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Characteristics of Environmental influences on Child Health Outcomes (ECHO) Cohorts Recruited During Pregnancy

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Abstract

Purpose: The objective of this study was to characterize the study designs, recruitment strategies, and other study characteristics among cohorts that initiated during pregnancy as part of the Environmental influences on Child Health Outcomes (ECHO) program.

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Methods: ECHO research programs (cohorts) were reviewed. Only those who had or were currently recruiting during pregnancy were surveyed in 2018 about research recruitment strategies (participant incentives, study burden, community collaboration, and cultural adaptations). Data are presented with cohort characteristics (location, inclusion and exclusion criteria, sociodemographics, medical information, behavioral factors, and biospecimens).

Results: Forty-seven of the 84 ECHO pediatric cohorts recruited during pregnancy. Findings demonstrate various recruitment strategies, domains of data collection, and biospecimen collection are all characteristics of successful cohorts.

Clinical Implications: These data that includes over 50,000 children from families across the country, many in underserved areas, will be used for research with the potential to lead to profound policy changes. Policies on prenatal conditions such as maternal age, obesity, depression and drug use can be examined using study data, including biological markers, from pregnancy through childbirth and into childhood will inform national policies on the role of early life exposures and underlying mechanisms of disease progression.

Keywords

pregnancy; child health; longitudinal studies; biomarkers; outcome assessment; ECHO

Introduction

There is strong evidence that exposures early in life, even before birth, profoundly influence child growth, development, and well-being that lead to life-long health consequences (Catalano, 2010; Paneth & Monk, 2018). Establishment and retention of prenatal or birth cohorts that involve longitudinal data collection into childhood and beyond is essential for further explaining the environmental origins of disease, disease trajectories, and risk and protective factors (Breton et al., 2017). Recruiting during pregnancy is often for obstetric related research; yet it is essential for examining the impact of environmental influences on fetal growth, birth outcomes and complications (Ferguson et al., 2017). By recruiting into child health studies during pregnancy and retaining the mother and child in the research study for multiple years, multidisciplinary researchers gain information essential for making connections between early life environment and later health outcomes.

However, research in pregnancy and childhood often is fraught with poor participant recruitment due to the high regulatory burden, anxiety about the birth event, stress of coordinating prenatal care and monthly visits, and changes in lifestyle and family expectations (Manhas et al., 2016). This challenge has resulted in significant variation in racial and ethnic diversity of study participants, social and family structure, and an understanding of the burden of biospecimen collection and data collection tools. Study characteristics e.g., ethical considerations, incentives, and research staff interpersonal skills, have been shown to be important contextual factors in the decision to participate in research, especially during pregnancy where maternal child nurse researchers could make a difference (Barratt et al., 2013; Niranjana et al., 2019; Webb Hooper et al., 2019).

The strategy of maternal child research recruiting during pregnancy can be understood by examining established pediatric cohorts, such as those that are part of the national Environmental influences on Child Health Outcomes (ECHO) Program. The National Institutes of Health (NIH) launched the seven-year ECHO program with the goal of enrolling over 50,000 children from previously established cohorts and retain them as research participants over multiple life stages in order to understand the etiology of maternal child health outcomes, such as premature birth, obesity, autism, asthma, and positive health i.e., biological, functional, or behavioral assets that strengthen resiliency and improve outcomes (Forrest et al., 2018). Although all ECHO cohorts have an established track record for successful conduct of longitudinal research, the greatest challenge to success in a large-scale longitudinal study such as ECHO is the early recruitment and majority retention of children and their families. The objective of this study is to characterize the study designs, recruitment strategies, and other study characteristics among the ECHO cohorts that recruited during pregnancy.

Methods

Together with the ECHO Data Analysis Center, the research team developed a survey targeting ECHO cohorts that were currently recruiting or had previously recruited pregnant women for pediatric longitudinal research (n=47 cohorts). This brief survey (n=15 questions) was administered in 2018 and included questions about study design, participant incentives, study burden, community collaboration, and cultural adaptations, as well as sociodemographic information on biological mothers, biological fathers, and children. Surveys were completed by the principal investigators or the lead research coordinator for each cohort using a secure web-based system and a pdf-fillable document.

Analysis focused on factors that individual participants would consider at the time of enrollment in order to identify practices for that may influence recruitment of pregnant women in longitudinal research studies. Descriptive statistics were used to evaluate recruitment practices (use of health care providers, recruitment setting together with study design (location, duration, staff), data collection strategies (length of study visit, specimen collection, re-contact), and cohort demographics.

