Division of Epidemiology, Statistics, and Prevention Research (DESPR) NICHD

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TABLE OF CONTENTS

EXECUTIVE SUMMARY

The Division of Epidemiology, Statistics, and Prevention Research (DESPR) conducts a research program in the fields of reproduction and maternal and child health, as part of the intramural research component of the National Institute of Child Health and Human Development (NICHD). Historically, epidemiology and biometry appeared on the NICHD organizational chart in 1967 as the Epidemiology and Biometry Branch. The Branch became the Epidemiology and Biometry Research Program in 1970. The Program was renamed the Division of Prevention Research in 1990, and became the Division of Epidemiology, Statistics, and Prevention Research in 1991. Dr. Mark Klebanoff was appointed acting director in 1998, and director in 1999.

The Division consists of the following components:

- The Office of the Director (OD) provides overall supervision and guidance of the research activities of the Division. The OD contains the Computer Sciences Section (CSS), which provides first-line support to the Division regarding computer software, systems, and data management. The OD is also responsible for planning and coordinating the National Children's Study, the largest and longest health study of environmental effects on child health ever conducted in the United States. In addition, the OD contains the Collaborative Studies Unit, the extramural component of the Division that is responsible for managing the District of Columbia (DC) Infant Mortality Initiative. The OD maintains a small program of epidemiologic research, usually in collaboration with the other Branches of the Division.
- The Biometry and Mathematical Statistics Branch (BMSB) conducts research in statistical methodology and provides statistical consultation to the research staff of the Division and other components of the Institute. Methodological research projects of the Branch often derive from problems identified during consultations.
- The Epidemiology Branch conducts most of its research in the areas of human fecundity and fertility, pregnancy complications and adverse pregnancy outcomes, childhood injuries, and pediatric infectious diseases. The Branch also contains the Pediatric Epidemiology Section, which focuses on birth defects.
- The Prevention Research Branch provides a focus within the NICHD for behavioral research in health promotion and disease prevention. Its major interests lie in the prevention of problem behaviors among adolescents, reducing the risk of motor vehicle crashes among young drivers, and improving family management of childhood diabetes.

Major recent accomplishments of the DESPR include a substantial increase in involvement with training and an exemplary publication record of Division investigators (see *Appendix C*).

Over the past four years, the Division has substantially increased its number of trainees and has established procedures to assure effective mentoring of trainees during this phase of their careers. The Division has also taken a leading role in training outside the National Institutes of Health (NIH) by co-sponsoring, with the Institute of Human Development and Child and Youth Health (IHDCYH) of Canada, the First Summer Institute for Reproductive and Perinatal Epidemiology in 2005. Five Division investigators, along with four Canadian investigators, comprised the faculty of the Summer Institute, which provided a one-week training experience for 20 graduate students at leading institutions in the United States, Canada, South America, and Europe.

DESPR has also emphasized collaboration and communication among its investigators throughout the reporting period. In addition, Division personnel have continued extensive involvement in professional organizations, on advisory panels for various governmental agencies and foundations, and on editorial boards of professional and scientific journals.

The Division is most proud of the outstanding research that is conducted within DESPR itself. Division investigators have authored 268 peer-reviewed manuscripts from 2001 through 2004 (see *Appendix C*). Moreover, the Division's tenure-track investigators and postdoctoral fellows have been highly productive in a number of ways. For instance, investigators in the Epidemiology Branch have:

- Maintained a program of research examining the environmental determinants of fecundity and fertility, which continues to provide insight into the impact of environmental exposure on these problems.
- Made progress toward identifying angiogenic factors as potential predictors of preeclampsia.
- Progressed toward evidence-based definitions of labor protraction and arrest.

In the Prevention Research Branch, investigators have:

- Conducted an innovative program of research to address the leading cause of morbidity and mortality during late adolescence—automobile accidents; this research includes evaluation of a large-scale intervention and more detailed studies of the etiology of at-risk driving by adolescents.
- Begun to evaluate a clinic-based multi-site intervention designed to improve management of type 1 diabetes during late childhood and early adolescence.

DESPR is deeply involved in the mainstream of epidemiologic, prevention, and public health research. The remainder of this report summarizes the research accomplishments of the Division for the fiscal years 2001 through 2005.

OFFICE OF THE DIRECTOR (OD)

In addition to providing overall direction, guidance, and management to the Division, the OD maintains a small research program, which focuses primarily on risk factors for adverse pregnancy outcomes, with a main emphasis on abnormal genital flora, and, secondarily, on the long-term effects of intra-uterine factors. The OD is also responsible for planning and coordinating the National Children's Study. In addition, as mentioned, the Collaborative Studies Unit manages the DC Initiative to Reduce Infant Mortality in Minority Populations.

ABNORMAL GENITAL FLORA

Abnormal Genital Flora and Preterm Birth

The association between maternal genital tract infection and adverse outcomes of pregnancy is among the most active areas of investigation in both obstetrics and perinatal epidemiology. DESPR director Dr. Mark Klebanoff co-chaired the protocol subcommittee, as part of his role as a member of the steering committee for the NICHD Maternal-Fetal Medicine Units Network, that directed the recently completed randomized clinical trials of treatment of bacterial vaginosis and trichomoniasis during pregnancy to prevent preterm birth. Results of this trial were published in 1999 and 2001. During the past four years, several secondary analyses from this trial were also completed. For instance, DESPR investigators were first authors of one secondary analysis that described the natural history of spontaneous resolution of bacterial vaginosis during pregnancy. They reported that, contrary to findings from previous data, bacterial vaginosis was not more strongly associated with preterm birth when diagnosed very early in pregnancy, than when diagnosed later. DESPR investigators were co-authors on an additional five manuscripts derived from this study.

Longitudinal Study of Vaginal Flora

Bacterial vaginosis is associated with a variety of adverse health outcomes including preterm birth, miscarriage, pelvic inflammatory disease, postoperative infections of the genital tract, and HIV acquisition. However, little is known about how bacterial vaginosis is acquired and maintained, or why this condition is more than twice as prevalent among African American women compared to other women. To determine factors associated with the incidence of abnormal vaginal flora, researchers from OD and all three Branches of the Division collaborated in the Longitudinal Study of Vaginal Flora.

This study, conducted under contract with the University of Alabama at Birmingham, enrolled 3,620 non-pregnant women of reproductive age and followed them quarterly for one year. At each visit, investigators collected detailed information on behavioral, demographic, and microbiological factors to determine factors associated with the acquisition and maintenance of bacterial vaginosis. Within the past four years, investigators have published a manuscript describing the relationship of symptoms to the presence of bacterial vaginosis. Additional manuscripts reporting on the associations between contraceptive use and bacterial vaginosis, and between psychosocial stress and bacterial vaginosis incidence and remission are under review. Other manuscripts on douching as a risk factor for bacterial vaginosis, and on the association between periodontal disease and bacterial vaginosis are in preparation.

PREGNANCY AND CHILDHOOD EFFECTS OF INTRA-UTERINE EXPOSURE TO ORGANOCHLORINE COMPOUNDS

DDE (dichlorodiphenyldichloroethylene), a major and persistent metabolite of the organochlorine pesticide DDT (dichlorodiphenyltrichloroethane), has both estrogenic and anti-androgenic properties. These findings raise the possibility that DDE may contribute to genital tract malformations, such as hypospadias and cryptorchidism, as well as to a possible decline in sperm counts over the past 50 years. In addition, although several incidents of heavy exposure to

polychlorinated biphenyls (PCBs), a family of organochlorine compounds with many industrial uses, have resulted in reduced birth weight and adverse childhood neurodevelopment, the effects of more usual levels of these compounds are uncertain.

