NIH > *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

DIPHR

1967-2017 · 50th ANNIVERSARY

Division of Intramural Population Health Research, NICHD

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MESSAGE FROM THE DIRECTOR
The mission of the Division of Intramural Population Health Research is to conduct research leading to the promotion of population health and well-being.

I am privileged to be serving as the interim Division Director following the departure of Dr. Germaine Buck Louis in September 2017.

We accomplish our mission by conducting innovative etiologic and interventional research from preconception through adulthood, while working to translate our discoveries into clinical practice or public policy to maximize the health of all populations. While this is an ambitious undertaking, we readily embrace it by working in trans-disciplinary research teams across Branches and with external collaborators to find answers about how to become and stay healthy. In addition, Division scientists actively mentor a variety of fellows at varying professional stages (i.e., post-baccalaureate through post-doctoral) and generously provide their expertise as needed throughout the NICHD, National Institutes of Health, other governmental agencies, and to our professional societies.

The Division provides a unique opportunity for conducting a wide range of research initiatives focusing on health across the lifespan. Our 2018 Annual Report describes some of our recent discoveries including new evidence about how behaviors, lifestyles and environmental exposures affect men and women's reproductive health and pregnant women's ability to deliver a healthy newborn. Our research also focuses on keeping infants and children healthy, including for children with chronic diseases such as type 1 diabetes. We are also making advances regarding the onset and timing of risky adolescent behaviors that may or may continue into early adulthood, and in the early origin of health disparities.

Another exciting avenue of research is focusing on exposures during critical and sensitive windows of human development and their implications for future generations. It is exciting and rewarding to conduct research that not only will keep people healthy across the lifespan, but the health of generations to come.

The development of new methods and statistical tools is another unique aspect of our research. We openly share our products. Finally, the Division practices reproducible research and was an early pioneer in building data sharing platforms. We encourage scientists and students to utilize and leverage our resources for advancing knowledge by reviewing materials at the Division's online data sharing platform and also the NICHD's platform.

 Lastly, our work is not possible without the continued support of our Institute Director, Diana W. Bianchi. I am also looking forward to working with Dr. Bianchi on a national search to identify the next Division Director. Please visit our website for information about our research, training opportunities, collaborations, and career opportunities.

I welcome any questions or comments you may have about the Division.

Sincerely yours,

Constantine A. Stratakis, MD, D(med)Sci
Acting Director, DIPHR, NICHD
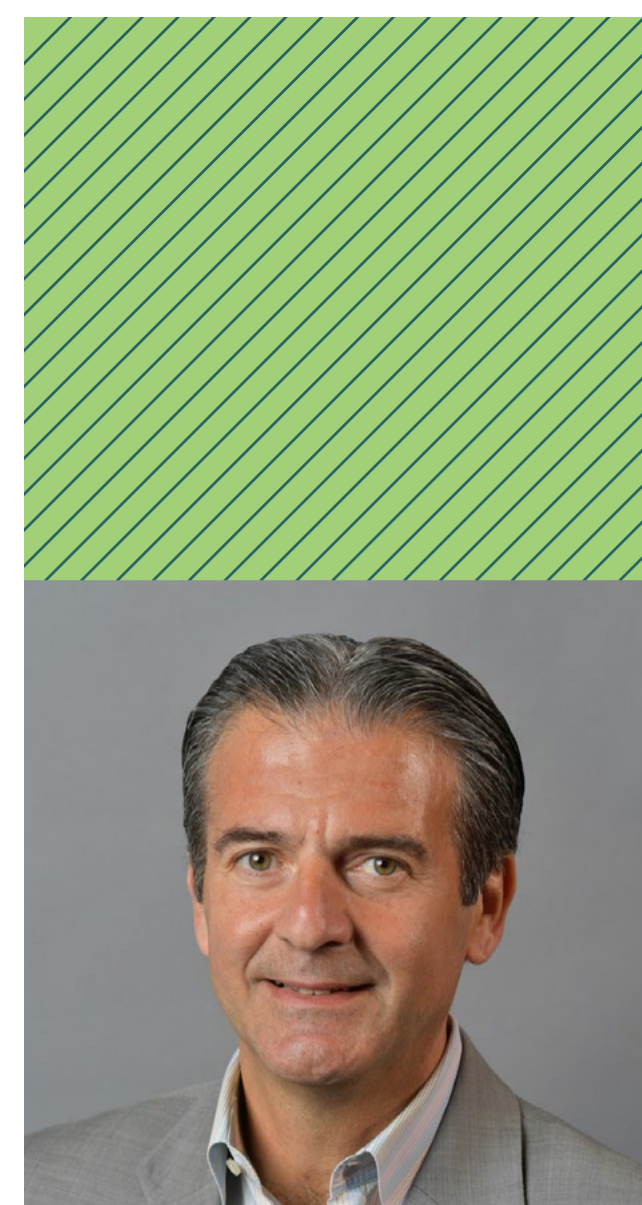
Constantine A. Stratakis, M.D., D(Med)Sci.
Acting Director, DIPHR, NICHD

The Division of Intramural Population Health Research (DIPHR) comprises the Office of the Director, which provides administrative oversight and support for its three intramural research branches - Biostatistics and Bioinformatics Branch, Epidemiology Branch, and Social and Behavioral Sciences Branch.

In 2017, the Division Director, Dr. Germaine Buck Louis, retired from federal service. The NICHD Director, Dr. Bianchi appointed **Dr. Constantine Stratakis** – the Scientific Director of NICHD – as Acting Director of DIPHR, in anticipation of conducting a national search for a permanent DIPHR Director.

Dr. Jagteshwar (Una) Grewal is the Deputy Director for the Division. In this capacity, she assumes considerable responsibility for scientific administration and managerial leadership in the Division She oversees the training/mentoring program for all fellows and supervises the continued professional development of all DIPHR scientists. As a population scientist, Dr. Grewal continues her research on fetal growth and development, perinatal epidemiology, and birth defects. She is a collaborator with the NICHD Fetal Growth Studies where she leads research on the nutritional component. In addition,Dr. Grewal serves as the Program Manager for all of the Division's support contracts.

Dr. Jennifer Weck is a Laboratory Health Specialist who provides guidance and support for the Division's extensive biospecimen collection protocols and repository. Dr. Weck contributes her expertise in reproductive endocrinology, and her training as a physiologist is most relevant for the Division's research initiatives. Dr. Weck oversees the Division's Biospecimen Repository Access and Data Sharing (BRADS) program, which is an online resource for researchers looking to leverage existing data and biospecimens for a host of health and disease outcomes. Additionally, Dr. Weck serves as the Contracting Officer's Representative for the Division's two support laboratories and the NICHD's Biospecimen Repository.

Finally, the Division would not be successful without the continued commitment and support of its program analyst - Adrienne Lonaberger - who oversees the many tasks essential for the Division's continued success. These efforts include assistance with strategic and fiscal planning, forecasting activities and the preparation and distribution of administrative and public reports.

STAFF
Constantine A. Stratakis, M.D., D(Med)Sci.
Acting Division Director

Jagteshwar (Una) Grewal, Ph.D., M.P.H.,
Deputy Director

Adrienne Lonaberger,
Program Analyst

Jennifer Weck, Ph.D.,
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FELLOWS
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Samrawit Yisahak, Ph.D.,
Postdoctoral IRTA Fellow

▼ Biostatistics and Bioinformatics Branch

The mission of the Biostatistics and Bioinformatics Branch (BBB) is to: 1) conduct both collaborative and methodological research that is important to the mission of the Division and Institute; 2) provide training in areas of statistical research that will advance the Division's and Institute's research programs; and 3) serve as a resource for the Division, Institute, NIH, and other professional and government organizations.

The research component of the BBB's mission is multifaceted. First, providing first-rate statistical collaboration requires understanding of the scientific issues and state-of-the-art statistical methodology relevant to the scientific problem. Therefore, investigators within the Branch play a key role in all aspects of the study. Second, the Branch develops new statistical methodology for designing and analyzing data. Analytical issues encountered in collaborative research directly motivate much of the Branch's independent research. An important component of our collective methodological research is the translation of our novel methodology back to the NICHD scientific constituents through the development of software using free-ware (e.g., R code) and in presenting our work at major scientific meetings.

A majority of the Division's studies are longitudinal and involve sampling frameworks such as schools, families (parent-child triads), couples, maternal/fetal pairs, and individuals. Particular methodological problems that have been addressed include: 1) the joint modeling of longitudinal data and time to event or understanding the association of longitudinal profiles and an outcome of interest; 2) multi-dimensional couple-based latent risk model with an application to infertility; and 3) the development of new approaches for designing and analyzing complex data.

An important analytical issue for many Division studies is the characterization of the time to an event. In many studies, correlated event times are measured (e.g., repeated time-to-pregnancy and gestation at birth in consecutive pregnancies) and interest is in identifying environmental, genetic, or behavioral factors that influence these durations. A major research focus during 2018 has been on developing new statistical methods for modeling of complex data, including couple-based modeling and fecundity, longitudinal measurements and binary events, and on methods for biomarkers of various types. In particular, BBB investigators have proposed a Bayesian joint model of menstrual cycle length and fecundity, a semi-parametric transformation approach for modeling fecundity in the presence of a sterile fraction, and a class of joint models for multivariate longitudinal measurements and a binary event.

BBB investigators are involved in all aspects of the study from its earliest concept, including study design, implementation, ongoing quality control, and analysis. We are also involved in collaborations with Division of Intramural Research (DIR) investigators as well as with extramural staff in and outside NICHD. Further, we serve on important NIH and external committees such as the NICHD's Institutional Review Board, the NIH Biometry and Epidemiology Tenure Advisory Panel, and numerous Data and Safety Monitoring Boards for the NIH. BBB investigators serve as associate editors on a number of the top biostatistics journals. BBB investigators also serve as editorial board members of leading substantive journals including Clinical Trials and Fertility and Sterility.
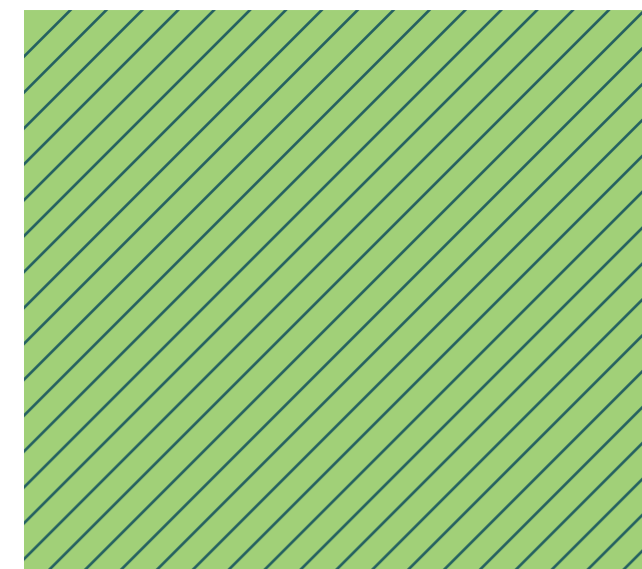
Aiyi Liu, Ph.D.,
Senior Investigator and Acting Chief

STAFF
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Senior Investigator

Zhen Chen, Ph.D.,
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Division of Intramural Population Health Research

Aiyi Liu, Ph.D.