Results

All of the 47 ECHO cohorts that recruited during pregnancy (100%) completed the survey on study design, recruitment strategies, and current participant retention, and all results presented hereafter are specific to these cohorts. Most cohorts (72%) intentionally recruited healthy families into non-interventional research studies and only three cohorts (6%) provided an intervention to enrolled children (Table 1). There were 19 cohorts (40%) who intentionally recruited minority or under-served populations or enrolled other family members beyond the mother-child dyad such as the father or a grandparent. Almost all cohorts (94%) recruited participants within a health care setting, such as prenatal clinics, with some cohorts also using social media (25%) or other community-based methods/ locations (36%). Seventeen cohorts (36%) used multiple languages during recruitment (e.g., English and Spanish). Most cohorts (85%) recorded reasons for non-enrollment. All cohorts

recorded multiple sources of contact information during recruitment, and all but one cohort (n=98%) provided incentives for study participation.

Almost all cohorts (96% to 98%) collected information on maternal sociodemographic characteristics, self-reported substance use in pregnancy, and other pregnancy-related medical information (Table 2). All but one of the cohorts collected data on the mother from at least one domain. More than half of the cohorts assessed maternal societal and psychosocial factors such as perceived stress, depression (64%); self-reported health behaviors (66%); measured anthropometrics (57%); animal exposures (57%); environmental exposures (51%); physical home environment (57%); and primary residential location (83%). Family medical history (28%); opioid use (38%); mental health (45%); self-reported anthropometrics (43%); and built environment (32%) data were collected. Few cohorts collected information on maternal neurocognitive function.

In general, cohorts collected less data specific to the father, with 40 cohorts (79%) collecting any data on the father. Paternal sociodemographics were collected (72%), but few collected information on paternal societal and psychosocial factors, neurocognitive function, medical history, substance use, and health behaviors.

Most cohorts (85%) collected at least one maternal biospecimen (Table 3). Many cohorts collected maternal blood (70%) and urine (64%). Approximately half of the cohorts collected maternal biospecimens specifically for DNA analysis (55%) or infant umbilical cord or placental samples (49%). Approximately one in five collected maternal saliva, stool, vaginal fluid, hair, or blood at birth. Many cohorts (77%) collected biospecimens from newborns at birth. Twenty-four cohorts (51%) collected neonatal blood or cord blood samples. Twenty-two cohorts (47%) obtained neonatal biospecimens for DNA analysis. Few cohorts collected other neonatal biospecimens. Paternal biospecimens were also less common (19%) with only seven cohorts (15%) collecting blood and fewer (11%) collected biospecimens for DNA analysis.

Discussion

A great obstacle to success in any clinical research is poor recruitment and retention. As a result, social, behavioral, and health care sciences have identified research designs and thoughtful approaches to improve recruitment and retention (Bower et al., 2014; Cui et al., 2015; Lloyd et al., 2017; Schoeppe et al., 2014; Vangeepuram et al., 2016). The ECHO cohorts included equally represent a longitudinal pattern, with a third of the cohorts having been initiated less than five years before the survey, a third having been initiated 6–10 years before, and a third having been initiated over 10 years before the survey. Together, the cohorts represent over a decade of recruitment of pregnant women into research. Aggregating these data represents a timespan that allows us to understand patterns of recruitment strategies and established best practices to successfully recruit and retain participants, especially when considered in light of similar published work.

Pregnant women who participate in research often comprise higher educational and socioeconomic backgrounds, and often represent less racial and ethnic diversity than the

overall population (Leung et al., 2013; Muggli et al., 2018). Less than half of the ECHO cohorts intentionally recruited minorities and used multiple language recruitment materials, perhaps acknowledging the difficulty of reaching these populations. Of the ECHO cohorts surveyed, multiple sources of contact were among key recruitment strategies. Partnering with organizations that work within the community of interest has been cited as an effective strategy for recruitment in minority populations, yet the vast majority of the ECHO cohorts were initiated in the health care system.

Pregnancy as a life-stage, in general, affords greater contact with the health care system, allowing for multiple sources of contact and a known locale for a substantial pool of potentially eligible participants (Bangma et al., 2019). Most ECHO cohorts recruited healthy families, with few having an interventional in study design. Those with special conditions during pregnancy may have a particular interest in their individual care and may be more frequently seen, thus an opportunity for targeted recruitment and research.