Division investigators, in collaboration with investigators from the Epidemiology Branch of the National Institute of Environmental Health Sciences (NIEHS), have utilized serum from the Collaborative Perinatal Project to address questions about these compounds and their effects on growth, development, and reproductive health. This serum bank is uniquely suited for such a project because relatively high levels of exposure to these organochlorine compounds were more common in the 1960s than more recently. In work published over the past four years, researchers have reported the following findings:

- Higher maternal serum concentration of DDE was associated with an increased risk of fetal death, but not with a clear increase in risk of androgen-related birth defects in male offspring.
- Higher maternal PCB concentrations were associated with slightly longer menstrual cycle length, indicating subtle effects on menstrual function.
- Women with the highest serum PCB concentrations took longer to become pregnant than women who had lower levels of serum PCB. However, maternal serum PCB concentrations were not associated with any adverse effect on the cognition, hearing, or physical growth of their children.

The National Children's Study

The National Children's Study is a long-term research project that will look at children's environments, and how those environments influence their health and development. For the Study, "environment" is defined broadly to include: physical surroundings; biological and chemical factors; geography; and social, educational, behavioral, familial, and cultural influences.

The Study, which was outlined in the Children's Health Act of 2000 (P.L. 106-310), is led by a consortium of federal agencies including the U.S. Department of Health and Human Services (NICHD and NIEHS at the NIH, and the Centers for Disease Control and Prevention) and the U.S. Environmental Protection Agency. The Study will involve a representative sample of 100,000 children from before birth to age 21 and their families.

Study leaders will award contracts for the initial Vanguard Centers and for a Data Coordinating Center at the end of fiscal year 2005. These Centers will work closely with the federal entities involved in the Study to refine both the initial study protocol and plans for enrollment and data collection. Enrollment is expected to begin in 2007, with up to eight Center locations, and will expand to more than 100 locations over a short period of time.

DC Initiative to Reduce Infant Mortality in Minority Populations

Through its Collaborative Studies Unit, the OD has continued to collaborate with the NIH Center for Minority Health and Health Disparities to sponsor the DC Initiative to Reduce Infant Mortality in Minority Populations. The Initiative is currently conducting data analysis from Phase II projects, while Phase III is starting up and continuing trials in three main research areas. Important findings from Phase I include:

- Among urban African American mothers who received inadequate prenatal care, mothers who chose to breastfeed were more educated, employed before birth, married, and used contraception postnatally.
- Mothers of infants in the intervention group initiated well-baby care when their children were at younger ages than controls.
- Infants in the intervention group had more frequent well-baby visits and were more likely to have completed their scheduled immunizations by age nine months.
- The highest risk for preterm birth, low birth weight, or small-for-gestational-age occurred in infants born to mothers who received no prenatal care and who tested positive for illicit drug use during pregnancy. As prenatal care levels increased, significant reductions in risk for preterm birth and low birth weight among infants exposed to illicit drugs during pregnancy were observed.

The results of this study indicate that access to care is less important than psychosocial factors in improving pregnancy outcomes.

In a separate part of the Initiative, the Cooperative Perinatal Studies and Interventions Project (called the Teen Moms Project) will conduct a community-based intervention for teen moms that aims to increase time between pregnancies. The project will also evaluate the effectiveness of the intervention in increasing healthy reproductive practices, communications skills, school attendance and/or employment, in addition to time between pregnancies among participants.

BIOMETRY AND MATHEMATICAL STATISTICS BRANCH (BMSB)

The BMSB is the statistical component of DESPR and is responsible for the statistical and applied mathematical activities of the Division. The mission of the Branch is to:

- Conduct research in statistical theory and methodology relevant to the research at the NICHD, particularly research in the areas of maternal and child health, growth and development, and related fields in DESPR;
- Develop quantitative procedures appropriate for application in biomedical and life sciences;
- Accomplish the statistical and applied mathematics activities of DESPR and, in particular, provide statistical expertise to DESPR investigators;
- Provide statistical consultation to NICHD staff;
- Consult and collaborate with intramural and extramural scientists on statistical and mathematical problems;
- Train junior statisticians through a program of postdoctoral fellowships and summer internships at all educational levels.

The Branch includes two tenured investigators (Drs. Kai Yu and James Troendle) and one tenure-track investigator (Dr. Aiyi Liu). Additional tenure-track recruitment is ongoing. Branch staff work closely with epidemiologists and prevention researchers in the role of statistical collaborators and act as the primary statisticians of the projects that the BMSB supports.

COLLABORATIVE AND CONSULTING ACTIVITIES

One primary goal of the BMSB is to provide statistical expertise to NICHD research activities through consultation and collaboration. Senior faculty members of the Branch provide statistical consultation and engage in independent statistical research with investigators inside and outside the NIH. The collaborative projects that BMSB supports are too numerous to list here, but this report includes several examples of projects with relatively unique statistical aspects to illustrate the contributions of the Branch to the work of DESPR and the NICHD. A more complete list of Branch activities is reflected in the *BSMB section of Appendix C*.

Preeclampsia

Investigators use the database and specimen repository from the Calcium for Preeclampsia Prevention (CPEP) Trial to evaluate the relationship of angiogenic factors to the pathogenesis of preeclampsia and their potential utility for identifying women at high risk of developing preeclampsia. Several important studies are under way on this topic, including case-control studies using the CPEP database, and planning for a future cohort study. A host of statistical techniques has allowed investigators to examine the levels of different angiogenic factors at different gestational ages. These techniques rely on a delicate balance between the cross-sectional nature and the longitudinal nature of the data used to make prediction of preeclampsia possible.

Graphical techniques introduced to analyze the data have resulted in fruitful discoveries. For example, the work demonstrated that the level of soluble fms-like tyrosine kinase 1 (sFlt-1) rises and the level of placental growth factor (PlGF) lowers more among women who later develop preeclampsia than among normotensive women, and that these changes occur some five weeks before the onset of preeclampsia. Smoothing techniques, such as the K-nearest neighbor non-parametric procedures, also allow researchers to study the change of the levels of the angiogenic factors during the course of pregnancy. Non-parametric hazard models enable the study of prediction of preeclampsia. Some techniques have been developed to minimize the expected value of the misclassification rate. These explorations have paved the way for a future cohort study on the prediction of preeclampsia using angiogenic factors.

Epidemiology of Bacterial Vaginosis

In ongoing analyses of newly collected data, investigators are exploring various aspects of abnormal genital tract flora, as well as the association among bacterial vaginosis, pregnancy outcome, and behavioral and biological factors associated with the acquisition, maintenance, and remission of bacterial vaginosis. Researchers have employed various models for the longitudinal study of bacterial vaginosis. In categorical or ordinal data, the modeling of correlation and the modeling of incidence requires more attention. One can no longer model them separately and combine them in an arbitrary way because the probability structure may not exist to accommodate them. A more sophisticated understanding of the mathematical foundation of the probability will enable researchers to sort out what is possible, and what may be inherently contradictory (in the mathematical sense). Combining the law of probability and the ideas of incidence and prevalence may also be important to study the onset, the recurrence, and other states of bacterial vaginosis.

Progression of Labor

In the management of active labor, it is important to know when to perform a cesarean section due to dystocia, or failure to progress. However, events such as cervical dilation are not observed continuously, but only intermittently when a woman is examined. If a parturient woman's cervix is 5 centimeters (cm) dilated at 1:00 PM and 7 cm at the next exam at 3:00 PM the actual time to progress from 5 cm to 6 cm can only be estimated. In addition, more data is available for a woman who progresses slowly because there is less change between examinations. A BMSB statistician addressed this problem by using an interval-censoring regression approach to study, with greater accuracy, the time to progress from one centimeter of dilation to the next. Researchers used this method to determine an updated description of natural labor progression and to evaluate the effect of analgesia on labor progression. Such methodology provides researchers with a new tool to study labor progression. Results from recent studies using this method have already made profound impact on obstetric practice and will be employed in the planned Safe Labor Project.

