Recruitment of a Pregnancy Cohort in Puerto Rico: Opportunities and Challenges

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ABSTRACT
We designed a cohort study of 900 pregnant women recruited at or before 20 weeks gestation to be followed to the completion of pregnancy to study the role of environmental factors in general, and phthalates and volatile organic solvents such as tetrachloroethylene in specific. The study focuses on northern Puerto Rico karst area that spans from Toa Baja to Aguadilla. Data collected include medical and pregnancy history, demographic variables, and self-reported environmental exposures. Biological samples include blood, urine, and hair. At delivery, cord blood and placental tissue will be collected and a postpartum interview will also be conducted. Recruitment began in February 2011 and 190 study subjects have been recruited through February 15, 2012. Initial recruitment centered in 3 hospitals and was expanded to 8 sites to meet the recruitment rates needed to complete the target of 900 pregnant women. Initially, recruitment rate was nearly 2 per week and following expansion of sites and increasing research staff, it increased to 6 per week. We estimate that at the current rate, we will complete reach the target of 900 pregnant women recruited by July 2013. We have shown that recruitment of a pregnancy cohort in Puerto Rico is feasible and that attention needs to be given to recruitment rates per site on a regular basis in order to optimize recruitment efficiency and ensure meeting the recruitment target in the time allotted.

BACKGROUND
In Puerto Rico nearly 1 in 5 babies are born preterm, the highest prevalence of preterm births of any jurisdiction in the United States. The reason for this high prevalence is unknown, but environmental factors are a major concern. Supported with funding from the National Institute of Environmental Health Sciences’ Superfund Research Program, the PROTECT program is recruiting a cohort of 900 women in Puerto Rico to study the potential contribution of environmental factors to preterm births. We have successfully developed the infrastructure to recruit and follow up pregnant women living in the northern Puerto Rico karst area.

AIM
The main aim of this project is to establish and maintain the infrastructure for the recruitment and follow-up of pregnant women living in the karst area of Puerto Rico to participate in longitudinal research that will serve as the central source for human subjects involved in program projects. This includes collecting data through questionnaires and abstraction of medical records, and collection biological samples such as blood, urine, and hair.

METHODS
The Protect Core C leads the recruitment of pregnant women and collection and management of biological samples and data for this study. We have recruited a team of 3 nurses and a physician that lead the recruitment and data collection, as well as coordination of biological samples collection done through hospital laboratories. They collect the hair and urine samples during the home visit. The project is also an opportunity for graduate students to participate in this research activity and are actively participating in all the facet of the project including assisting in recruitment, home visits, data entry and quality assurance processes.

RESULTS
From February 12, 2011 to February 15, 2012 a total of 374 pregnant women were screened in 8 recruitment sites. Among them, 270 were eligible and 190 agreed to participate, for a recruitment rate of 70%. So far, 40 have completed their pregnancy of which 30 had a live birth and the other 10 had a spontaneous abortion or stillbirth. Two challenges in the early phase of recruitment were the paucity of recruitment and the number of study subject that elected to withdraw. At week 30 of the study, we increased the research staff from 2 nurses to 3 nurses and a physician, and expanded recruitment sites to 8. As a result, we increased recruitment rate from 2 per week to 8 per week. We estimate that at the current recruitment pace we will complete recruitment by July 2013.

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