Given the decade-long span represented, some cohorts began recruitment before social media was part of the research environment, whereas other cohorts started recruitment with a focus on social media and text messaging. Studies on recruitment of pregnant women and social media platforms showed that targeted, paid advertisements led to improved recruitment rates compared to clinical approaches (Adam et al., 2016; Admon et al., 2016), yet only a third of the ECHO cohorts used social media.

Nearly all ECHO cohorts surveyed provided incentive or reimbursement for participation. One review found that financial incentives were important for the decision of healthy members of the general population to participate in clinical trials (Tishler & Bartholomae, 2002). Other reasons to participate in research include personal, social, or familiar reasons, especially in the case of genetics research (Hallowell et al., 2010).

The vast majority of the ECHO cohorts surveyed included pregnancy-related medical information and sociodemographic characteristics, as well as other information ranging from substance use in pregnancy, mental health data, and stress-related exposures. The participating cohorts reflect a breadth of domains collected that, together with the data collected concurrently during ECHO, will allow for deep understanding of how maternal and paternal environmental exposures, substance use, neurocognitive functions and physical and built environment impact child health outcomes (Gillman & Blaisdell, 2018).

Prior studies identified biospecimen collection as a recruitment barrier (Barratt et al., 2013), yet most surveyed cohorts collected maternal and neonatal biospecimens reflecting the high willingness of pregnant women to enroll in studies collecting such samples. In preparatory work for the National Children's Study, however, results demonstrated that various types of biological sample collections were acceptable to pregnant women considering participation in longitudinal research (Kerver et al., 2013). Biological sampling has been shown to be feasible and acceptable, although the extent, invasiveness and time required for sample collection are related to successful completion of sampling (Abdul-Rahman et al., 2016). Additionally, research has shown the importance of collecting data from both parents (Younes et al., 2018). A small minority of ECHO cohorts collected biospecimens from

fathers, representing a pervasive gap. Future studies are encouraged to prioritize paternal biospecimens to understand paternal influences on child health (Sharp & Lawlor, 2019).

Clinical Implications

This descriptive review of a national children's health study, ECHO, provides an insight to the individual cohort structure and research design of those cohorts in the ECHO program that recruited in pregnancy. These national data will be publicly available and thus will provide a rich data source for multidisciplinary maternal and child health researchers. The maternal-child health paradigm is about more than just providing maternal education; ECHO has the potential to facilitate a wide spectrum of maternal-child research.

These data will be used for research with the potential to lead to profound practice changes, including those regarding prenatal conditions such as maternal age, obesity, depression and drug use. ECHO, most especially during this time of a global SARS-CoV2 viral pandemic, will serve as a resource to assist maternal child health researchers investigating the complex origins of health and disease.

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Callouts

- Recruitment in pregnancy, though challenging, provides child health researchers the opportunity to study families for multiple years, which is essential for making connections between early life environment and health outcomes, to explore the etiology of chronic conditions such as asthma.
- Exposures early in life, even before birth, profoundly influence child growth, development, and well-being that lead to life-long health consequences, such as maternal smoking on birth weight.
- The ECHO cohorts recruited during pregnancy include ethnically diverse populations.
- Survey data were collected on maternal-child demographics, environmental exposures, biospecimens and social determinants of health.
- Study data, including biological markers, collected from pregnancy through childbirth and into childhood, especially during a pandemic, will inform national policies on the role of early life exposures and underlying mechanisms of disease progression to inform maternal child nurses and child health researchers.

Clinical Implications

- Maternal child nurses can use the national children's health outcomes study (ECHO) environmental influences design as a resource to prioritize and implement nursing care initiatives.
- Introduce this transdisciplinary and translational research as a source for evidence-based practice models for maternal child nursing in obesity, asthma, prenatal-postnatal care, positive health measures and neurodevelopment.
- Explore pregnancy and early child developmental outcomes to inform maternal child nurse clinical practice guidelines, research and policies on environmental exposures and influences.
- Engage maternal-child researchers to further explore the environmental influences on pregnancy, early development and chronic disease onset.
- Discuss social determinants of health, especially in maternal child health, that impact future nursing education, research, practice and policy issues.

Table 1.