Hermansky-Pudlak Syndrome (HPS)

HPS is a genetic disease of the pulmonary system. The NICHD recruited patients into a randomized, double-blind, placebo-controlled trial of pirfenidone in the treatment of HPS. The primary outcome measure was forced vital capacity (FVC) of the lungs, followed longitudinally every four months. Investigators derived a repeated-measures model of FVC that included patient-to-patient variability in the slope and accounted for patient dropout in a robust manner. Results indicated that pirfenidone seems to benefit HPS patients by reducing loss of FVC.

Longitudinal Investigation of Fertility and the Environment (LIFE) Study

To date, the extent to which select environmental compounds bioaccumulate and biomagnify within the food chain, and the ensuing risks for human reproduction and development remain unclear; however, these issues serve as the impetus for study. The LIFE Study primarily addresses persistent and naturally occurring compounds capable of bioaccumulating in the environment, along with known and potential lifestyle behaviors believed to impact human reproduction and development.

A BMSB investigator has developed an analysis plan to address the statistical complexities of this project. First, the number of cycles required to become pregnant do not denote a purely continuous time, but rather provide only discrete values (e.g., 1 cycle, 2 cycles, etc.). The analysis will address this concern by utilizing methods designed specifically for such variables. Second, during their year of participation, a couple may experience an early pregnancy loss and then become pregnant again, resulting in two attempts at conception and two pregnancies that are not independent of each other. The analysis will address this concern primarily by using Generalized Estimating Equation methods. Third, many of the chemicals studied may be present in some of the participants at levels too low for current assays to detect. The proper way to analyze such values is controversial, so BMSB statisticians developed new methods specifically to address this problem. Fourth, the LIFE Study has several hypotheses, raising concerns that some outcomes may be significant by chance alone. Branch investigators will employ state-of-the-art methods to address this so-called "false discovery rate." Finally, any study that requires participants to submit information on a daily basis will have to face the problem of missing data.

BMSB statisticians will employ various methods, including multiple imputations, to enable subjects who have missed occasional days to be included.

STATISTICAL RESEARCH ACTIVITIES

Most methodological research problems the BMSB deals with are motivated by the consultative and collaborative projects mentioned in the previous section. As a result, the nature of the statistical research projects is quite variable. The following projects reflect the current research activities of the Branch members.

Multiple Comparison Procedures that Control the False Discovery Proportion or the Number of False Discoveries

In gene expression microarray experiments, often thousands of hypotheses are tested simultaneously to identify a small set of genes for further study. Branch staff developed stepwise permutation procedures to control, with specified confidence, the actual number of false discoveries or the actual proportion of false discoveries. The methods should aid researchers by allowing them to present more meaningful adjusted p-values for these tests.

A Likelihood Ratio Test for the Non-parametric Behrens-Fisher Problem

The non-parametric Behrens-Fisher hypothesis (NBFH) specifies that the probability an observation from one population exceeds an observation from a second population equals the probability of the reverse relationship. Using empirical maximum likelihood, researchers can find a likelihood ratio test numerically. The power compares favorably to the generalized Wilcoxon test, which is commonly used in such situations.

More recently, Branch efforts have extended the empirical likelihood approach to data with independent right censoring. For this work, Branch staff constructed a special imputed permutation, which has approximately the same property as an ordinary permutation. Findings indicated that tests had power similar to the logrank test when the alternative is of Lehmann type, and exceeded that of the logrank for non-Lehmann alternatives. Investigators also constructed tests for the NBFH by simulating, from the constrained empirical maximum, likelihood estimates of the underlying distributions.

Confidence Intervals for the Odds Ratio of Two Binomial Populations

The odds ratio is an important measure of association for prevalence case-control data because the risk ratio and risk difference are not estimable. Confidence interval methods based on asymmetric likelihoods are made more efficient when investigators simultaneously consider both tails. Shorter intervals can also be obtained using the method of maximization to eliminate the nuisance parameter from the likelihood. Combining the two gives unbiased intervals, which in simulation are shorter than any other existing unbiased method over a wide range of parameters.

Sequential Testing with Non-Transient Effects

In certain clinical trials, analysts assume that any efficacy found at one set time on treatment will continue, thus implying clinical superiority. Some trials are designed to stop early if efficacy is shown after an initial time on treatment. If not, then the trial follows the patients further and

tests efficacy again. The Bonferroni adjustment allows researchers to obtain critical cut-points for sequential testing that control the chance of a type I error for the clinical decision.

Slow Convergence of the Bootstrap in High Dimensions

Branch staff examined properties of two types of bootstrap applied to the maximum of a large number of two-sample t-statistics. Using the bootstrap resampling that is conservative may lead to dramatically lower power than a permutation test. Branch members explored some reasons for the behavior of the bootstrap tests and found that spurious correlation, carried forward into the bootstrap samples, at least partially explained the anti-conservative nature of the one bootstrap test.

Sample Size Calculation for Estimating the Reference Range

Reference ranges are commonly taken as the 2.5 percentile and 97.5 percentile points of a distribution. Branch members studied the problem of sample size calculation, when one is intending to use either a non-parametric or transformation to Gaussian method to estimate a reference range. Methods of calculation were considered that required the ratio for a reference limit of the 90-percent confidence interval width to the 95-percent reference range width to be small. The analysis found that the sample size calculations were greatly improved by the use of the bootstrap method.

Post-Test Analysis Following a Sequential Medical Study

For ethical, administrative, and economic reasons, sequential test designs are commonly used in clinical trials and other medical studies. As a result of interim looks at data, the conventional inference procedures are biased due to data-based random stopping of the sampling process. BMSB members have developed various bias-reduced methods for both primary and secondary endpoints of various types (e.g., normal, binary, etc.).

Receiver Operating Characteristic (ROC) Curves Analysis and Diagnostic Biomarkers

Sensitivity and specificity are two key features for evaluation of diagnostic biomarkers. For biomarkers with continuous measurements, the plot of sensitivity against one minus specificity over all possible values of the biomarker results in an ROC curve of the biomarker. BMSB members developed sequential testing procedures for comparing the area of two ROC curves. The investigators also developed methods for combining multiple biomarkers to achieve locally optimal sensitivity, for non-parametric inference on linear combinations of biomarkers, and for designs of studies with pooled measurements in the context of ROC curve areas.

Statistical Methods for Analysis of Pooled Data

In case-control studies, to determine the association between exposures and diseases, the values of the exposures are often pooled (in an effort to reduce study cost). As a result, one observes not the individual values of exposure, but the average of several individual values. BMSB members developed both parametric and non-parametric methods to recover the distribution from pooled data.

Multistage Evaluation of Measurement Errors

In epidemiologic studies evaluating the association between outcomes and exposures, measurements of exposures are often subject to error. Accurately assessing the amount of error and adequately correcting such error is important because otherwise substantial bias may be introduced to the estimates of regression coefficients or relative risks, as well as sample size and power. BMSB members developed sequential testing procedures for the planning and analysis of reliability studies to assess an exposure's measurement error. They developed methods and tabulated critical values for a number of two-stage designs.

Distribution-Free Estimation of Maximum Linear Separation of Two Multivariate Distributions

BMSB members investigated linear separations of two continuous multivariate distributions. Under mild conditions, the optimal linear separation exists uniquely. A kernel-smoothed approach was proposed to estimate the optimal linear combination and the corresponding separation measure. The proposed method yielded consistent estimators, allowing construction of confidence intervals. In applications to diagnostic medicine problems, the suggested technique provides the maximum area under the so-called ROC curve based on linear combinations of biomarkers.

Non-parametric Deconvolution of Density Estimation Based on Observed Sums

This research develops methodologies for distribution-free estimation of a density function based on observed sums or pooled data. The suggested technique is an extension of constricting empirical distribution functions. Important applications of the proposed methodology are inference on ROC curves in the presence of pooled data. The methods are exemplified using data from a study of biomarkers associated with coronary heart disease.

