature birth (e.g., fetal or maternal complications)	N/R	N/R
Pregnancy-Related	Interval between pregnancies	N/R	N/R
Pregnancy-Related	Maternal caffeine consumption	N/R	N/R
Pregnancy-Related	Whether a mother breastfeeds	N/R	N/R
Pregnancy-Related	Maternal foreign travel / infections	Should be essential rather than recommended data element given urgency and timeliness of infections like Zika	N/R
Pregnancy-Related	Primary admission diagnosis to NICU	Necessary to fully understand postnatal outcomes	N/R

Note: N/R = no response.