Dr. Liu's research in 2018 focused on developing innovative methods or the design of quantitative traits genome-wide association studies and for nonparametric analysis of complex data, such as those from dietary intervention studies.

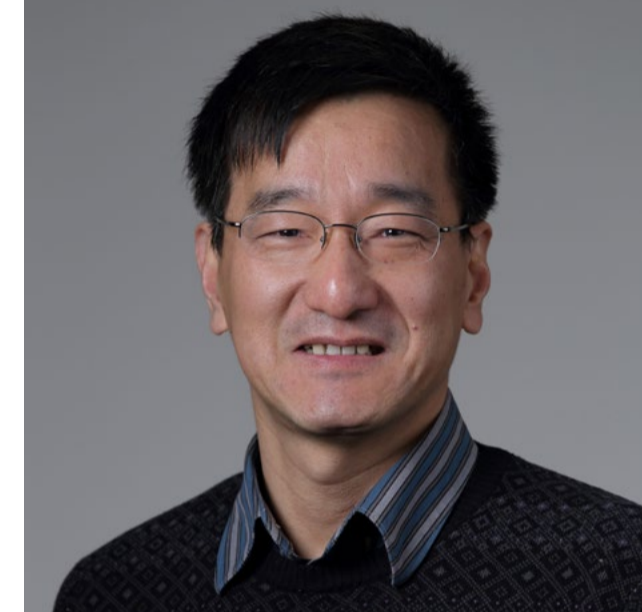An example of each is listed below.

1) A pooling strategy to effectively use genotype data in quantitative traits genome-wide association studies.

The goal of quantitative traits genome-wide association studies is to identify associations between a phenotypic variable, such as a vitamin level, and genetic variants, often single-nucleotide polymorphisms. When funding limits the number of assays that can be performed to measure the level of the phenotypic variable, a subgroup of subjects is often randomly selected from the genotype database and the level of the phenotypic variable is then measured for each subject. Because only a proportion of the genotype data can be used, such a simple random sampling method may suffer from substantial loss of efficiency, especially when the number of assays is relatively small and the frequency of the less common variant (minor allele frequency) is low. A pooling strategy can be used to more efficiently estimate the phenotypic-genotypic association.

With such a strategy, subjects in a randomly selected reference subgroup are aligned with randomly selected subjects from the remaining study subjects to form independent pools; blood samples from subjects in each pool are mixed; and the level of the phenotypic variable is measured for each pool.

2) Rank-based tests for dietary intervention assessments accounting for clusters

Dietary intervention studies often target multiple foods which are naturally clustered. Tests that compare these clustered outcomes between independent groups may lose efficiency if the cluster structures are not properly accounted for. A cluster-adjusted multivariate test procedure for the comparison in the amounts of intake of multiple foods can substantially gain powers in detecting intervention effects.

▶ Aiyi Liu, Ph.D.
Senior Investigator and Acting Branch Chief

▶ **KEY PUBLICATIONS**
1. Zhang W, Liu A, Albert PS, Ashmead RD, Schisterman EF, Mills JL. A pooling strategy to effectively use genotype data in quantitative traits genome-wide association studies. *Statistics in Medicine.* 2018;37(27):4083-4095. PMID: 30003569. PMCID: PMC6204292.

2. Zhang W, Liu A, Tang LL, Li Q. A cluster-adjusted rank-based test for a clinical trial concerning multiple endpoints with application to dietary intervention assessment. *Biometrics.* 2019. PMID: 30690718.

Zhen Chen, Ph.D.

Dr. Chen's research in 2018 spans three areas: chemical mixture modeling, diagnostic accuracy estimation and causal inference.

In chemical mixture modeling, Dr. Chen and his collaborators have developed a kernel machine-based approach to link a large number of exposures to a health outcome and proposed a latent class model to study the association between couples' exposures to multiple environmental pollutants and their infertility. Using data from a study on endometriosis diagnosis, Dr. Chen and his co-authors developed a constrained ROC surfaces estimation approach and proposed a rank-based procedure for correlated ROC curves. Dr. Chen and his fellows also developed a regularized approach to mediation analysis when there are multiple mediators. Two examles of Dr. Chen's 2018 work are listed below.

1) Multi-dimensional couple-based latent risk model with an application to infertility

Motivated by the Longitudinal Investigation of Fertility and the Environment (LIFE) Study that investigated the association between exposure to a large number of environmental pollutants and human reproductive outcomes, we propose a joint latent risk class modeling framework with an interaction between female and male partners of a couple. This formulation introduces a dependence structure between the chemical patterns within a couple and between the chemical patterns and the risk of infertility. The specification of an interaction enables the interplay between the female and male's chemical patterns on the risk of infertility in a parsimonious way. We took a Bayesian perspective to inference and used Markov chain Monte Carlo algorithms to obtain posterior estimates of model parameters. Using the LIFE Study dataset, we found that in addition to the effect of PCB exposures on females, the male

partners' PCB exposures play an important role in determining risk of infertility. Further, this risk is subadditive in the sense that there is likely a ceiling effect which limits the probability of infertility when both partners of the couple are at high risk.

2) Semiparametric approach to correlated ROC surfaces

END⦿
A Study of the National Institutes of Health

In application of diagnostic accuracy, it is possible that a priori information may exist regarding the test score distributions, either between different disease populations for a single test or between multiple correlated tests. Motivated by a study on diagnosing endometriosis, we propose an approach to estimating diagnostic accuracy measures that can incorporate different stochastic order constraints on the test scores when an ordinal true disease status is in consideration. We show that the Dirichlet process mixture provides a convenient framework to both flexibly model the test score distributions and embed the a priori ordering constraints. We also utilize the Dirichlet process mixture to model the correlation between multiple tests. In taking a Bayesian perspective to inference, we develop an efficient Markov chain Monte Carlo algorithm to sample from the posterior distribution and provide posterior estimates of the receiver operating characteristic surfaces and the associated summary measures. The proposed approach is evaluated with extensive simulation studies, and is demonstrated with an application to the endometriosis study.
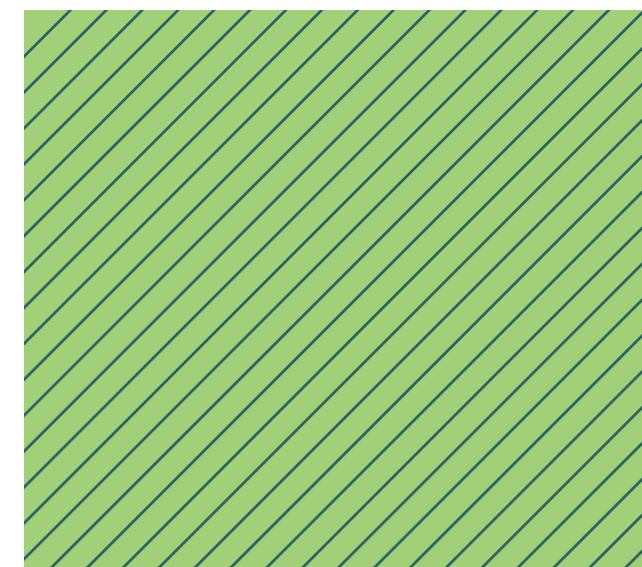
Zhen Chen, Ph.D.
Investigator

▶ KEY PUBLICATIONS
1. Hwang BS, Chen Z, M. Buck Louis G, Albert PS. A Bayesian multi-dimensional couple-based latent risk model with an application to infertility. *Biometrics*. 2018;0(0). PMID: 30267541.

2. Chen, Z, Hwang, BS. A Bayesian semi-parametric approach to correlated ROC surfaces with stochastic order constraints. Biometrics. 2019; 1– 12. https://doi.org/10.1111/biom.12997

Rajeshwari Sundaram, Ph.D.

Many Division studies are interested in the characterization of time to an event, recurrent events and multistage models.

"Using novel newly developed statistical methods, we addressed the risk for spontaneous labor in the prolonging the duration of second stage of labor vis-a-vis risk for neonatal or maternal morbidity. Thus, allowing one to quantitatively assess the cost of extending the duration of second stage of labor beyond the recommendations provided by Society for Maternal Fetal Medicine and American Society for Reproductive Medicine."

In many studies, correlated event-times are measured (e.g., repeated time-to-pregnancy, gestation at birth in consecutive pregnancies, progression of labor in pregnant women, recurrent crashes or near crashes by teenage drivers). Furthermore, interest is also in focusing on identifying time-varying exposures, environmental or behavioral factors that influence these durations.

There are many new analytic challenges for appropriate analysis of such data. For example, progression of labor can be classified as a multistage data as women progress through various stages of labor and have only intermittent examinations and unobserved start time providing significant analytical challenges; time to pregnancy and other outcomes related to maternal and child health pose new analytic challenges since, unlike with traditional survival analysis, time-to-pregnancy analysis must account for the fact that there is no risk of pregnancy without intercourse during a particular window in time. Naturalistic driving studies also provide such data on recurrent events where a driver is at-risk for crash/near crash

only if they are driving.

My focus is in developing statistical methods to address these types of data in presence on non-standard missingness, as well as accounting for the underlying (biological/behavioral) structure of the event of interest. These methods have been developed with a view towards individualized risk predictions. I am also interested in studying joint modeling of the longitudinal processes with time-to-event with a view towards risk prediction. Lastly, another objective of the methods development also includes borrowing information across various studies to build better prediction models.

Rajeshwari Sundaram, Ph.D.
Senior Investigator

KEY PUBLICATIONS

Ma L, Sundaram R. Analysis of Gap Times Based on Panel Count Data With Informative Observation Times and Unknown Start Time, *Journal of the American Statistical Association*, 113:521, 294-305 (2018).

Lee Y, Wang M-C, Grantz SK, Sundaram R. Joint Modeling of Competing Risks and Current Status Data: An Application to Spontaneous Labor Study, *Journal of the Royal Statistical Society*: Series C (Applied Statistics) (2019). doi: 10.1111/rssc.12351

Epidemiology Branch

In 2018, the Epidemiology Branch of the Division of Intramural Population Health Research continued to pursue international and long-term collaborations. Aligning with its threefold mission: 1) to plan and conduct investigator-initiated original epidemiologic research focusing on reproductive, pregnancy, and infant and child health endpoints to identify etiologic mechanisms, at-risk subgroups, and interventions aimed at maximizing health and preventing, diagnosing, and/or treating disease; 2) to provide service to the Division, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health (NIH), Department of Health and Human Services, and the profession via consultation, collaboration, and assistance to advance the scientific discipline of epidemiology and the goals of the Institute; and 3) to recruit highly qualified students at various stages of their professional careers for training in reproductive, perinatal, pediatric, and methodological epidemiologic research.

The Branch is organized around key areas of epidemiologic research spanning across the life course from reproductive health, to pregnancy, infant and child health, in addition to methodologic research. Regardless of title, Branch members work collaboratively to advance the Division and Institute's mission. The Branch conducts team science and is committed to using trans-disciplinary, cutting-edge techniques to address critical data gaps throughout the life course. Current Epidemiology Branch initiatives are furthering our understanding of health challenges in several areas. In reproductive health, the Epidemiology Branch is focused on clinical trials designed to evaluate inexpensive interventions to improve reproductive health and fertility in men and women, allowing for substantial possible public health impact. The Branch also investigates the effects of diet and lifestyle on male and female reproductive health,

representing another area for major potential public health impact for couples seeking pregnancy. Moreover, in the field of pregnancy and fetal development, the Branch studies the genetic and environmental determinants, etiology, and health consequences of gestational diabetes, fetal growth of both singletons and twins in relation to obesity and pregnancy complications, and the impact of air pollution on pregnant women and their offspring. To advance understanding of infant and child health, Branch investigators also focus on the genetic and lifestyle determinants of birth defects through strategic collaborations, and the impacts of conception using advanced reproductive technologies on subsequent child growth, motor development, and cardiovascular health. Collectively, the Branch is improving public health through providing evidence to help inform clinical guidance and public policy regarding care of individuals and couples intending to reproduce, pregnant women and their fetuses, and infants and children.