Adaptive Change Point-Detection Policy Applied to a Limit of Detection Problem

BMSB members, in collaboration with Epidemiology Branch staff, proposed generalized classical maximum likelihood tests for homogeneity of the observed sample in a simple form that avoids the complex direct estimation of unknown parameters. An application of the problem is an issue related to limits of detection connected to measurement error effects in occupational medicine.

Longitudinal Data Analysis

This ongoing project investigates theory, methods, and applications of statistics and probability with current emphasis on longitudinal data analysis. The major motivating examples for applications are the following two NICHD studies: the Successive Small-for-Gestational-Age Study (in Alabama and Scandinavia), and the Longitudinal Study of Vaginal Flora.

EPIDEMIOLOGY BRANCH

The mission of the Epidemiology Branch is threefold: 1) to conduct timely epidemiologic research initiatives focusing on reproductive, perinatal, and pediatric health endpoints that identify underlying etiologic mechanisms, on at-risk subgroups, and on interventions aimed at diagnosing or treating disease using state-of-the-art methodologies; 2) to provide professional service within and outside the NIH community; and 3) to support the training mission of the NIH by recruiting and mentoring interns and fellows interested in careers in reproductive, perinatal, or pediatric epidemiology.

The Epidemiology Branch currently comprises 11 full-time research positions, including three tenured investigators (Drs. Germaine Buck Louis, Richard Levine, and James Mills), three tenure track investigators (Drs. Ruth Brenner, on leave to the National Children's Study, Enrique Schisterman, and Jun Zhang), and five individuals in other professional research positions (Drs. Mary Hediger, Kimi Lin, Courtney Lynch, Gitanjali Saluja, and Ms. Mary Conley). Dr. Germaine Buck Louis is the chief of the Epidemiology Branch and is administratively responsible for the Branch portfolio and for ensuring the Branch meets its stated mission.

Epidemiologic research initiated and conducted by Branch investigators focuses on three predominant themes—reproductive health, obstetric and perinatal outcomes, and child health—that reflect the Branch's mission with regard to reproductive, perinatal, and pediatric epidemiology. In pursuit of the Branch's mission, its staff have received numerous awards in recognition their research accomplishments (see *Appendix B*).

With regard to professional services, the Branch plays an active role within and outside the NIH and the NICHD. Examples of the types of service include grant review, standing and temporary committee representation, and service for other governmental agencies, other health organizations, the National Academies, and professional societies.

Of particular note is the Epidemiology Branch's commitment to the NIH training mission. Since 2000, the Branch has mentored 10 postdoctoral fellows, six predoctoral fellows, and two post-baccalaureate fellows. In addition, the Branch has mentored 35 summer interns and four other interns, most of whom produced publications reflecting collaborative research with their mentors (see the *Branch section of Appendix C*). Three predoctoral fellows have also received awards from professional societies in recognition of their research excellence.

The Epidemiology Branch has also organized workshops to focus on critical and pressing data gaps that face epidemiologic studies of health and disease endpoints responsive to the Branch mission. Workshops vary from highly biologic to methodologic. Of note in this area is the Branch's involvement (particularly the efforts of Drs. Buck Louis, Mary Hediger, Mark Klebanoff, Enrique Schisterman, and Jun Zhang) in the development of the First Summer Institute in Reproductive and Perinatal Epidemiology, a program offered jointly by the NICHD and the Institute of Human Development and Child and Youth Health (IHDCYH) of Canada. From a candidacy pool of 88 applicants, 20 students were selected to participate in this intensive training program. The Branch plans to continue to offer this Summer Institute annually in

conjunction with the IHDCYH to foster research interest in reproductive, perinatal, and pediatric epidemiology. An overview of the Branch's etiologic and methodologic research accomplishments in reproductive health, obstetric and perinatal outcomes, and child health follows.

REPRODUCTIVE EPIDEMIOLOGY

PCBs and Endometriosis

An evolving body of evidence from experimental laboratory animals, primates, and humans suggests an environmental etiology for endometriosis, particularly involving hormonally active agents such as PCBs. Using a cohort of women who underwent laparoscopy for suspected endometriosis, Branch investigators explored the relation between PCB congeners and risk of endometriosis in the context of other lifestyle factors. Researchers interviewed 84 women prior to their undergoing a laparoscopy and collected blood specimens for toxicologic analysis. Risk of endometriosis was significantly elevated (greater than three-fold) for women whose anti-estrogenic PCB levels were in the highest tertile in comparison to women whose levels were in the lowest tertile. Risk remained elevated after controlling for gravidity, current cigarette smoking, and serum lipids; the confidence interval included 1.0. These data support a possible relation between anti-estrogenic PCBs and endometriosis. The outcomes await confirmation in larger studies.

In a subsequent analysis, women with endometriosis were found to have a lower body mass index, both at the time of diagnosis and historically, in comparison to women who underwent laparoscopy but who did not have the disease. These findings suggest that endometriosis may have an intra-uterine or early childhood origin, thus underscoring the need to identify critical early windows relevant for gynecologic health.

Epidemiologic investigation that focuses on an environmental etiology of endometriosis is challenging given that diagnosis requires laparoscopic confirmation (limiting options for sampling frameworks) and the degree of error associated with the quantification of PCB concentrations at the lower bound of the exposure distribution. The Epidemiology Branch currently conducts methodological research to resolve these issues. Specifically, Branch investigators examined the relation between PCB concentrations in serum and omentum fat removed at laparoscopy to determine how well serum measures reflect the body burden of these chemicals. Of the 20 organochlorine compounds analyzed, 29 percent were present in both serum and fat samples; moderate linear correlations ($r > 0.6$) were observed between lipid adjusted serum and fat concentrations for PCBs numbered 138, 153, 180, 188, 194, 206, and for DDE. In addition, 49 organochlorine compounds were present in adipose samples, but measured below the limits of detection in serum samples. These findings underscore the potential for discrepant estimation of human health effects based on the medium used to quantify exposure.

The Epidemiology Branch will launch a newly designed study to determine the relation among environmental chemicals, endometriosis risk, and severity of disease, while also exploring new options for diagnosing disease in population-based research. This effort will likely begin in 2006.

The LIFE Study

The LIFE Study is a prospective cohort study that seeks to recruit 1,000 couples, from counties in Michigan and Texas, who live in close proximity to bodies of water where exposure to persistent environmental compounds is presumed likely. Couples from medically underserved or socioeconomically disadvantaged areas are of particular interest, given that many of these subpopulations are disproportionally exposed to environmental toxins and under-represented in many prospective pregnancy studies. The study will recruit couples prior to discontinuing contraception for the purpose of becoming pregnant and will follow them through 12 months of trying, and throughout pregnancy for couples that achieve pregnancy (estimated 80 percent of couples). The LIFE Study's primary outcomes of interest include: time-to-pregnancy; pregnancy loss as measured by a human chorionic gonadotropin (hCG) confirmed pregnancy; infertility or the absence of an hCG-confirmed pregnancy after 12 at-risk menstrual cycles; and decrements in gestation or birth weight for couples who have a live born infant.

Couples will participate in a 25-minute baseline interview and will receive instruction on the use of home fertility monitors and pregnancy test kits for counting the time required for pregnancy and for detecting pregnancy, respectively. Investigators will collect blood and urine samples at baseline from both partners of the couple to measure environmental exposures (for example, organochlorine pesticides, PCBs, polybrominated diphenyl ethers, metals, perfluorinated compounds, cotinine, and phytoestrogens). They will also request two semen samples from male partners and two saliva samples from female partners. Using the semen samples, researchers will globally assess male fecundity as measured primarily by sperm concentration and morphology; using the saliva samples, they will measure cortisol levels as a marker of stress among female partners to assess the relationship among environmental factors, stress, and human reproduction at a later time.