Recruiting strategies and study design characteristics among ECHO cohorts

	All cohorts	
	n=47	
Recruiting strategies and study designs	n	(%) [†]
Years of follow-up		
2 years (newly established cohorts)	7	(15%)
3–5 years	9	(19%)
6–10 years	17	(36%)
11–15 years	6	(13%)
>15 years	8	(17%)
Target populations		
Intentionally recruited healthy families	34	(72%)
Intentionally recruited minority or under-represented populations	19	(40%)
Enrolled family members beyond mother/offspring dyad	22	(47%)
Recruitment locations		
Health care system-related environment	44	(94%)
Social media	12	(26%)
Community-based methods	17	(36%)
Other methods/locations	4	(9%)
Recruitment techniques		
Recruited in multiple languages	17	(36%)
Recorded multiple sources of contact information	47	(100%)
Provided incentives for participation	46	(98%)
Recorded reasons for non-enrollment	40	(85%)
Study procedures		
Provided intervention to offspring	3	(6%)
Biospecimen collected from mother, father, and/or neonate	41	(87%)
Blood collected from mother, father, and/or neonate	36	(68%)

[†]Percentages based on a denominator of 47 (all ECHO cohorts who enrolled women during pregnancy for longitudinal data collection).

Table 2.

Domains of Data collected among ECHO cohorts

	All cohorts	
	n=47	
Maternal Domains of Data Collection	n	(%) [†]
Any information	46	(98%)
Socio-demographics (age, language, SES-related)	45	(96%)
Societal and psychosocial factors (stress, discrimination, violence)	29	(62%)
Neurocognitive function and development	3	(6%)
Family medical and psychiatric history	13	(28%)
Self-reported alcohol, tobacco, drug use	45	(96%)
Self-reported diet, activity, sleep behaviors	31	(66%)
Measured activity, sleep, cardiorespiratory behaviors	2	(4%)
Opioid use/misuse	18	(38%)
Pregnancy-related medical information	46	(98%)
Mental health (stress, depression, anxiety)	21	(45%)
Self-reported anthropometrics**	20	(43%)
Measured anthropometrics	27	(57%)
Animal exposures	25	(53%)
Measured home environmental exposures (smoke, allergens, pollution)	24	(51%)
Self-reported home environmental exposures (smoke, mold, products)	40	(85%)
Physical home environment (type, energy sources, contents)	27	(57%)
Built environment (food, activity, retail)	15	(32%)
Primary residential location	39	(83%)
Paternal Domains of Data Collection		
Any information	40	(85%)
Socio-demographics (age, language, SES-related)	34	(72%)
Societal and psychosocial factors (stress, discrimination, violence)	1	(2%)
Neurocognitive function and development	4	(9%)
Family medical and psychiatric history	3	(6%)
Self-reported alcohol, tobacco, drug use	12	(26%)
Self-reported diet, activity, sleep behaviors	5	(11%)

[†]Percentages based on a denominator of 47 (all ECHO cohorts who enrolled women during pregnancy for longitudinal data collection).

Table 3.

Biospecimens collected among ECHO cohorts

	All cohorts	
	n=47	
Maternal Biospecimen	n	(%) [†]
Any biospecimen	40	(85%)
Blood	33	(70%)
Urine	30	(64%)
Saliva (non-genetic purposes)	7	(15%)
DNA sample	26	(55%)
Gingival crevicular fluid	1	(2%)
Oropharyngeal swab	1	(2%)
Stool / rectal sample	7	(15%)
Cervical fluid sample	3	(6%)
Vaginal fluid sample	8	(17%)
Hair	13	(28%)
Finger or toe nails	3	(6%)
Fat biopsy	0	(0%)
Amniotic fluid	1	(2%)
Maternal blood at birth	11	(23%)
Umbilical cord or placental sample	23	(49%)
Neonatal Biospecimen		
Any biospecimen	36	(77%)
Blood	24	(51%)
Urine	4	(9%)
Saliva (non-genetic purposes)	2	(4%)
DNA sample	22	(47%)
Stool / rectal sample	6	(13%)
Hair	3	(6%)
Meconium	14	(30%)
Umbilical cord blood	32	(68%)
Paternal Biospecimen		
Any biospecimen	9	(19%)
Blood	7	(15%)
Urine	3	(6%)
DNA sample	5	(11%)
Semen sample	4	(9%)

[†]Percentages based on a denominator of 47 (all ECHO cohorts who enrolled women during pregnancy for longitudinal data collection).