High quality scientific investigation in these various domains across the life course has yielded many awards recognizing the hard work of Epidemiology Branch team members. During 2018 alone, five postdoctoral fellows received the Fellows Award for Research Excellence (FARE) award, one of which was a travel award. Additionally, an MRSP fellow received a poster award at the Society of Pediatric and Perinatal Epidemiologic Research (SPER) conference. In addition, two principle investigators were promoted to a Senior Investigator with Tenure position within the Epidemiology branch. The excellence found within the Branch paired with the freedom and opportunity that comes with having large and unique data sets available makes the Branch uniquely positioned to pursue trans-disciplinary, high-risk research in novel and emerging areas of reproductive, perinatal, pediatric, and methodologic epidemiology.

▶ Enrique F. Schisterman, Ph.D., M.A.,
Senior investigator and branch chief

▶ **STAFF**
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Katherine Laughon Grantz, M.D., M.S., *Investigator*

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Keewan Kim, Ph.D., *Research Fellow*

Pauline Mendola, Ph.D., M.S., *Senior Investigator*

James L. Mills, M.D., M.S., *Senior Investigator*

Sunni L. Mumford, Ph.D., M.S., *Earl Stadtman Investigator*

Carrie Nobles, Ph.D., M.P.H., *Research Fellow*

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Earl Stadtman Investigator

Edwina H. Yeung, Ph.D., Sc.M.,
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Cuilin Zhang, M.D., Ph.D., M.P.H.,
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Postbaccalaureate Fellow

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Postdoctoral Fellow

Victoria Andriessen, B.S.,
Postbaccalaureate Fellow

Griffith Bell, Ph.D.,
*Postdoctoral Fellow
(departed in 2018)*

Alaina Bever, B.S.,
*Postbaccalaureate Fellow
(departed in 2018)*

Matt Connell, D.O.,
*Clinical Fellow
(departed in 2018)*

Kerry Flannagan, Ph.D.,
Postdoctoral Fellow

Ellen Francis, M.S.,
Predoctoral Fellow

Josh Freeman, M.S.,
Predoctoral Fellow

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*Postdoctoral Fellow
(departed in 2018)*

Elise Heisler, B.S.,
*Postbaccalaureate Fellow
(departed in 2018)*

Tiffany Holland, B.A.,
*Postbaccalaureate Fellow
(departed in 2018)*

Jenna Kanner, B.A.
Postbaccalaureate Fellow

Lindsay Levine, B.A.
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Marion Ouidir, Ph.D.,
Visiting Fellow

Hyojun Park, Ph.D.,
*Postdoctoral Fellow
(departed in 2018)*

Georgia Pitsava, M.D.,
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Alexandra Purdue-Smith, Ph.D.,
Postdoctoral Fellow

Jeannie Radoc, B.S.,
MSRP Fellow

Mohammad Rahman,
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Jessica Zolton, M.D.,
Clinical Fellow

Enrique F. Schisterman, Ph.D., M.A.

The field of reproductive epidemiology focuses on the many factors that affect human fecundity and fertility, which are defined as the biologic capacity of men and women for reproduction irrespective of pregnancy intentions and the ability to have a live birth, respectively.

The discipline also investigates impairments and disorders such as conception delay, anovulation, infertility, and semen quality in relation to environmental, lifestyle, and genetic factors.

Dr. Schisterman is tackling the gaps in infertility literature paired with identifying low-cost interventions that are needed to address the public health issue of infertility. He has made it a priority to implement randomized clinical trials with the intent of identifying these interventions. His research also has intersecting methodological and substantive components that aim to outline a more standardized methods approach in epidemiologic studies. Dr. Schisterman has solved important methodological challenges in the course of addressing his substantive research questions. His methodological work addresses exposure assessment, including cost-effective ways to gather what can be expensive information, and study design topics, such as efficient study designs in the context of time-varying exposures which are difficult to measure. Dr. Schisterman recently completed two major clinical trials: 1) the Effects of Aspirin in Gestation and Reproduction (EAGeR) trial, examining the effects of low cost, low dose aspirin therapy on fertility outcomes, and 2) the Folic Acid and Zinc Supplementation Trial (FASZT), examining the effects of folate/zinc supplementation in men on semen quality and fertility outcomes.

EAGeR
The Effects of Aspirin in Gestation & Reproduction

The EAGeR Trial: In a 2018 analysis, data from the EAGeR participants revealed links between potentially modifiable risk factors of preconception blood pressure, though not related to fecundability, and pregnancy loss (PMID: 29610265) and between testosterone and anti-Müllerian hormone levels and time to pregnancy and pregnancy loss (PMID: 29428315). The team provided novel findings demonstrating the need to monitor preconception blood pressure as part of women's general health as they may have consequential effects during pregnancy. In continuing with the team's prior investigations of inflammation in fecundability, we found preliminary evidence suggesting systemic inflammation was associated with reduced fecundability (PMID: 2931712), thus adding to the emerging knowledge of the role of low-grade inflammation, though usually undetected, in hindering the body's natural processes.

FAZST ♂

FASZT is Dr. Schisterman's most recent randomized clinical trial, evaluating the effects of folic acid and zinc supplementation in men on semen parameters and live birth among couples seeking treatment for infertility. In 2018, participant follow-up concluded and publications on this study are forthcoming.

Methodologic work by Dr. Schisterman is a result of his multidisciplinary training in statistics and epidemiology. He collaborated on many methods-based projects specifically focusing on outlining a standard approach for accounting for data missingness (PMID: 29165572). Dr. Schisterman expanded his work on data missingness, finding that the use of either multiple imputation steps (PMID: 29165547) or inverse-probability-weighted estimations are useful tools in order to overcome missing data while ensuring correct

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Senior Investigator and Chief

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Neil J. Perkins, Ph.D., M.S.,
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Lindsey A. Sjaarda, Ph.D., M.S.,
Staff Scientist

Victoria Andriessen, B.S.,
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Matthew Connell, D.O.,
Clinical Fellow (departed in 2018)

Epidemiology Branch

conclusions. Dr. Schisterman went a step further and identified pooling approaches that result in higher precision and power (PMID: 30003569 and PMID: 30022497). These methodologic developments improve study designs and solve analytic challenges. Dr. Schisterman also received a highly competitive extramural grant from the Long-Range Research Initiative of the American Chemistry Council, with the goal of providing the methodological tools necessary to assess and address issues related to study design, biomarker measurement, and analytic assessment.

Kerry Flannagan, Ph.D.,
Postdoctoral Fellow

Tiffany Holland, B.A.,
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(departed in 2018)*

Jeannie Radoc, B.S.,
MSRP Fellow

Jessica Zolton, M.D.,
Clinical Fellow

KEY PUBLICATIONS

Nobles CJ, Mendola P, Mumford SL, Naimi AI, Yeung EH, Kim K, Park H, Wilcox B, Silver RM, Perkins NJ, Sjaarda L, Schisterman EF. Preconception Blood Pressure Levels and Reproductive Outcomes in a Prospective Cohort of Women Attempting Pregnancy. *Hypertension.* 2018;71(5):904-910. PMID: 29610265 PMCID: PMC5897130.

Radin RG, Sjaarda LA, Silver RM, Nobles CJ, Mumford SL, Perkins NJ, Wilcox BD, Pollack AZ, Schliep KC, Plowden TC, Schisterman EF. C-Reactive protein in relation to fecundability and anovulation among eumenorrheic women. *Fertil Steril.* 2018;109(2):232-239 e231. PMID: 29317123 PMCID: PMC5815923.

James L. Mills, MD, MS

Nutritional factors can be extremely important determinants of reproductive outcomes. Our work on folate and neural tube defects (NTD) has moved in two directions.

First, we have continued to explore biochemical factors important in folate metabolism. In a quantitative traits GWAS designed to identify folate-related variants that could influence NTD risk, we found that the MTHFR variant C677T was the only major factor affecting folate status. The reported effect of MTFHR A1298C was due entirely to linkage disequilibrium. This was demonstrated by showing no effect of MTHFR A1298C when the analysis was restricted to MTHFR 677CC participants. Thus, the MTHFR C677T variant, which we and others have described previously as a risk factor for NTDs, is likely to be the most important folate-related genetic risk factor. In a related study, we demonstrated that formate, a one-carbon donor critical for folate function, was significantly lower in those who are homozygous for the MTHFR C677T variant. Formate concentrations were positively correlated with potential precursors such as serine, methionine and choline indicating that diets rich in these nutrients might ameliorate the adverse effect of the MTHFR 677TT genotype.

Second, in the public health area, we published a peer reviewed analysis in the BMJ demonstrating that fortification was highly effective and low risk. In an editorial in the AJCN, we provided support for food fortification and in analysis of the best level to put into food.

We also investigated the effect of the nutrient iodine on conception. Iodine deficiency by WHO standards was common in the LIFE study (44%). Women who were iodine deficient had a 46% reduction in fecundability compared with iodine sufficient women.

Genetic risk factors for birth defects and pediatric endocrine disease is a second major research area. Our study of the genomics of Cushing disease showed that chromosomal instability in the corticotropinomas was associated with larger tumor size and higher rates of invasion of the cavernous sinus. Thus, chromosomal instability may predict poorer prognosis and might be useful to identify patients at high risk.

Our investigation of copy number variants in patients with hypoplastic right heart syndrome showed duplications overlapping part of the gene ERBB4, a critical factor in cardiomyocyte differentiation, in two cases. Four copy number variants were found near WNT signaling genes providing areas for future pathophysiologic investigations. We participated in a consortium that identified novel risk loci for cleft palate. CTNNA2 was genomic-wide significant. It is involved in control of the cranial neural crest and is expressed in oral structures. SULT2A1, which approached genome-wide significance, is expressed in multiple areas of the palate in mice providing strong biological plausibility for this finding.

Our extensive genomic data from a normal Irish population has led to other important collaborations. As part of the International League Against Epilepsy Consortium on Complex Epilepsy, we identified 11 novel genome-wide significant loci, some associated with generalized and some with specific focal epilepsy.

James L. Mills, MD, MS
Senior Investigator

Pauline Mendola, Ph.D.

Dr. Mendola leads the Air Quality and Reproductive Health study which added air pollution and ambient temperature data to the Consortium on Safe Labor, the LIFE Study, and the NICHD Consecutive Pregnancy Study.

"The reproductive risks associated with ambient environmental exposures are often small but have large population-level impact. Everyone breathes, we are all exposed. These exposures are modifiable and addressing them can prevent adverse pregnancy outcomes."