The findings from the LIFE Study will provide valuable information regarding the effects of environmental contaminants on sensitive markers of human reproduction and development and will fill critical data gaps. Moreover, the researchers will analyze these environmental exposures in the context of other lifestyle exposures, such as use of cigarettes and alcohol, consistent with the manner in which human beings are exposed. Recruitment of couples will commence in 2005. More information on the LIFE Study is available at *http://www.lifestudy.us*.

Oxidative Stress as Mediator of Reproductive Outcomes

Oxidative stress is implicated as a risk factor for a variety of gynecologic disorders (for example, endometriosis) and adverse pregnancy outcomes (for example, pregnancy loss). No research to date has investigated factors or processes that lead to increased oxidative stress in women of reproductive age. To this end, the Epidemiology Branch is exploring the relation between hormonally active environmental agents, such as PCBs and other organochlorines pesticides, and oxidative stress, and, subsequently, the effects on two reproductive outcomes: endometriosis and time-to-pregnancy. A goal of this avenue of research is to assess the relation among environmental toxicants, oxidative stress, and reproductive outcomes. This assessment will build on two recently completed studies in which environmental chemicals were quantified for study participants and necessary covariate data are available. Branch investigators are using directed acyclic graphs to aid in visualizing causality and to help in the evaluation of research questions.

BioCycle Study

In scientific literature, oxidative stress is shown to be involved in a variety of health outcomes. Oxygen free radicals, which are the actual agents of cellular damage, cannot be directly measured; the radical species are quickly converted into more stable molecules. As a result, there is controversy regarding appropriate methodology for quantifying levels of oxidative stress in relation to health risk. In women, this issue is further complicated by endogenous sex hormones, which play a strong role balancing oxidative stress levels; sex hormone levels are not static during the menstrual or ovarian cycles.

To address these issues, Branch investigators initiated the BioCycle Study, which will measure multiple markers of oxidative stress in a cohort of 250 women of reproductive age over the course of two menstrual cycles. The findings will provide a clearer picture of the role of oxidative stress in female reproductive function with respect to normal variation within and between women. Additionally, the results of this study may pioneer a way for the conduct of future research in the area of oxidative stress and women's health.

A Pilot Study on Early Indicators of Polycystic Ovary Syndrome (PCOS)

Because its signs may first appear at puberty, PCOS is generally considered a disease of adolescence or adults; but some work suggests that its origins may be earlier, and that signs (e.g., polycystic ovaries, insulin resistance) may be detectable in childhood. The question remains whether ovarian enlargement or the appearance of polycystic ovaries precede, are subsequent to, or are unrelated to the development of insulin resistance, central adiposity (visceral fat), and dyslipidemia in young girls.

Branch investigators are collaborating with a research team at the Cincinnati Children's Hospital Medical Center to support the assessment of central adiposity (by ultrasound or magnetic resonance imaging), ovarian morphology, and biomarkers of insulin resistance. The investigators will study a cohort of about 200 to 400 elementary-school aged white and African American girls, ages seven to eight years, who will also be evaluated longitudinally for pubertal development. The findings from this project will serve either as a basis, or as a pilot for the development of a definitive study on the prepubertal and early pubertal biomarkers and clinical signs of PCOS.

PERINATAL (OBSTETRIC) EPIDEMIOLOGY

A significant source of data regarding the etiology of preeclampsia is the Calcium for Preeclampsia Prevention (CPEP) Trial, a double-blind randomized clinical intervention trial. This trial, completed in 1996, randomized 4,589 healthy nulliparous women to receive a daily supplement of 2,000 mg of calcium or a placebo. Overall, the trial failed to observe either a reduction in the incidence or severity of preeclampsia or a delay of its onset. Investigators are now using biospecimens from the CPEP repository to explore new etiologic links, such as the placental growth factors described in the following two Branch-conducted studies.

Circulating Angiogenic Factors and the Risk of Preeclampsia

The hypertensive syndrome of preeclampsia may result from high concentrations of soluble fms-like tyrosine kinase 1 (sFlt1) in maternal blood. sFlt1, an anti-angiogenic protein, binds the pro-angiogenic proteins, vascular endothelial growth factor (VEGF) and placental growth factor (PlGF). This binding prevents their interaction with endothelial cell receptors and, thereby, induces endothelial dysfunction.

Branch investigators performed a case-control study of preeclampsia nested within the CPEP Study. They found that, during the last two months of pregnancy in normotensive control women, the concentration of sFlt1 increased and the concentration of free PlGF decreased. These changes occurred earlier and were more pronounced in the women for whom preeclampsia later developed. sFlt1 levels increased beginning approximately five weeks before the onset of preeclampsia. Free PlGF levels were significantly lower in the women who later developed preeclampsia than in the women who remained normotensive during pregnancy, with the greatest difference occurring during the five weeks before the onset of preeclampsia, coincident with the increase in the sFlt1 level. Alterations in the levels of sFlt1 and free PlGF were greater in women who had an earlier onset of preeclampsia and in women for whom preeclampsia was associated with delivery of a small-for-gestational-age infant. Increased levels of sFlt1 and reduced levels of PlGF predicted the subsequent development of early onset preeclampsia. This finding, especially in concert with observations of reduced PlGF in urine during midpregnancy and in weeks before the onset of preeclampsia, may lead to the development of a predictive test for preeclampsia; and, based on these findings, a pharmaceutical company has begun development of a treatment.

Urinary PlGF and the Risk of Preeclampsia

In the case-control study described above, investigators also analyzed urine specimens, obtained before labor or delivery, for concentration of PlGF. In women who remained normotensive during pregnancy, concentrations of urinary PlGF increased during the first two trimesters, peaked at 29 to 32 weeks of gestation, and decreased thereafter. Among women who subsequently developed preeclampsia, the pattern of urinary PlGF was similar, but levels were significantly reduced beginning at 25 to 28 weeks' gestation. Decreased urinary PlGF at mid-gestation was strongly associated with subsequent early development of preeclampsia.

A Multi-Center Randomized Clinical Trial on Management of Early Pregnancy Failure

Miscarriage occurs in approximately 15 percent of all clinically recognized pregnancies, and its cause is often unknown. Clinical treatment following pregnancy failure has included either expectant management or surgical intervention, such as dilation and curettage (D&C). In recent years, clinicians have begun to question whether immediate evacuation by surgical intervention is necessary for uncomplicated cases of early pregnancy loss. Although expectant management is clearly an option for incomplete miscarriage, its success rate for embryonic/fetal demise or anembryonic gestation ranges from 25 percent to 76 percent; further, the interval to spontaneous expulsion is unpredictable and may take up to one month. Therefore, expectant management is less appealing than surgical treatment to some women who experience pregnancy loss given an uncertain duration for completion.

The Branch successfully conducted a multi-center randomized clinical trial comparing misoprostol treatment with vacuum aspiration for early pregnancy failure. In the study 652 women were randomized to medical/treatment arm or surgical management/control arm (491 and 161 women, respectively) at four U.S. hospitals. The study showed that treatment of early pregnancy failure with misoprostol (800 μg vaginally) and repeated after 48 hours, when necessary, was efficacious and safe. Specifically, the success rate was 84 percent for the treatment arm and 97 percent in the control arm of the trial. The risks for hemorrhage or pelvic infection were less than or equal to 1 percent, or comparable to vacuum aspiration. Women reported that side effects associated with misoprostol treatment were minimal and that the treatment was tolerable.

