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Feasibility and informative value of environmental sample collection in the National Children's Vanguard Study

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ABSTRACT

Background: Birth cohort studies provide the opportunity to advance understanding of the impact of environmental factors on childhood health and development through prospective collection of environmental samples.

Methods: We evaluated the feasibility and informative value of the environmental sample collection methodology in the initial pilot phase of the National Children's Study, a planned U.S. environmental birth cohort study. Environmental samples were collected from January 2009–September 2010 at up to three home visits: pre-pregnancy ($n=306$), pregnancy ($n=807$), and 6-months postnatal ($n=117$). Collections included air for particulate matter ≤ 2.5 μm ($PM_{2.5}$), nitrogen dioxide, ozone, volatile organic compounds (VOCs), and carbonyls; vacuum dust for allergens/endotoxin; water for VOCs, trihalomethanes (THMs), and haloacetic acids (HAAs); and wipe samples for pesticides, semi-volatile organics, and metals. We characterized feasibility using sample collection rates and times and informative value using analyte detection frequencies (DF).

Results: Among the 1230 home visits, environmental sample collection rates were high across all sample types (mean=89%); all samples except the air $PM_{2.5}$ samples had collection times <30 min. Informative value was low for water VOCs (median DF=0%) and pesticide floor wipes (median DF=5%). Informative value was moderate for air samples (median DF=35%) and high for water THMs and HAAs (median DF=91% and 75%, respectively).

Conclusions: Though collection of environmental samples was feasible, some samples (e.g., wipe pesticides and water VOCs) yielded limited information. These results can be used in conjunction with other study design considerations, such as target population size and hypotheses of interest, to inform the method selection of future environmental health birth cohort studies.

1. Introduction

Increasing recognition that exposure to environmental chemicals during fetal development or early childhood may be linked to adverse pregnancy outcomes, childhood and adult morbidity, and mortality has prompted the implementation of numerous birth cohort studies worldwide (Wigle, 2003; Branum et al., 2003). In the United States, five birth cohort studies funded by the Environmental Protection Agency (EPA) and National Institute of Environmental Health Sciences (NIEHS), were launched from 1998–2003, each focusing on the relationship between exposures to select classes of environmental chemicals, such as pesticides, metals, or endocrine disrupters, and infant growth and development within populations in focused geographic areas (e.g, New York City, Salinas Valley, CA) (Kimmel et al., 2005; Eskenazi et al., 2005). More than 37 European birth cohort studies are

Abbreviations: 4,4′-DDD, Dichlorodiphenyldichloroethane; 4,4′-DDE, Dichlorodiphenyldichloroethylene; 4,4′DDT, Dichlorodiphenyltrichloroethane; HAAs, Haloacetic acids; IQR, interquartile range: 25th-75th percentiles; LOD, Limit of Detection; MTBE, Methyl tert-butyl ether; NCS, National Children's Study; NO_2, Nitrogen dioxide; O_3, Ozone; $PM_{2.5}$, Particulate matter 2.5 μm diameter; RR, Relative Risk; THMs, Trihalomethanes; VOCs, Volatile organic compounds

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investigating the effects of a wide array of environmental exposures during pregnancy or early childhood and child health (Gehring et al., 2013; Vrijheid et al., 2012). Likewise, large-scale studies of the effects of environmental chemical exposures on maternal and child health have been conducted in Canada, Japan, and Korea (Ha et al., 2011; Kawamoto et al., 2014; Arbuckle et al., 2013). These studies have used a combination of indirect methods, such as questionnaires and modeling, as well as direct methods, such as biomarkers and environmental sample collection, to characterize environmental exposures (Gehring et al., 2013; Vrijheid et al., 2012).

The US National Children's Study (NCS) is a birth cohort study that planned to enroll and follow 100,000 children throughout the United States from before birth through age 21 years (Baker et al., 2014). Broad in scope and with a large sample size, detailed environmental exposure assessment methods were proposed, including questionnaires, observations, biological specimens, and environmental samples (Landrigan et al., 2006). Measurement of chemicals in environmental samples was one of the key exposure assessment approaches considered for the NCS, because it is objective, non-invasive, and potentially provides information about sources and routes of exposure. Environmental samples can be particularly useful when biomarkers are not available or have very short half-lives or when questionnaires are impractical or not validated (Needham et al., 2005; Ozkaynak et al., 2005). However, environmental sample collection can be costly compared to less direct exposure measures (Whitmore et al., 2005). In 2009, the NCS began its pilot study ("the Vanguard Study") to evaluate data collection methodologies and protocols. Following the 2014 National Academies of Sciences assessment of the NCS, (Institute of Medicine and National Research Council, 2014) the National Institutes of Health Advisory Committee to the Director recommended discontinuation of the NCS (NIH, 2014). Notwithstanding these events, the results from the NCS Vanguard Study are valuable and can provide critical information to epidemiologists planning future children's environmental health studies. The current paper reports on the ability to collect samples (feasibility) and the utility of the information obtained to observe an exposure-disease relationship (informative value) from the environmental samples collected at home visits during the initial phase of the NCS Vanguard Study from 2009–2010.