In 2018, key discoveries included the increase in early pregnancy loss associated with ozone and fine particulate matter, the relationship between maternal exposures in pregnancy and infant growth restriction, and the high risk for gestational diabetes among Asian-Pacific Islander women exposed to volatile organic compounds in ambient air. A new protocol was approved to add ambient environmental measures to the NICHD Fetal Growth Studies Singleton and Twin cohorts. This new project will examine air pollution and temperature in relation to acute changes in placental vascular resistance and maternal blood pressure as well as chronic exposure in relation to fetal growth and organ volumes.

In the B-WELL-Mom Study (Mendola, PI), we aim to increase understanding of factors that predict poor asthma control during pregnancy as well as add to our knowledge of the basic immunology of pregnancy. Asthma is a common chronic disease and some women experience exacerbation and worsening of their asthma during pregnancy while others improve. The maternal immune response to pregnancy suggests that humoral immune responses are preserved and allergy may be an important predictor in determining the clinical course of women with asthma during pregnancy. We will examine in-depth immune function and lung inflammation to assess the impact of immune regulatory processes throughout pregnancy and the postpartum period that may be associated with changes in asthma control. Daily exposure to air pollutants provides another challenge to the maternal immune system, both for women with and without asthma. Among asthmatics, the change in severity/control may be differentially affected by external factors including air pollution and dietary antioxidants.

In collaboration with Northwestern University and the University of Alabama at Birmingham, we recruited 311 women with asthma (164 with poor asthma control and 147 well-controlled asthmatics) and 107 women without asthma. Recruitment ended in August 2018 and followup visits are anticipated until mid-summer 2019. Data are based on three study visits during pregnancy and one post-partum visit and diary measures of lung function and symptoms. Study visits include flow cytometry for T-regulatory cells and other CD4 cell populations, spirometry and lung inflammation measures.
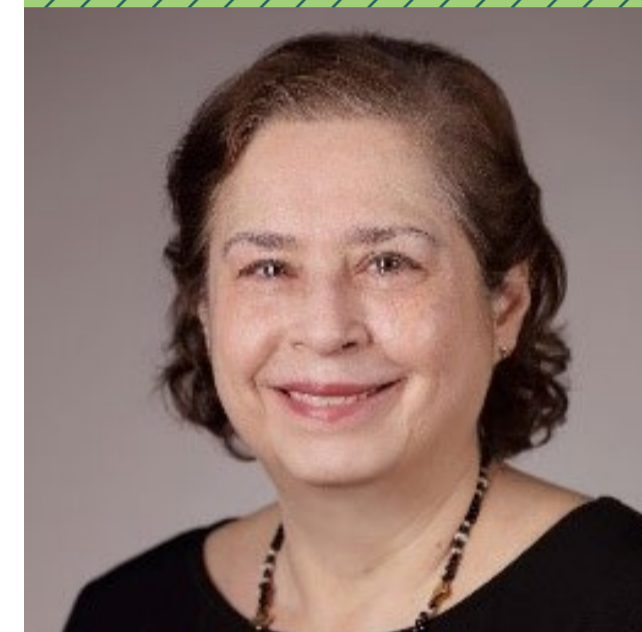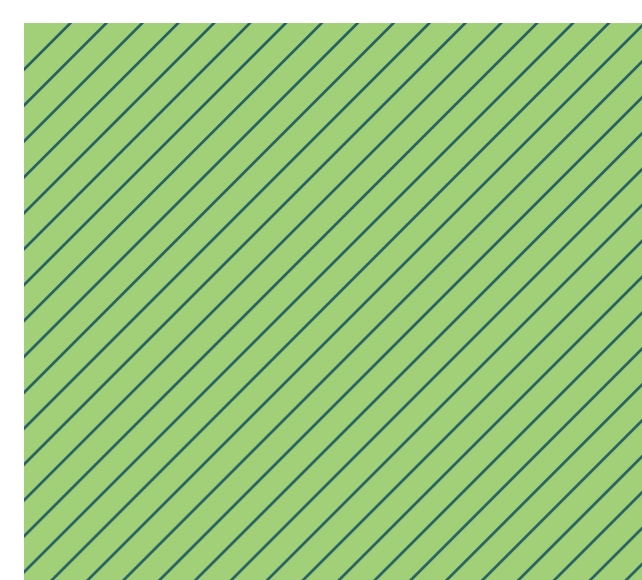
Pauline Mendola, Ph.D,
Senior Investigator

KEY PUBLICATIONS

Ha S, Sundaram R, Louis GM, Nobles C, Seeni I, Sherman S, Mendola P. Ambient air pollution and the risk of pregnancy loss: a prospective cohort study. *Fertility and Sterility*. 2018; 109(1):148-153. PMID: 29153729. PMCID: PMC5758402.

Nobles CJ, Grantz KL, Liu D, Williams A, Ouidir M, Seeni I, Sherman S, Mendola P. Ambient air pollution and fetal growth restriction: physician diagnosis of fetal growth restriction versus population-based small-for-gestational age. *The Science of the Total Environment*. 2018; 650(Pt 2):2641-2647. PMID: 30296771. PMCID: PMC6203640.

Cuilin Zhang, M.D., Ph.D., M.P.H.

Dr. Cuilin Zhang's research interest is at the interface of genetic and non-genetic biological markers and potentially modifiable exogenous factors, focusing on their interplay in relation to the development of complex diseases.

More specifically, her current research activities focus primarily on the roles of genetic and environmental factors in the pathogenesis of gestational diabetes, type 2 diabetes, and obesity and health consequences of these complications.

In 2018 Dr. Zhang and her colleagues made key discoveries related to the etiology and long-term complications of gestational diabetes using data from the Diabetes & Women's Health Study, a retrospective cohort study of approximately 4,000 women from the U.S. and Denmark who had diabetes in pregnancy and followed up for at least 10 years. Eight genetic variants were identified for their significant role in gestational diabetes, which offers potential to improve our understanding of the etiology of gestational diabetes and particularity the biological mechanisms for insulin biosynthesis and secretion in pregnancy (Ding et al. Diabetologia 2018). Further, gestational diabetes was identified as an early indicator of subsequent subclinical renal dysfunction (Rawal et al. Diabetes Care 2018). These findings suggest that women with gestational diabetes-complicated pregnancies may represent a high-risk group that could benefit from regular monitoring for early-stage renal damage and that timely detection may help clinicians initiate treatment to prevent or delay further disease progression.

"Our findings suggest that women who have had gestational diabetes may benefit from periodic checkups to detect early-stage kidney damage and receive subsequent treatment."

Using data from the NICDH Fetal Growth Studies and a comprehensive panel of biomarkers, Dr. Zhang and her colleagues identified targeted and non-targeted metabolomics and lipodomics associated with implicated in glucose homeostasis and fetal growth. Notably, it was discovered that thyroid function in pregnant women may be involved in the pathophysiology of gestational diabetes (Rawal et al. *Journal of Clinical Endocrinology and Metabolism* 2018). These findings, in conjunction with previous evidence of thyroid-related adverse pregnancy outcomes, support the potential benefits of thyroid screening among pregnant women. In addition, a significantly increased risk of gestational diabetes was observed in association with saturated fatty acid levels as early as the first trimester of pregnancy (Zhu et al. *American Journal of Clinical Nutrition* 2018) providing impetus for future investigations that target circulating saturated fatty acids in pregnant women to improve our understanding of their distinct nutritional, metabolic, and physiologic roles in cardiometabolic outcomes. In 2018, new research also discovered that HbA1C levels can potentially help identify women at risk for gestational diabetes early in pregnancy, when lifestyle changes may be more effective in reducing their risk (Hinkle et al. *Scientific Reports* 2018). Furthermore, new research found that women's adipokine levels (Hinkle et al. *International Journal of Obesity* 2018) and vitamin D status (Francis et al. *Nutrients* 2018) in pregnancy appear to be involved in regulating fetal growth. While more work is needed, the data offer insight into how maternal body fat composition may influence different aspects of fetal growth.

Fetal Growth Study
NICHD

**Cuilin Zhang,
M.D., Ph.D., M.P.H.**
Senior investigator

KEY PUBLICATIONS

Zhu Y, Tsai MY, Sun Q, Hinkle SN, Rawal S, Mendola P, Ferrara A, Albert PS, Zhang C. A prospective and longitudinal study of plasma phospholipid saturated fatty acid profile in relation to cardiometabolic biomarkers and the risk of gestational diabetes. *American Journal of Clinical Nutrition.* 2018; 107 (6): 1017-1026. PMID: 29868913 PMCID: PMC6248709

Rawal S, Olsen SF, Grunnet LG, Ma RC, Hinkle SN, Granström C, Wu J, Yeung E, Mills JL, Zhu Y, Bao W, Ley SH, Hu FB, Damm P, Vaag A, Tsai MY, Zhang C. Gestational Diabetes and Renal Function: A Prospective Study with 9 to 16 Year Follow-up after Pregnancy. *Diabetes Care.* 2018; May 4. pii: dc172629. PMID: 29728364. PMCID: PMC6014536

Lastly, in 2018 data analysis was initiated for the [Collaborative Perinatal Project Mortality Linkage Study](), which aims to investigate long-term associations of overall and cause-specific mortality with a spectrum of pregnancy-related complications.
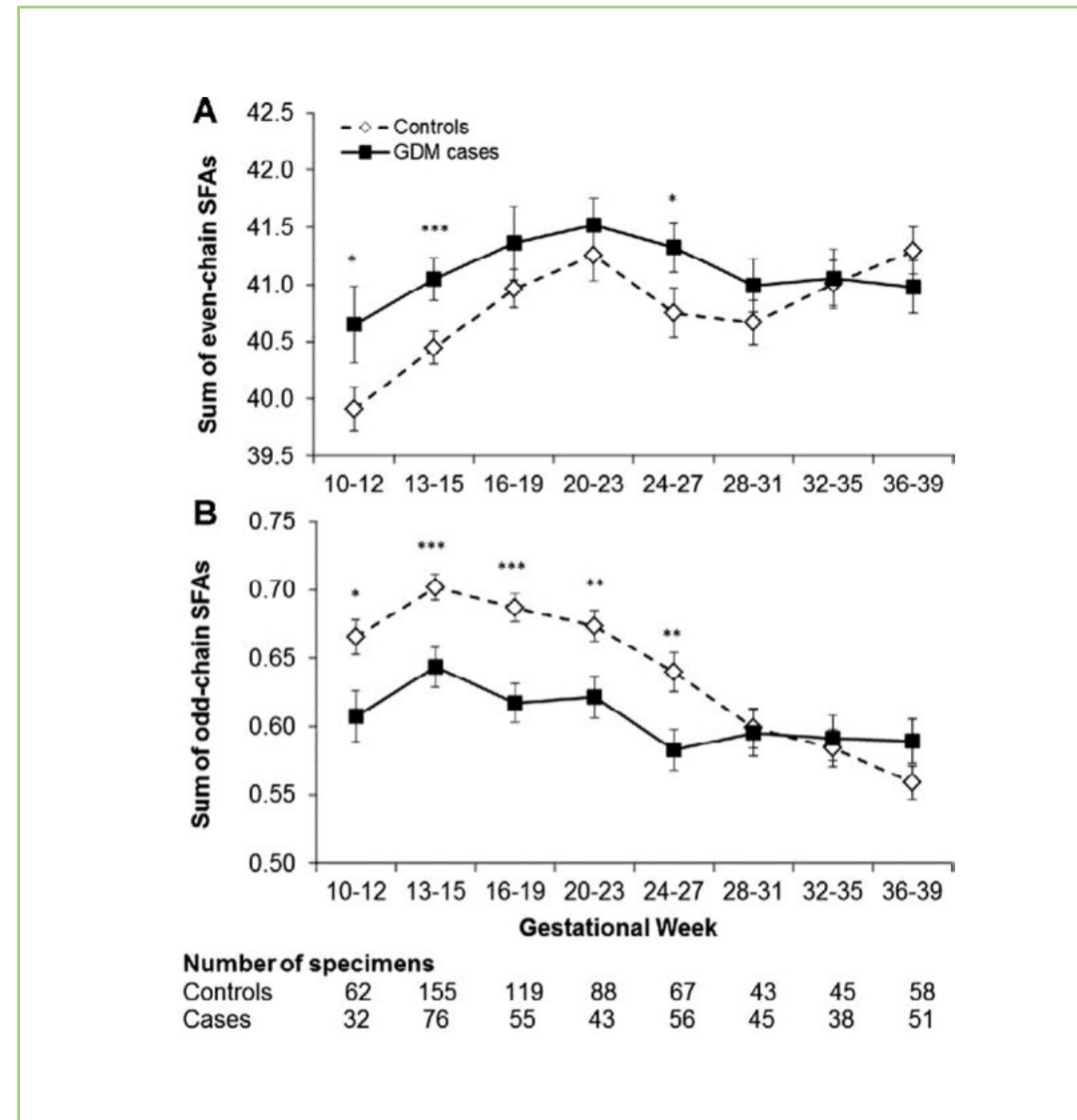
Edwina Yeung, Ph.D., ScM