Consortium on Safe Labor

In the past half-century, labor and delivery practices have been influenced by the Friedman Curve, a mathematical model of how the stages of labor should progress during normal delivery that was originally created in the early 1950s. However, labor management has changed substantially since then, in part, reflecting changes in the obstetric population, such as increased obesity and more advanced age. To determine the usefulness of the Friedman Curve to modern obstetrics, the Branch reevaluated the labor curve and found that the definitions of labor protraction and arrest were too stringent for contemporary clinical management of parturient women, thus underscoring the need for new evidence-based definitions of labor protraction and arrest. To address this data gap, Branch investigators are planning a large multi-center observational study to collect existing medical record data on approximately 200,000 deliveries from several U.S. hospitals. The research will involve digitized tracings of labor progress from patients at multiple hospitals; the investigators will then collate and merge the data electronically with post-pregnancy and neonatal records. Advanced statistical methods, such as interval-censored regression, will allow the researchers to examine labor progression and to, possibly, redefine labor protraction and arrest. The ultimate goal is to identify a meaningful cut point for operative intervention, meaning that these findings may have a profound effect on decisions about the need for cesarean delivery.

Early Pregnancy Loss and Folate Status

Women who had a spontaneous abortion between gestational ages six and 12 weeks and whose pregnancies had been confirmed by hCG tests were identified at the Department of Obstetrics and Gynecology of Uppsala University Hospital, Sweden. Control pregnancies were primarily selected from pregnant women who sought prenatal care and were frequency-matched to cases by gestational week; fetal viability in controls was verified by ultrasound.

Branch investigators found that low folate levels were associated with a significantly increased risk of miscarriage when the fetal karyotype was abnormal (odds ratio 1.95), but not when the fetal karyotype was normal (odds ratio 1.11). Thus, in some cases, low plasma folate levels were associated with an increased risk for early miscarriage. High plasma folate levels were not associated with an increased risk for miscarriage, although the highest levels seen in the Swedish population were lower than the highest levels present in the U.S. population.

PEDIATRIC (CHILD AND ADOLESCENT) EPIDEMIOLOGIC RESEARCH

Branch research on children, generally defined as being from infancy through adolescence, focuses largely on four areas: 1) infectious diseases, often in collaboration with NICHD's Laboratory of Developmental and Molecular Immunity (LDMI); 2) birth defects; 3) injuries and drowning; and 4) growth, development, and behavior. The following section describes some of the Branch's research in these areas.

Phylogenetic Lineages of Group B Streptococcus (GBS) and Early Onset Disease

GBS is the most common cause of bacterial disease in newborns; many infants acquire this infection in the intra-uterine environment or during birth. Genetics studies have suggested that one phylogenetic lineage of serotype III GBS is highly virulent, but more recent studies failed to confirm this observation. Branch investigators, in collaboration with researchers from the University of Utah, used multi-locus sequence typing to examine a large sample of serotype III GBS collected from a NICHD multi-center study and identified a lineage that is associated with invasive GBS disease in newborns. Unlike earlier studies, this study used serotype III GBS isolates that were prospectively and systematically collected from newborns with early onset disease, and from newborns colonized with GBS but who did not develop the disease.

Sialic Acid O-Acetylation and the Immunogenicity of GBS

The capsular polysaccharide of GBS is the primary antigen used for GBS vaccine development. A recent discovery showed that a significant portion of the sialic acid residues on GBS capsules is O-acetylated, and that the O-acetylation occurs at varying levels. In other species of bacteria, O-acetylation is related to the bacteria's ability to induce antibody response in humans. Branch investigators, in collaboration with University of California, San Diego researchers, are studying the correlation between the degree of O-acetylation of GBS and the type-specific immunoglobulin G (IgG) antibody levels in mothers who carried GBS. The results of this study may have important implications for GBS vaccine development.

Using Polysaccharide Conjugate Vaccine to Protect Children from Typhoid Fever

Typhoid fever, caused by *Salmonella typhi*, remains a common, but serious infection for children throughout the developing world. Resistant strains of typhoid fever are difficult to treat, so promising vaccines can offer hope to many. The existing typhoid vaccine, Vi polysaccharide vaccine, conferred about 70-percent protection to adults and to children five years and older. To address the protection of children younger than age five, LDMI scientists linked Vi to a recombinant exoprotein A of *Pseudomonas aerginosa* (Vi-*r*EPA) to develop a conjugate vaccine. Branch investigators, in collaboration with LDMI scientists, conducted phase I, phase II safety and immunogenicity studies, and a randomized double-blind efficacy trial of the conjugate vaccine. The trial included approximately 12,000 children, ages two to five years, in Vietnam. At 27 months after vaccination, the vaccine had an efficacy of 91 percent, the highest ever reported for typhoid vaccine and the first positive outcome demonstrated in children younger than five years of age. A follow-up of the children at 46 months after vaccination showed an efficacy of 89 percent.

The standard typhoid conjugate vaccine contains 25 µg of Vi. Studies of other conjugate vaccines indicated that larger doses of polysaccharide in the vaccines elicited antibodies for

longer periods. To determine if this relation applied to the Vi-rEPA conjugate vaccine, Branch investigators, again collaborating with LDMI scientists, conducted a study of the safety and immunogenicity of vaccines with different doses of Vi in Vietnamese children, ages two to five years. The results showed that at one year after vaccination, the average level of IgG anti-Vi was not significantly different between the lower dose (12.5 µg of Vi) and the existing standard dose.

Plans are now under way to evaluate the safety, immunogenicity, and compatibility of Vi-*r*EPA, when it is injected into infants concurrently with Diptheria-Tetanus-Pertussis (DTP) vaccination according to the routine immunization schedule. The study will randomize 300 healthy full-term newborns to receive either Vi-*r*EPA, *Hemophilus influenzae* type b conjugate vaccine concurrently with DTP, or DTP alone at two, four, and six months of age. The infants in the conjugate vaccine groups will receive vaccinations with the same conjugate again at one year of age.

Genetic Risk Factors in Children with Neural Tube Defects (NTDs)

Previous studies, several of which were conducted by Branch investigators, showed that both the homozygous (TT) and heterozygous (CT) forms of the methylenetetrahydrofolate reductase (MTHFR) C677T single nucleotide polymorphism (SNP) are associated with lower tissue concentrations of folate and lower enzyme activity than the non-variants. Branch researchers sought to explore the possibility that the CT form would be a risk factor for NTDs as well. The investigators found that the CT genotype was associated with a significantly increased risk of NTDs. In fact, calculations revealed that the CT genotype was responsible for at least as many NTDs in the population as the TT genotype (14.9 percent versus 11.3 percent, respectively). These results show that the population at increased risk—and the population that will benefit from food fortification—is much larger than previously appreciated.

Methyleneterahydrofolate dehydrogenase (MTHFD1) is an enzyme critical to the synthesis of purines, pyrimidines, and, consequently, deoxyribonucleic acid (DNA). Therefore, this enzyme gene is also an attractive risk factor candidate for NTDs. Branch investigators found that mothers of children with NTDs had a higher frequency of the homozygous (QQ) form of the SNP MTHFD1 R653Q than control mothers, whose children did not have NTDs. Surprisingly, there was a lower number of QQ cases overall than expected. Thus, the study revealed an overrepresentation of the homozygous variant in mothers of children with NTDs, but an under-representation in cases overall. Although unusual, this outcome suggests that the QQ variant may be lethal for some fetuses, while the QQ variant in mothers is a risk factor for their having children with NTDs.

Intra-Uterine Alcohol Exposure and Child Health

This NICHD-University of Chile Alcohol in Pregnancy Study was designed: to identify women who drank heavily during pregnancy; to look at multiple outcomes in their children, including peripheral neuropathy, growth-related hormone levels, timing of development of fetal alcohol syndrome (FAS) features, and ophthalmologic problems; and to examine the effect of patterns of drinking on fetal outcomes. The study researchers began by screening 9,628 women who came to a clinic in Santiago, Chile, for prenatal care. After interviews in the clinic, the study team visited 887 women at their home to identify very heavy drinkers ($\geq$ 48 g per day). In all, they identified 101 such drinkers, advised the women of the need to stop drinking, offered counseling,

and recruited them for the study. The study group then found 101 matched non-drinking control subjects via the same mechanisms. The study team has followed all the children since delivery, but is blinded to their alcohol exposure status. Researchers have conducted genetic/dysmorphology examinations, including facial photographs for computer reading, developmental examinations, and neurologic and nerve conduction studies in the children.