2. Materials and methods

2.1. Study population

As described previously (Baker et al., 2014), 1399 women were enrolled in the NCS initial Vanguard Study from 2009–2010 from seven locations: Queens County, New York; Duplin County, North Carolina; Salt Lake County, Utah; Orange County, California; Montgomery County, Pennsylvania; Waukesha County, Wisconsin; and four adjacent counties in South Dakota (Brookings County) and Minnesota (Yellow Medicine County, Pipestone County and Lincoln County) (Baker et al., 2014). The initial Vanguard Study protocol included up to three home visits per participant: pre-pregnancy (women likely to become pregnant, $n=306$), pregnancy (any trimester, $n=807$), and child 6-month (6 months after birth, $n=117$). All home visits included environmental sample collection, an interview, biospecimen collection, a physical exam, and an observational walk-through of the residence. Participants could refuse any portion of a study visit.

2.2. Environmental sample collection

The NCS Research Plan of 2007 defined study hypotheses about specific environmental exposures and health outcomes (NCS, 2007). Several hypotheses related prenatal exposures to health outcomes in children; these hypotheses determined the chemicals measured in the environmental samples. One hypothesis suggested exposure to air pollutants (e.g., carbonyls, O_3, NO_2, $PM_{2.5}$, and VOCs) may increase risk of asthma development (McConnell et al., 2002; Brauer et al., 2002; Delfino et al., 2003; Corradi et al., 2003). Another suggested to exposure to disinfection byproducts in tap water (e.g, THMs and HAAs) may have a negative impact on fetal growth and development (Hinckley et al., 2005). A third suggested exposure to allergens and endotoxin may increase risk of developing asthma and allergies (Lau et al., 2005). A fourth suggested exposure to persistent chemicals (e.g., metals, pesticides, and SVOCs, and polychlorinated biphenyls) may increase risk of neurodevelopmental problems in children, such as decreased intelligence and increased risk of attention deficit hyperactivity disorder (Palmer et al., 2006; Eskenazi et al., 1999; Daniels et al., 2003).

Environmental sampling methods for the NCS were selected based on review of the literature and review of protocols from other studies, such as the National Human Exposure Assessment Survey (NHEXAS), National Health and Nutrition Examination Survey (NHANES), and American Healthy Homes Survey (AHHS). The criteria for selection of sampling methodology in the NCS included validity of method, collection efficiency, successful implementation in prior environmental health studies, cost, and logistical feasibility. The environmental sample collection protocols for each visit are described in Table 1. To reduce costs and participant burden, some samples were only collected from a random subset of participants or when a specific source was identified in the home. The pre-pregnancy visit protocol included one air sample (fine particulate matter [$PM_{2.5}$]) and one wipe sample (pesticides). Two air samples (carbonyls and volatile organic compounds [VOCs]) were randomly collected in 10% of homes.

The pregnancy visit protocol included one vacuum sample of fine dust for analysis of allergens and endotoxin and three wipe samples for analysis of pesticides, metals, semi-volatile organic compounds (SVOCs). A water sample was scheduled for all homes served by a private well or unknown water source for analysis of VOCs. Water samples for analysis of disinfection byproduct samples (trihalomethanes [THMs] and haloacetic acids [HAAs]) were collected from 10% of homes served by a municipal water supply. The child 6-month visit protocol included two air samples for analysis of $PM_{2.5}$ and carbonyls, one vacuum sample for analysis of allergens and endotoxin, and three wipe samples for analysis of pesticides, metals, and SVOCs. Air VOCs samples were scheduled for collection in 10% of homes. Collection of air nitrogen dioxide (NO_2) and air ozone (O_3) samples were planned for 100% of homes with an indoor source, such as a gas stove (NO_2) and a laser-jet printer (O_3). Additionally, NO_2 and O_3 samples were scheduled for collection in 3% and 5% of homes with no identified source, respectively. At all visit types, procedures specified that collection status (collected/not collected), reason for non-collection, and collection location information were to be recorded on hard-copy sample collection forms.

2.3. Air sampling and analysis

$PM_{2.5}$ was collected with active air sampling, while carbonyls, VOCs, NO_2, and O_3, were collected passively. The samples were placed in the room most often used by the participant (mother or child depending on the visit), other than the kitchen, for 6–8 days. The kitchen was excluded because it is generally not the most-used room and concern that inconvenient placement could lead to non-compliance. $PM_{2.5}$ samples were collected using a personal environmental monitor (SKC, Eighty-Four, PA) with a