Dr. Yeung leads the Upstate KIDS Study and its ongoing follow-up in her focus to understand the developmental origins of health and disease (DOHaD).

Upstate KIDS was designed to determine whether infertility treatments adversely affect the growth and development of children. Over 6,000 newborns were enrolled between 2008 and 2010, with almost one third conceived by infertility treatments. In 2018, Dr. Yeung's team investigated whether infertility risk factors were related to children's health. In one manuscript using developmental information longitudinally collected from the Ages and Stages Questionnaires (ASQ) at 4, 8, 12, 18, 24, 30, 36 months of age, children of women diagnosed with polycystic ovarian syndrome (PCOS) were found to have higher risk of failing the ASQ than children of mothers without the diagnosis (PMID: 29668891). Both singletons and twins were affected, although in different domains of development (PMID: 29789346). In a separate paper, however, growth between birth through 3 years of age, did not differ. Key investigations in 2018 also include how adipokines and environmental chemicals, measured using newborn dried blood spots, affect neonatal and early child health (PMID: 29781193, PMID: 29972605, PMID: 30296759, PMID: 30219610). This body of work contributed not only contributed to identifying early determinants of pediatric health but also to the utility of dried blood spots in epidemiological research at the population level.

In collaboration with the University at Albany, clinical visits at multiple sites across New York State for the Upstate KIDS CVD Follow-Up Study will continue until fall of 2019. The clinical visits are aimed to capture childhood cardio-metabolic outcomes (i.e., obesity, high blood pressure, metabolism) and biospecimens in the children and the mothers. Details of the visit measures can be found online (www.upstatekidsstudy.org). A secondary objective of the Upstate KIDS CVD Follow-Up Study is to assess epigenetic differences as measured by DNA methylation using collected biospecimens. To this end, genetic consents were collected anew beginning in 2016 for using the dried blood spots previously stored and in 2018 laboratory measures of DNA methylation were initiated among over 1000 newborns whose parent provided genetic consent.

Related to the understanding of the underlying epigenetic mechanisms for the DOHaD, Dr. Yeung measured DNA methylation with Illumina's Infinium EPIC (850K) microarray using approximately 400 cord blood samples of newborns from the Effects of Aspirin in Gestation and Reproduction (EAGeR) trial. Given previous findings, including her own in Upstate KIDS, showing that maternal pre-pregnancy obesity is associated with long term child obesity and developmental risks, she investigated how maternal pre-conception anthropometry was associated with newborn DNA methylation. EAGeR, as a preconception cohort, uniquely has clinically measured anthropometry measures including waist circumference and measured leptin. As published in Epigenomics, she found small differences, particularly with hypomethylation in certain genes with increasing adiposity specific to the type of adiposity measure (PMID: 30618290).

Edwina Yeung, PhD, ScM
Investigator

KEY PUBLICATIONS

Bell GA, Sundaram R, Mumford SL, Park H, Mills J, Bell EM, Broadney M, Yeung EH. Maternal polycystic ovarian syndrome and early offspring development. *Human Reproduction.* 2018; 33(7):1307-1315. PMID: 29668891. PMCID: PMC6251548.

Yeung EH, Guan W, Mumford SL, Silver R, Zhang C, Tsai MY, Schisterman EF. Measured maternal prepregnancy anthropometry and newborn DNA methylation. *Epigenomics* 2019 Jan 8. doi: 10.2217/epi-2018-0099 PMID: 30618290. PMCID: PMC6371845.

Sunni L. Mumford, Ph.D., M.S.

As diets become increasingly complex, so too does the relation between diet and health outcomes. Despite diet's importance for human survival, its relation to fecundity remains an understudied area with many critical data gaps. Considering the current obesity epidemic and the need to understand modifiable factors to improve health, research on the impact of dietary and lifestyle factors on reproduction and infertility has important implications for women, men, couples, and generations.

Dr. Mumford's current research and future plans are focused on closing the literature gaps on lifestyle and dietary factors that impact hormone levels, anovulation, and infertility. To this end, she has been involved in leading and collaborating on several projects related to diet and reproduction in multiple Epidemiology Branch studies. Dr. Mumford recently completed two major clinical trials and one cohort study; EAGeR, on the effects of low cost, low dose aspirin therapy on fertility outcomes, FASZT, on the effects of folic acid and zinc supplementation on semen quality and fertility outcomes, and IDEAL, on the impact of diet, exercise, and lifestyle on fecundability—a follow-up of the female partners of FAZST participants.

EAGeR has resulted in findings that have emphasized the importance of understanding preconception and maternal nutrition and how it relates to time to pregnancy and reproductive health outcomes. Dr. Mumford's important findings have demonstrated the importance of preconception vitamin D levels for increasing live birth and decreasing pregnancy loss (PMID: 29859909), and for the bioavailability of androgens (PMID: 29548752). In addition, Dr. Mumford found associations between plasma mono- and poly-unsaturated fatty acid levels and fecundability

in women of a healthy weight and with history of pregnancy loss further highlighting the importance of fatty acid compositions for health (PMID: 30124893). Dr. Mumford has led the team on identifying modifiable dietary risk factors that potentially affect a woman's infertility, such as preconception carotenoid levels (PMID: 29767694). Dr. Mumford's work has truly bridged the gap of our understanding of dietary intake and the complex role it has on fecundability.

FAZST is Dr. Mumford's most recent large clinical research study, evaluating the effects of folic acid and zinc supplementation on semen parameters, has recently completed follow-up and publications on this study are forthcoming.

IDEAL is Dr. Mumford's most recent large observational research study, evaluating the impact of diet, exercise, and lifestyle on fertility and reproductive health. The IDEAL study is a detailed follow-up of the female partners of FAZST participants. Data regarding multiple aspects of diet, exercise, sleep, stress, and lifestyle were collected and the study completed follow-up at the end of 2018. Publications on this study are forthcoming.

Sunni L. Mumford, Ph.D., M.S.,
Earl Stadtman Investigator

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Zeina Alkhalaf, B.A.,
Postbaccalaureate Fellow

Josh Freeman, M.S.,
Predoctoral Fellow

Keewan Kim, Ph.D.,
Research Fellow

Lindsay Levine, B.A.
*Postbaccalaureate Fellow
(departed in 2018)*

Alexandra Purdue-Smith, Ph.D.,
Postdoctoral Fellow

KEY PUBLICATIONS
Mumford SL, Garbose RA, Kim K, Kissell K, Kuhr DL, Omosigho UR, Perkins NJ, Galai N, Silver RM, Sjaarda LA, Plowden TC, Schisterman EF. Association of preconception serum 25-hydroxyvitamin D concentrations with livebirth and pregnancy loss: a prospective cohort study. *Lancet Diabetes Endocrinol.* 2018;6(9):725-732. PMID: 29859909 PMCID: PMC6109429.

Kim K, Schisterman EF, Silver RM, Wilcox BD, Lynch AM, Perkins NJ, Browne RW, Lesher LL, Stanford JB, Ye A, Wactawski-Wende J, Mumford SL. Shorter Time to Pregnancy With Increasing Preconception Carotene Concentrations Among Women With 1-2 Previous Pregnancy Losses. *Am J Epidemiol.* 2018;187(9):1907-1915. PMID: 29767694 PMCID: PMC6118073.

Katherine Laughon Grantz, M.D.

Dr. Grantz's independent research focuses on providing evidence to guide clinical management strategies for pregnancy complications to optimize maternal and neonatal outcomes.

Consortium on Safe Labor
Funded by the National Institutes of Health

In the [Consortium on Safe Labor Study](#), her research has provided empirical evidence to inform clinical guidance regarding the management of contemporary parturient women based upon empirically supported guidance. In 2018, researchers assessed the morbidity associated with continuing the second-stage duration of labor, weighing the probability of spontaneous vaginal birth without morbidity compared with birth with serious maternal or neonatal complications. Rates of spontaneous vaginal birth without serious morbidity steadily decreased for increasing second-stage duration except for the first half hour for nulliparous women. There was no inflection point at a particular hour mark for either spontaneous vaginal delivery without morbidity or births with morbidity. These findings will assist in the decision making for extending second-stage duration. (PMID: 29324600)

> "The good news is that only one day of bleeding was not significantly associated with reduced growth. But our results suggest that even if bleeding stops before the second trimester, a pregnancy with more than one day of bleeding is at somewhat of a greater risk for a smaller baby."
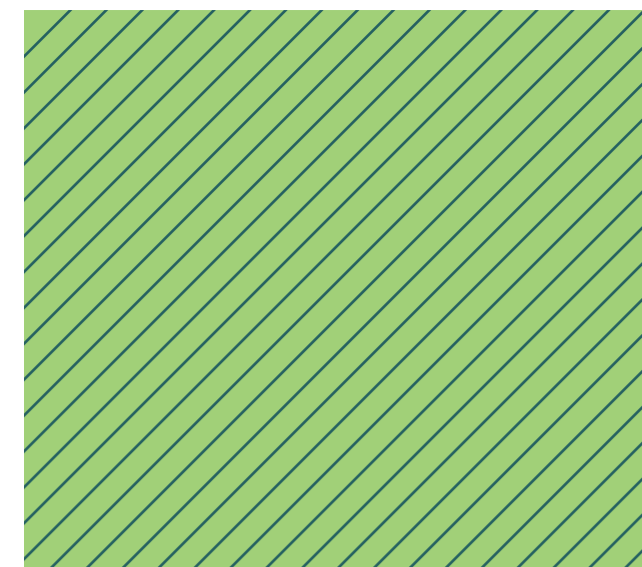
Fetal Growth Study
NICHD

In the [NICHD Fetal Growth Studies](#), Dr. Grantz is leading work to answer important clinical questions on fetal growth. In 2018, researchers developed a model to compute fetal growth velocity percentiles for any given set of gestational week intervals, and determine the association between fetal growth velocity and birthweight. Findings suggest that growth velocity adds additional information over a single measurement of fetal size alone which has potential to change clinical practice (PMID: 29803819). Researchers also compared and contrasted the NICHD Fetal Growth Studies with two recently completed international longitudinal cohort studies that have also developed intrauterine fetal growth charts, INTERGROWTH-21st and World Health Organization Multicentre Growth Reference Study. The percentiles for fetal dimensions and estimated fetal weight varied among the studies, therefore when applying these standards to a clinical population, different percentages of small- (SGA) and large-for-gestational age fetuses will be identified (PMID: 29275821). The relationship between first trimester vaginal bleeding and fetal growth patterns was also assessed. First trimester vaginal bleeding was common, affecting 18% of pregnancies. More than 1 day of bleeding was associated with asymmetric, decreased fetal growth, with statistically significant differences beginning in the third trimester and an increased risk of SGA at birth. The magnitude of decrease in birthweight was small and it remains unknown whether early pregnancy bleeding is associated with short-term or long-term morbidity and if additional intervention would be of benefit (PMID: 29742672).