In adults, peripheral neuropathy has long been recognized as a complication of high alcohol consumption; however, researchers have never reported nerve-conduction studies in children exposed to alcohol prenatally. The NICHD-Chile study investigators performed nerve-conduction velocity studies in newborns, and again when the infants were between 12 to 14 months of age, to see whether prenatal alcohol exposure could cause peripheral nerve damage. The alcohol-exposed children had poorer results at the newborn examination; these results did not improve at one year. Thus, abnormal peripheral nerve conduction should be added to the list of complications of prenatal alcohol exposure.

Epidemiology and Prevention of Childhood Drowning

Unintentional injuries are the single leading cause of death among children, and drowning is the second leading cause of death from unintentional injury. Drowning rates are particularly high among toddlers and among adolescent males. During the past four years, Branch investigators have continued investigations of the epidemiology of childhood drowning with the goal of providing information that could lead to more effective prevention strategies.

Although four-sided fencing around swimming pools is a known effective strategy for prevention of drowning among toddlers who gain unauthorized access to a pool, rates of drowning remain consistently high among this age group—a fact that suggests a need for additional preventive strategies. One potential strategy is increasing the children's swimming ability through participation in swimming lessons. A study that elucidates the relation between swimming lessons and a reduced risk of drowning would provide the scientific basis for guidelines and policies about swimming lessons for young children; such policies could potentially save many young lives. Furthermore, due to the rarity of the outcome, a carefully designed case-control study is the most appropriate manner in which to evaluate risk factors associated with childhood drowning. Epidemiology Branch investigators conducted a pilot study to determine the feasibility and costs of conducting a case-control study to evaluate the effect(s) of swim lessons on drowning risk among young children. Based on the results of the pilot study, researchers designed a full case-control study.

Participating Medical Examiners' offices in 18 jurisdictions (142 counties) across the United States identify drowning victims, while random-digit dialing identifies appropriately matched controls. Researchers then conduct structured interviews with families of case and control children to identify risk and protective factors for childhood drowning. Data collection began in 2003 and is expected to continue through late 2005.

In a separate study conducted in collaboration with the Consumer Product Safety Commission, Epidemiology Branch investigators examined the circumstances surrounding deaths in swimming pools among older children (ages 5 to 19 years). Researchers abstracted information from death certificates, newspaper clippings, and medical examiner reports for deaths resulting

from unintentional drowning in a swimming pool. Investigators found that drowning rates in swimming pools were unexpectedly high among foreign-born youth and were highest among African American males. A much higher proportion of drowning among African American youth occurred in publicly accessible pools, compared to drowning among white youth, who were more likely to drown in private pools. These findings elucidate the need for targeted drowning prevention efforts because different population subgroups have unique risks.

Health Behavior in School-age Children (HBSC) Study

The HBSC study is a cross-national research survey conducted in collaboration with the World Health Organization Regional Office for Europe. Initiated in 1982 in three countries, the HBSC now includes more than 35 participating countries and regions. The United States mounted a demonstration survey in 1996 and has been a fully participating member since 1997. The United States contributes to the international survey while simultaneously supporting a nationally representative school-based survey of nearly 15,000 students in grades six through ten using an enhanced protocol. The most recent survey, completed for the 2001-2002 school year, was partially sponsored by the Epidemiology Branch; DESPR's Prevention Research Branch plans another round of surveys for the 2005-2006 school year.

Major findings by Branch investigators include the following:

- An analysis of the 1996 survey found that, for students in grades six, eight, and ten, 18 percent of adolescents reported symptoms of depression, representing 25 percent of females and 10 percent of males. The study concluded that depression is a substantial and largely unrecognized problem facing adolescents, even young adolescents.
- A second key finding stems from 1997-1998 HBSC international data from which investigators calculated BMI (kg/m^2) from self-reported height and weight and compared the prevalence of overweight, a BMI at or above the 95^{th} percentile, among 29,242 boys and girls, ages 13 and 15 years, in 15 countries or regions of Europe and the United States. The study revealed the highest prevalence of overweight in the United States, followed by Ireland, Greece, and Portugal, and the lowest in Lithuania. The prevalence of overweight in the United States ranged from 11 percent to 15 percent at various ages, far exceeding the 5 percent expected at or greater than the 95^{th} percentile.
- Analyses using the 2001-2002 United States data examined the timing of pubertal maturation in association with risky behaviors in adolescence. The analysis found that more mature boys with facial hair and post-menarcheal girls at every age were nearly twice as likely or more to have ever smoked or to report getting drunk. An increase in the prevalence of risk behaviors in early adolescence may be a consequence of secular trends toward earlier pubertal maturation.

METHODOLOGIC RESEARCH

This body of Branch research focuses on methodologies for improving assessment of exposures, regardless of study endpoint, and strategies for reducing measurement error.

Epidemiological Methods for Modeling of Laboratory Exposure Measurements

Epidemiological studies concerned with the evaluation of human health risks due to certain exposures often rely upon laboratory measurements that use biospecimens, often present at very low concentrations. Branch investigators have found that using a limit of detection, as estimated by laboratories, can impact interpretation of results for human health effects associated with exposures. Traditional laboratory practices may be inconsistent with epidemiological methodologies when laboratories do not give care to the analytical tools employed when analyzing results; these inconsistencies can lead to biased estimates.

Additionally, adequate exposure assessment necessitates consideration of measurement error. Error associated with the measurement of exposure or health outcome and biases that may arise due to laboratory equipment, variation between technicians, temporal changes, and biological variability, may affect study findings in an unpredictable manner. Branch investigators continue to evaluate biases associated with laboratory processes and the impact on estimating health risks.

Pooling of Biospecimens

As laboratory analytical methods have improved, development of promising biomarkers has increased exponentially. However, many analyses are costly or require the use of valuable samples for measuring new biomarkers. Thus, methodologies that permit judicious use of specimens offer promise to investigators in allocating resources and in using biospecimens. Branch investigators are researching the use of pooled biospecimens—groups of individual specimens physically combined within the same case status for analyses—to assess how best to pool biospecimens when estimating health risk following a particular exposure. Specifically, the Branch researchers are investigating the following approaches: Youden's index, the area under the receiver operating curve (AUC), and the partial AUC.

ROC Curve Analysis of Biomarkers of Oxidative Stress

Lipid peroxidation, formed in lipid molecules with unregulated exposure to oxygen, is associated with various adverse reproductive outcomes, including infertility. However, substantive epidemiological research is hindered by an incomplete understanding of commonly used biomarkers of oxidative stress, making it difficult to fully interpret findings. The ROC curve has great potential as a tool to evaluate the effectiveness of biomarkers of oxidative stress. However, because ROC curves are relatively new to medical literature, methodological advancements are needed to clarify their use in evaluating of oxidative stress. Branch investigators are interested in the development of ROC methodology, particularly in matched studies, under varying distributional assumptions, and in the context common epidemiological challenges posed by confounding, selection bias, and measurement error.

Measurement Error and General Exposure Assessment Issues

Appropriate assessment of exposure demands attention to issues of measurement error. Epidemiologists are frequently concerned with differential misclassification; however, random error can also lead to bias toward the null. The reliability approach, which entails a validation study to derive estimates of error, allows for use of a variety of correction methods. Branch investigators are using the reliability approach and extending its application to indices of ROC curve analysis, including the Youden Index. This research includes consideration of commonly used statistics, such as the correlation coefficient, using standard and Bayesian approaches.