3D
Fetal 3D Study
NICHD

Dr. Grantz also continued the [Fetal 3D Study](#) which is expected to be completed in 2019.

Katherine Laughon Grantz, M.D. M.S.,
Investigator

KEY PUBLICATIONS

Grantz KL, Kim S, Grobman W, Newman R, Owen J, Skupski D, Grewal J, Chien E, Wing DA, Wapner RJ, Ranzini AC, Nageotte MP, Hinkle SN, Pugh S, Hediger M, Buck Louis GM, Albert PS. Fetal Growth Velocity: the NICHD Fetal Growth Studies. *American Journal of Obstetrics and Gynecology.* 2018; Sep;219(3):285.e1-285.e36. PMID: 29803819

Bever AM, Pugh SJ, Kim S, Newman RB, Grobman WA, Chien EK, Wing DA, Li H, Albert PS, Grantz KL. Fetal growth patterns in pregnancies with first-trimester bleeding. *Obstetrics and Gynecology.* 2018; 131(6):1021-1030. PMID: 29742672. PMCID: PMC6223322.

NICHD press release: https://www.nichd.nih.gov/news/releases/050918-early-pregnancy-bleeding

Division of Intramural Population Health Research

Fasil Tekola-Ayele, Ph.D.

Aberrant fetal growth is known to be a risk factor for cardiometabolic diseases in later life. The mechanisms that underlie these links between early growth and later life cardiometabolic diseases are not well understood. Fetal growth also exhibits differences among individuals and populations; what underlies population differences in fetal growth and consequent cardiometabolic outcomes has remained puzzling because environmental factors explain only a small proportion of these differences. Dr. Tekola-Ayele's genetic-epidemiology research program seeks to understand these dynamics. The overarching goal of the team is to understand genomic factors that influence early growth and the link between early growth and cardiometabolic diseases/disparities in diverse ancestral populations.

The first research goal utilizes genomic data generated from the NICHD Fetal Growth Studies cohort and other resources to unravel maternal-placental-fetal genetic and epigenetic factors (including genetic ancestry, cardiometabolic disease genetic risk, and epigenetic/transcriptomic signatures) that influence fetal growth in diverse populations. In a study of twin gestations from the NICHD Fetal Growth Studies cohort, we found that the influence of genetic factors steadily increases with gestational age compared

> "Integrative genomic research approaches may give clues regarding the complex maternal-placental-fetal system that drives in-utero growth and cardiometabolic disease risk."

to environmental influences that showed the highest influence during early gestation. The study also demonstrated that the genetic influence on fetal weight peaks at the end of second trimester of pregnancy (PMID: 29740100). In another study that compared the cumulative burden of genetic loci known

to be associated with birthweight among ancestrally diverse global populations, we found ancestral differences in the burden of the birthweight-reducing loci (PMID: 29792231). The team is currently undertaking analyses of genetic, epigenetic, and transcriptomic data to identify maternal genetic loci that influence longitudinal fetal growth; determine the contributions of maternal genetic ancestry and cardiometabolic genetic factors to individual and population difference in fetal growth; and identify placental transcriptomic/epigenetic signatures of maternal dyslipidemia, obesity, and blood pressure.

A second research goal of Dr. Tekola-Ayele's team is to unravel genetic mechanisms and biological pathways in the link between in-utero growth and cardiometabolic disease risk in later life. We investigated the extent to which genetic influences on birthweight overlap with fifteen different adult cardiometabolic traits. Our study found high degree of shared genetic influences and identified novel loci that jointly influence birthweight and adult coronary artery disease and obesity traits (PMID: 30858448). To leverage existing large-scale population biobanks for future genetic-epidemiology studies of early growth-cardiometabolic links, we are exploring the potential to obtain DNA of high quality from sources other than whole blood. A pilot study has been designed to evaluate whether stored serum can yield sufficient DNA that is usable for future genomic research using banked serum samples from the Collaborative Perinatal Project, a national pregnancy cohort that enrolled more than 48,000 women and their offspring between 1959 and 1966. The pilot phase experiment is underway.
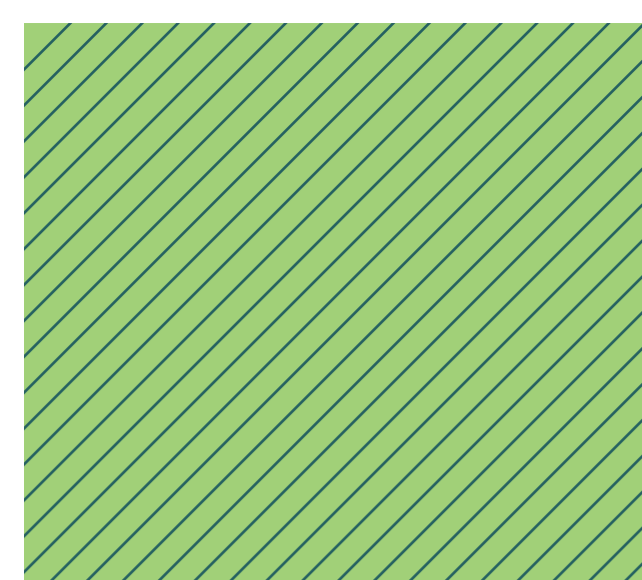
Fasil Tekola-Ayele Ph.D.,
Earl Stadtman Investigator

KEY PUBLICATIONS
Tekola-Ayele F, Workalemahu T, Amare AT. High Burden of Birthweight-lowering Genetic Variants in Africans and Asians. *BMC Medicine*. 2018; 16(1):1-8. PMID: 29792231.

Workalemahu T, Grantz KL, Grewal J, Zhang C, Louis GMB, Tekola-Ayele F. Genetic and Environmental Influences on Fetal Growth Vary During Sensitive Periods in Pregnancy. *Scientific Reports*. 2018; 8(1): 1-8. PMID: 29740100.

Division of Intramural Population Health Research

In 2018, the Health Behavior Branch of the Division of Intramural Population Health Research became the Social and Behavioral Sciences Branch (SBSB).

Our new name reflects our expansive mission to conduct research to understand the social and behavioral determinants of health and health-related behaviors; to develop and test educational, behavioral, and environmental strategies for improving health and health-related behaviors; and to conduct research on the problem of disparities in health, the developmental mechanisms underlying health disparities over the life course, and modifiable intervention targets to reduce disparities. SBSB also recruits, trains, and mentors highly qualified students and trainees for professional careers in the social and behavioral sciences.

Our research integrates approaches from diverse disciplines including psychology (community, clinical, and developmental), nutrition, health education, and epidemiology (social, psychiatric, and developmental). Collaborations with other Division researchers and throughout the NIH's Intramural Research Program further enhance the trans-disciplinary nature of our work. Our research addresses key contributors to the population burden of disease including obesity, cardiovascular disease, mental illness, and injury. Its developmental focus strives to identify and intervene early in life on pathways to disease for maximal impact on population health.

The Branch's research programs are organized along axes of substantive research domains and key developmental stages.

Our risk behavior and young driver research centers on adolescence. Adolescence is a critical period for the development of behavior patterns associated with subsequent morbidity and mortality, including diet, physical activity, sleep, substance use, and driving. Influences on these behaviors encompass personal and environmental factors, including social influences and physical contexts (e.g., place of residence, local programs, policies, and resources). The SBSB research program on young drivers employs state-of-the-art survey, observation, naturalistic driving, test track, simulation, and neuroimaging methodology to examine driving risk and prevention.

SBSB research on eating behaviors in children and families uses experimental and observational methods to investigate influences on, and interventions to improve, eating behaviors leading to optimal growth and development in clinical and general populations. This work is of substantial public health importance because the poor diet quality of the U.S. population, characterized by excessive intake of total energy, added sugar, fat and sodium, and inadequate intake of fruits, vegetables and whole grains is well-documented. Poor diet (not including malnutrition) is now the largest contributor to early death globally, and is associated with numerous adverse health outcomes independent of obesity.

SBSB research on the social determinants of mental health and health disparities takes a life course approach, from the prenatal period through childhood and adolescence, and investigates developmental mechanisms that reach into and beyond middle adulthood.

Stephen E. Gilman, ScD,
Branch Chief and Senior Investigator

STAFF
Risë B. Goldstein, Ph.D., M.P.H.,
Staff Scientist

Denise Haynie, Ph.D., M.P.H.,
Staff Scientist

Leah Lipsky, Ph.D.,
Staff Scientist

Tonja Nansel, Ph.D.,
Senior Investigator

Bruce G. Simons-Morton, Ed.D., M.P.H.,
Senior Investigator

Social and Behavioral Sciences Branch (cont.)

FELLOWS

Grace Betts, B.S.,
Postbaccalaureate Fellow

Brian Fairman, Ph.D.,
Postdoctoral Fellow

Pnina Gershon, Ph.D.,
Postdoctoral Fellow

Christine Hill, B.S.,
*Postbaccalaureate Fellow
(departed in 2018)*

Kuba Jeffers, B.A.,
Postbaccalaureate Fellow

Jamil Lane, M.P.H.,
Summer Intern

Jeremy Luk, Ph.D.,
*Postdoctoral Fellow
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Katherine Maultsby, B.S.,
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Namrata Sanjeevi, Ph.D.,
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Kellienne Sita, B.S.,
*Postbaccalaureate Fellow
(departed in 2018)*

Ndeah Terry, B.S.,.
Postbaccalaureate Fellow

Jing Yu, Ph.D.,
Postdoctoral Fellow

2018 AWARDS

Pnina Gershon, Ph.D.,
*Postdoctoral Fellow (Mentor:
Bruce Simons-Morton, Ed.D.,
M.P.H.), Fellows Award for
Research Excellence, National
Institutes of Health, Bethesda, MD*

Stephen Gilman, Sc.D.,
*Senior Investigator and Branch
Chief: NICHD Mentor of the Year
Award; All of Us NICHD Working
Group Award; and OHE Strategic
Planning Committee Award*

Jeremy Luk, Ph.D.,
*Postdoctoral Fellow (Mentors:
Bruce Simons-Morton, Ph.D., and
Stephen Gilman, Sc.D.), Fellows
Award for Research Excellence,
National Institutes of Health,
Bethesda, MD*

Jeremy Luk, Ph.D.,
*Postdoctoral Fellow (Mentors:
Bruce Simons-Morton, Ph.D.,
and Stephen Gilman, Sc.D.),
Gordis Award finalist, Research
Society on Alcoholism, 2018*

Leah Lipsky, Ph.D.,
*Staff Scientist, NICHD Award
for Mentoring*

Stephen E. Gilman, ScD

Socially mediated insults during early development have long-term consequences for mental and physical health. Our research seeks a better understanding of the environments that have both positive and negative influences on development from the prenatal period onward to generate new insights into mechanisms that underlie the early life origins of health disparities, identify developmentally sensitive periods for the emergence of disparities, and uncover opportunities for reducing disparities at the population level.

Our research focuses on both healthy and abnormal child development, environmental factors at multiple levels of analysis (individual, family, and neighborhood), associated biomarkers of exposure and impact, and long-term outcomes with an emphasis on mental health and mental disorders. Inspired by the "Developmental Origins of Health and Disease" and "Life Course Epidemiology" movements, our work adopts multiple approaches in diverse populations to advance knowledge of the social determinants of human development (PMID: 30699022). Ongoing studies are described below.

The prenatal period and early childhood

Maternal immune activity during pregnancy has been repeatedly linked to neuropsychiatric disorders in offspring. To the extent that maternal inflammation during pregnancy causes deviations from typical neurodevelopmental trajectories in offspring that result in elevated risk of neuropsychiatric disorders such as schizophrenia, autism, and major depressive disorder, it is unlikely that neurocognitive functioning in childhood would remain otherwise intact. However, much less is known regarding the role of immune markers at specific points during gestation in children's neurocognitive development. This is important because impairments in neurocognitive function in domains of intellectual ability, language, and higher order

cognitive processes might serve as early markers of vulnerability to lifetime risk and recurrence of neuropsychiatric disorders. We have found that immune activity during the prenatal period is associated children's neurocognitive development (PMID: 29531226, PMID: 29972605, and PMID: 30375022). Other exposures during the prenatal period that are also relevant for child development include health-related behaviors such as maternal smoking (PMID: 29717267 and PMID: 30035359). As our work has found a close connection between neurological and neurocognitive domains of children's development (PMID: 30265034.), we are motivated in future studies to consider how early exposures have diverse effects across developmental areas.

Adolescence and adulthood

Trajectories established as early as infancy influence mental and physical health in later stages of the life course extending into adolescence and young and middle adulthood. One of our team's focus areas concerns the developmental vulnerability to suicide, a leading cause of death among young people and a major contributor to the disease burden associated with mental illness. Accordingly, we have undertaken a large-scale cohort study of the developmental origins of suicide mortality. We have linked data from 52,966 children born to mothers enrolled in the United States Collaborative Perinatal Project from 1959-1966 to the National Death Index to determine their vital status through 2016 and investigate the prenatal, socioeconomic, behavioral, cognitive, and neurologic risks for completed suicide. We are also conducting a nested case-control study to investigate the contributions of gestational immune activity to the fetal origins of suicide. This work is currently in progress. Related work in collaboration with our colleagues on the Next Generation Health Study concerns the social determinants of mental health problems during adolescence

Stephen E. Gilman, ScD,
*Branch Chief and
Senior Investigator*

STAFF
Brian Fairman, Ph.D.

Risë B. Goldstein, Ph.D., M.P.H.

Kuba Jeffers, B.A.

Jeremy Luk, Ph.D.

Jing Yu, Ph.D.

Social and Behavioral Sciences Branch (cont.)

(e.g., PMID: 29661939.). Finally, we continue our work toward understanding the long-term and potentially intergenerational influences of the early environment on health: how early childhood adversity leads to poor health in adulthood (PMID: 30277525 and PMID: 29888956) and how it may influence health across generations (PMID: 29188292).

KEY PUBLICATIONS

Ghassabian A, Albert PS, Hornig M, Yeung E, Cherkerzian S, Goldstein RB, Buka SL, Goldstein JM, Gilman SE. Gestational cytokine concentrations and neurocognitive development at 7 years. Translational Psychiatry. 2018;8(1):64. PMID: 29531226. PMCID: PMC5847536.

Santavirta T, Santavirta N, Gilman SE. Association of the World War II Finnish Evacuation of Children With Psychiatric Hospitalization in the Next Generation. JAMA Psychiatry. 2018;75(1):21-7. PMID: 29188292. PMCID: PMC5833542.

Division of Intramural Population Health Research

Bruce Simons-Morton, Ed.D., M.P.H.

Program of Research: I study adolescent health behavior using instrumented vehicle and survey methods.

Driving Research. We recruited a sample (n=90) of adolescents and their parents soon after the teens learner's permits, instrumented their vehicles with a data acquisition system, and followed them through the learner period and 12 months after licensure. Recent analyses have focused on the amount and quality of practice driving (https://doi.org/10.1016/j.ssci.2018.08.019), association of vehicle access to exposure and driving performance, and patterns of crashes and risky driving (PMID: 30006026 and PMID: 29890369.)

Adolescent Health Behavior. My research on adolescent health behavior is based on the NEXT Generation Longitudinal Study of Adolescent Health, which follows a nationally representative cohort from 10th grade for 7 years. According, we examine over-time patterns and influences on adolescent and young adult behaviors, including substance use, diet, physical activity, sleep, and driving, including aggressive and distracted driving, and driving or riding while impaired. In recent analyses we reported prospective associations between cannabis use and other unhealthy behaviors (PMID: 29807247), high rates of street racing (PMID: 29709225), the association between personal income and substance use (PMID: 29578821), and high rates of impaired driving (PMID: 29553357). In other analyses we reported associations between sexual minority status and adolescent eating behavior and weight status (PMID: 30344031) and sexual minority status and disparities in school, work, residence and transportation (PMID: 30077549). Also, we reported rates of tobacco and cannabis use among high school students (PMID: 28742412), associations between perceived and actual peer norms and drinking among emerging adults (PMID: 29400594), and sleep insufficiency among emerging adults (PMID: 30098487).

Bruce Simons-Morton, Ed.D., M.P.H., *Senior Investigator*

KEY PUBLICATIONS

Gershon P, Ehsani J, Zhu C, O'Brien F, Klauer S, Dingus T, Simons-Morton B. Vehicle ownership and other predictors of teenagers risky driving behavior: Evidence from a naturalistic driving study. *Accident Analysis and Prevention.* 2018; 118:96-101. PMID: 29890369. PMCID: PMC6198648.

Simons-Morton B, Haynie D, Bible J, Liu D. Prospective Associations of Actual and Perceived Descriptive Norms with Drinking Among Emerging Adults. *Substance Use and Misuse.* 2018; 1-11. PMID: 29400594. PMCID: PMC6146965.

Tonja Nansel, Ph.D.

Poor diet quality, characterized by excessive intake of discretionary foods (i.e., nutrient-poor foods typically high in energy, added sugar, fat, and sodium) and inadequate intake of fruits, vegetables, and whole grains, is now the leading cause of global premature mortality.

Insufficient evidence exists to inform interventions to achieve sustainable improvements in diet quality. The goal of this research program is to address this critical knowledge gap by investigating neurobehavioral influences on eating behaviors in children and families and developing novel intervention targets to facilitate long-term dietary change. Current and recent projects include the Cultivating Healthy Environments in Families of Youth with Type 1 Diabetes Study (CHEF), the Pregnancy Eating Attributes Study (PEAS), and Sprouts: Development of eating behaviors in early childhood.

CHEF was a randomized controlled trial of a behavioral nutrition intervention targeting improved diet quality in families of youth with type 1 diabetes, for whom diet plays a critical role in disease management. The trial demonstrated the efficacy of a family-based behavioral intervention grounded in health behavior theories to improve overall diet quality and intake of whole plant foods (PMID: 25952160). Findings further indicated that diet quality improved most in children demonstrating "picky" eating behaviors, widely considered as more resistant to improvements in dietary intake (PMID: 29389510). Despite concerns that increased attention to diet may increase disordered eating, these behaviors did not increase due to the intervention (PMID: 29371234). Finally, secondary analyses in the past year suggest that worse diet quality in youth with type 1 diabetes is associated with less favorable cardiometabolic risk factors (PMID: 30347780), and that greater adiposity is associated with less favorable bone mineralization (PMID: 30114458).

PEAS was an observational prospective cohort study investigating relationships of food reward sensitivity, behavioral control, and the home food environment with dietary intake and weight change during pregnancy, postpartum, and infancy. Participants were enrolled early in pregnancy (before 12 weeks gestation) and followed, with their infants, until 1 year postpartum. Data collection was completed in fall 2018, and primary analyses are currently underway. The study includes data on dietary intake, anthropometrics, biospecimens, medical records, self-reported eating and other health-related behaviors, functional magnetic resonance imaging, focus groups, and an experimental measure of overeating.

Sprouts, a follow-up study of PEAS participants, is an observational prospective cohort study that will examine associations of neurobehavioral factors, parent feeding practices, and early life food exposures on dietary intake and growth during early childhood (ages 3-5 years). Dietary intake, anthropometrics, biospecimens, laboratory-assessed behavioral data, and parent-reported feeding/eating behaviors will be collected from PEAS mothers, children and co-parents.

Tonja Nansel, Ph.D.
Senior Investigator

The mission of the Contraceptive Development Program is to conduct innovative research to develop new methods of contraception for men and women.

NICHD is the lead Federal agency for conducting research on contraception. The Contraceptive Development Program (CDP) in DIPHR has the mission to advance clinical development of novel contraceptive methods for men and women. CDP scientists coordinate and integrate the Program's components to produce groundbreaking contraceptive research. CDP utilizes technology transfer mechanisms to form collaborative partnerships, translating discoveries and clinical advances into products that address unmet contraceptive needs of women and men.

CDP uses R&D contracts to achieve the goal of new contraceptive method development. The Program evaluates new drugs that are not commercially available and must be synthesized under current Good Manufacturing Practice (cGMP) as recommended by FDA guidance. CDP maintains a contracted Chemical Synthesis Facility to produce novel drugs required for the program. Potential new drugs and devices require toxicology testing to demonstrate safety. IND-enabling preclinical studies must be performed under Good Laboratory Practice (GLP) meeting regulatory standards. Human trials require formulation and release of agents under cGMP, and stability studies covering the duration of the trial. CDP maintains a Biological Testing Facility to perform preclinical evaluation and batch preparation required for first-in-human studies and longer toxicology studies for later Phase clinical trials.

The Contraceptive Clinical Trials Network (CCTN)

CDP's CCTN evaluates safety and efficacy of new contraceptive drugs and devices for women and men. Results from clinical trials on new entities form the basis for advancing candidate drugs and devices through development with the goal of FDA regulatory approval. The CCTN comprises top clinical investigators at qualified institutions, including both domestic and international sites, with expertise to conduct all phases of contraceptive evaluation, from first-in-human through Phase III. The clinical sites serve as the training ground for the next generation of investigators in the field.

Pipeline of New Contraceptive Methods for Women and Men

Product development is challenging and has a low success rate with drugs for disease conditions. Once a candidate is identified, ~10% pass pre-clinical testing to enter clinical testing; only 12% of those products complete Phase III and FDA submission. Contraceptives are used by healthy people for long durations; so, long-term safety is critical. CDP has a pipeline of products in clinical evaluation, including hormonal or non-hormonal options for women, and novel hormonal methods for men. In 2018, eight clinical trials were actively recruiting for safety and contraceptive evaluation of new drugs or devices in the CDP pipeline. New methods for women include a novel vaginal ring that can be used for three months or a method that protects against HIV infection as well as pregnancy. A trial to evaluate a novel transdermal hormonal male contraceptive method in couples seeking to prevent pregnancy is underway in three US sites and six international sites. Each product in development fills an unmet need or provides greater safety to vulnerable populations at risk of unintended pregnancy.
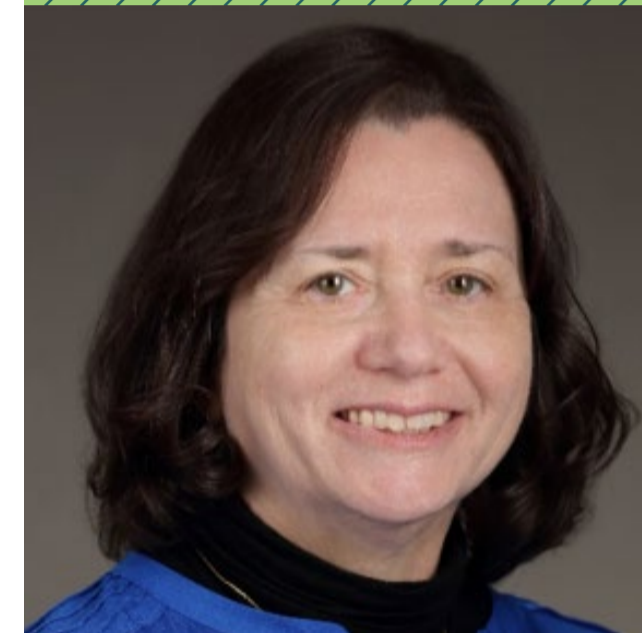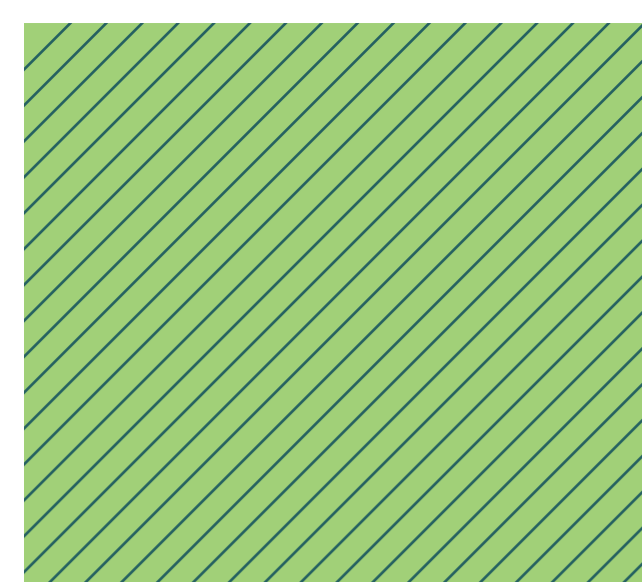
Diana Blithe, Ph.D.
Senior Scientist and Chief

STAFF
Jill Long, M.D., M.P.H., M.H.S.
Medical Officer

Min S. Lee, Ph.D.,
Chemist

KEY PUBLICATIONS
Male Contraceptive Development: Update on Novel Hormonal and Nonhormonal Methods. Long JE, Lee MS, Blithe DL. Clin Chem. 65:153-160, 2019. Review. PMID:30602479

Pipeline for contraceptive development. Blithe DL. Fertil Steril.106:1295-1302, 2016. Epub 2016 Aug 11. Review. PMID: 27523300

Diana Blithe, Ph.D.

Dr. Blithe and CDP collaborators develop contraceptive methods to address unmet needs for safety, acceptability and effectiveness. In the USA, 45% of pregnancies are unintended. One-third of reproductive age women are obese, increasing risks of diabetes, hypertension and venous thromboembolism (VTE). As risk factors increase, hormonal methods may be contraindicated; yet women face higher risks in pregnancy and need effective contraception.

INCREASING CONTRACEPTIVE OPTIONS FOR WOMEN
Contraceptive Vaginal Rings (CVR)

Nestorone®/Ethinyl Estradiol CVR provides a year of protection with advantages over existing rings: no refrigeration for storage; better for environment (dispose 1 ring vs 13 rings). Partnering with Population Council, Dr. Blithe's team conducted a pivotal efficacy trial. Substudies evaluated clotting factors, vaginal microbiome and endometrial safety. FDA approved the ring in 2018.

Nestorone®/17β Estradiol CVR provides protection for 3 months. Nestorone® blocks follicular development and 17-β estradiol supports bone health without increasing VTE risk. The ring is under evaluation for effectiveness over one year of use.

Multipurpose Prevention Technologies (MPT)
MPTs protect against pregnancy and infection from pathogens.

Dapivirine/Levonorgestrel (LNG) Vaginal Ring may provide 3 months of protection from both HIV infection and pregnancy. Preliminary evaluation of ovulation inhibition is underway.

Woman's Condom (WC). Dr. Blithe led a pivotal trial to determine acceptability and effectiveness of a novel female condom (WC) to prevent pregnancy and potentially transmission of infection.

Long-Acting Reversible Contraceptives (LARCs)
LARCs are the most effective and highly acceptable contraceptive methods for women. ParaGard Copper IUD is a safe option for women with health risks who wish to avoid pregnancy. Increased bleeding and cramping associated with Copper IUDs may deter use in nulliparous women, especially adolescents. In collaboration with Bill & Melinda Gates Foundation and FHI 360, CDP is comparing a Mini-Copper IUD with ParaGard in nulliparous women to determine effectiveness, bleeding characteristics and pain.

Progestin-only Contraception

LNG-Butanoate (LB) is being developed as a novel injectable method with no increase in VTE risk. Injections of long-acting LB may improve compliance over progestin-only pills, which require pill intake at the same time each day. LB injections suppress ovulation; studies are underway to optimize duration of action.

DEVELOPMENT OF CONTRACEPTIVE METHODS FOR MEN

The only reversible male contraceptive method is condoms, which have high failure rates and low acceptability for many men. High local testosterone (T) in testes supports spermatogenesis; lower T levels in serum maintain other androgen-dependent functions. Reversible contraception is achieved with exogenous progestins to suppress secretion of gonadotropins responsible for high T production, stopping sperm production. T replacement is delivered by injection or gel to maintain serum T-dependent functions.

Nestorone®/Testosterone (Nes/Tes) Gel. Dr. Blithe and the CDP-CCTN team demonstrated that Nestorone® (a potent progestin) and T gel caused gonadotropin suppression and inhibited sperm production. Normal sperm production recovered after treatment ended; thus, the regimen may be
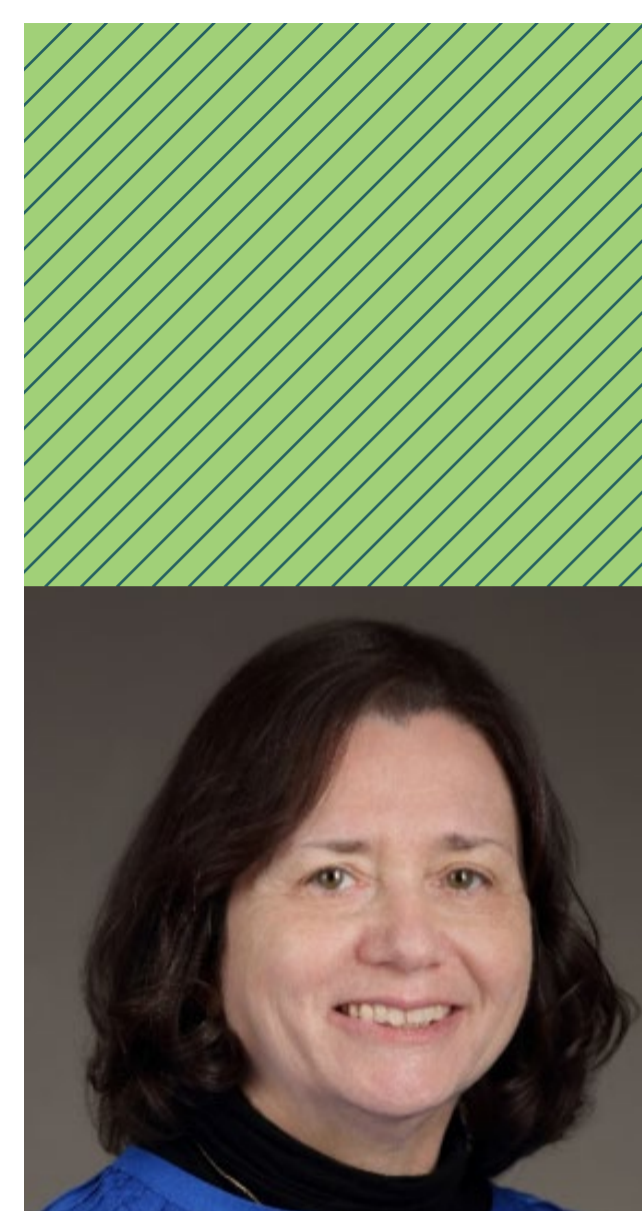
Diana Blithe, Ph.D.
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KEY PUBLICATIONS
Jensen JT, Edelman AB, Chen BA, Archer DF, Barnhart KT, Thomas MA, Burke AE, Westhoff CL, Wan LS, Sitruk-Ware R, Kumar N, Variano B, Blithe DL. Continuous dosing of a novel contraceptive vaginal ring releasing Nestorone® and estradiol: pharmacokinetics from a dose-finding study. *Contraception* 2018; 97:422-427. PMID: 29409834

Effects of 28 Days of Oral Dimethandrolone Undecanoate in Healthy Men: A Prototype Male Pill. Thirumalai A, Ceponis J, Amory JK, Swerdloff R, Surampudi V, Liu PY, Bremner WJ, Harvey E, Blithe DL, Lee MS, Hull L, Wang C, Page ST. *J Clin Endocrinol Metab.* 104:423-432, 2019. PMID: 30252061. Epub 2018 Sep 24.

Safety and Pharmacokinetics of Single-Dose Novel Oral Androgen 11β-Methyl-19-Nortestosterone-17β-Dodecylcarbonate in Men. Wu S, Yuen F, Swerdloff RS, Pak Y, Thirumalai A, Liu PY, Amory JK, Bai F, Hull L, Blithe DL, Anawalt BD, Parman T, Kim K, Lee MS, Bremner WJ, Page ST, Wang C. *J Clin Endocrinol Metab.* 104:629-638, 2019. PMID: 30252057; Epub 2018 Sep 24

effective and reversible for male contraception. In 2018, CDP began evaluation of Nes/Tes Gel for contraceptive effectiveness in couples willing to use this method for pregnancy prevention. Enrollment is ongoing in CCTN sites in the USA, UK, Sweden, Italy, Chile and Kenya.

Novel Progestogenic Androgens for Male Contraception

Dimethandrolone (DMA) and **11βMethyl Nortestosterone (MNT)** are novel agents with both androgenic and progestin activities, properties that suppress gonadotropins while maintaining androgen-dependent functions. CDP evaluated two pro-drugs (DMA-Undecanoate and MNT-Dodecylcarbonate). Oral and injectable routes of delivery are under evaluation.

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