PREVENTION RESEARCH BRANCH

The mission of the Prevention Research Branch is to conceptualize, design, and conduct research to identify determinants of health behavior and to test the efficacy and effectiveness of educational, behavioral, and environmental strategies that improve or protect maternal, child, and adolescent health. In the tradition of intramural research at the NIH, and in addition to independent research, the Branch is also responsible for training emerging researchers and engaging in professional services, including consultation, collaboration, and assistance to the Division, the NICHD, and the NIH, as needed. Branch staff include Bruce Simons-Morton, Ed.D., chief and senior investigator; Ronald Iannotti, Ph.D., staff scientist; Denise Haynie, Ph.D., staff scientist; and Tonja Nansel, Ph.D., tenure track investigator. Through Intramural Research Training Awards, the Branch has two predoctoral, two postdoctoral, and two post baccalaureate fellows.

The Branch's research focuses on three areas: adolescent problem behavior; motor vehicle crash risk and prevention among young drivers; and family management of childhood diabetes. The following section describes some Branch activities in these areas.

RESEARCH ON ADOLESCENT PROBLEM BEHAVIOR

Early adolescent problem behavior is a vexing problem that can have profound health implications for America's youth. The prevalence of substance use, school disengagement, aggression, and other conduct problems increases during early adolescence and is negatively associated with school achievement, adult health, and economic outcomes. Precocious problem behavior can also distract significantly from the normal and healthful trajectory of adolescent development. The Prevention Research Branch is working to develop a better understanding of adolescent problem behavior and to develop practical, theory-based interventions to prevent it. The program of research in this area includes one national survey and three randomized trials: one designed to test the effects of a multiple problem behavior prevention program; one designed to prevent aggressive behavior and school disengagement; and one to evaluate the effects of a mentor-delivered aggression-prevention program among children who report to the emergency department because of injury from a fight.

Preventing Problem Behavior among Middle School Students (*Going Places*)

The recently completed *Going Places* Study represented a unique test of the efficacy of a multi-component intervention for preventing multiple problem behaviors, including substance use, aggression, and misconduct. Investigators randomized seven middle schools in one school district to intervention or comparison group and assessed two cohorts of students at the beginning of middle school, at the end of the sixth, seventh, and eighth grades, and at beginning of ninth grade. The intervention consisted of a skills-oriented curriculum, school-wide intervention, and parent education. The evaluation of treatment group effects indicated that the program had significant effects on smoking progression, outcome expectations for smoking, and friends who smoked, but not on drinking, aggression, or misconduct. The effect on smoking progression was mediated by friends who smoked, indicating that the increase in friends who

smoked was less among those in the intervention schools than among those in the control schools. In a series of observational analyses, Branch investigators also found that parenting behaviors were protective against substance use and that selection of friends was at least as important as socialization by friends in the progression of substance use.

Preventing Aggression among Middle School Students (*Steppin' Up*)

The purpose of the *Steppin' Up* study is to test the efficacy of school-based interventions to increase school engagement and decrease aggressive behavior among middle school students. Two middle schools in low-income East Baltimore neighborhoods are participating. Students meet in small groups with the *Steppin' Up* staff during an elective period each week. The youth intervention is based on goal-setting and problem-solving techniques employed previously in the *Going Places* Study. The parent intervention component focuses on monitoring and involvement. In addition, teachers will receive in-service training on classroom management and student empowerment. After extensive piloting of the intervention and measurement protocols, the first year of the main trial will occur during the 2005-2006 school year.

Violence Prevention among High-Risk Youth in the Emergency Department

This effort is a collaborative study, funded by the Maternal and Child Health Bureau at the Health Resources and Services Administration and led by Dr. Cheng at the Johns Hopkins University. Investigators recruited families of adolescents who presented in the emergency department as having been injured in a fight and randomized them to community service referrals or to a special mentoring program. Investigators contacted families are contacted at six and 18 months after the intervention for follow-up. Follow-up data collection and preliminary data analyses are ongoing; results are expected in 2006.

Health Behavior in School Age Children (HBSC) – United States

This study is the U.S. component of an international survey of early adolescents, ages 11, 13, and 15 years (see page 20 of this report for a description of the survey). The 2005-2006 module will be the third administration of this survey in the United States; previous surveys were conducted in 1996-1997 and 2000-2001. The survey assesses the prevalence of health problems, health behaviors, and a limited number of psychosocial and contextual indicators, including questions on adolescents' physical activity, substance use, dietary habits, body image, bullying, and fighting. There are currently no other national surveys in the United States for this age group that examine these research topics. The great advantage of this survey is that it allows for comparisons in the United States over time and in comparison with a wide range of countries in Europe and North America.

RESEARCH ON YOUNG DRIVERS

The Branch has a well-established program of research on young drivers, including a series of studies that focus on intervention to increase parental management of newly licensed young drivers, and a series of studies that examine the nature of teen driving risk. Four intervention studies have been initiated or are underway or approved.

Teen Driving Intervention Studies

These studies seek to test the efficacy and effectiveness of the *Checkpoints* Program for increasing parental management of teen drivers. The *Checkpoints* intervention includes persuasive communications such as a nine-minute video, *Who Wants to Be A Driver*? The materials were designed to increase perceived risk, outcome expectations, and self-efficacy for parental management and to promote the adoption of a parent-teen driving agreement.

Maryland Young Driver Intervention 1 Study

This study tested the efficacy of the *Checkpoints* Program when administered at the time of licensure. In one Maryland Motor Vehicle Administration (MVA) office, investigators recruited 450 families at the time the teen successfully tested for a license and randomized them to either intervention or control. Intervention families watched the video and were encouraged to adopt the *Checkpoints* Parent-Teen Driving Agreement. Intervention group differences were significant at three months, six months, and nine months post intervention. In addition, teens and parents exposed to the *Checkpoints* Program reported greater restrictions on teen drivers compared with the control group. This study demonstrated the efficacy of a brief intervention delivered as part of routine practice in a single MVA licensing office.

Connecticut Young Driver Study

In this project, Branch investigators recruited a large sample of families at the time the teen successfully tested for a learner's permit and assessed teen driving privileges and driving outcomes, including risky driving behavior, traffic offences, and crashes, five times from baseline to 12 months post-licensure. Participants in the intervention group received intervention materials over an extended period prior to licensure. The first 450 families were treated as a vanguard sample to allow testing and modification of the protocol before implementation with more than 3,000 families. Analyses of treatment group differences with the vanguard sample indicated effects on parental restrictions through 12 months. Analyses of the full trial are ongoing.

Michigan Driver Education Checkpoints

This is the first study that attempts to use driver education classes to increase parental management of newly licensed teens. Branch investigators felt that Michigan was an ideal location for this study because it has a unique two-stage driver education program in which teens get their permits after attending a short driver education course, obtain substantial adult supervised driving experience, and then attend a second driver education course just prior to licensure. A trained research assistant will deliver *Checkpoints* in randomized classes, showing families the *Checkpoints* video and instructing families in the negotiation and completion of the first part of the *Checkpoints* Parent-Teen Driving Agreement. The study will follow approximately 450 parent-teen dyads for six months post-licensure. The investigators are also planning a follow-up study to test the efficacy of having trained driver education instructors implement *Checkpoints* in routine driver education practice in Michigan.

INDIANA TEEN DRIVING STUDY

With funding from the state of Indiana, Branch investigators are testing the feasibility of implementing the *Checkpoints* materials in a sample of pediatric practices in the state. The research will seek to determine whether health care providers might provide an effective alternative venue for such instruction.

YOUNG DRIVERS INTERVENTION II: IMPROVING THE EFFECTIVENESS OF PARENTAL MANAGEMENT OF NOVICE TEEN DRIVERS

This recently approved contract will allow the further evaluation of the effectiveness of parental management of newly licensed teen drivers. This effort consists of several studies designed to examine specific effectiveness issues, such as the relative advantages of interventions at time of permit or licensure, and the effects of intervention integrated into routine licensure practice. The first study will start in 2006 and will end in 2008.

Teen Driving Risk Studies

THE EFFECTS OF TEEN PASSENGERS ON RISKY DRIVING BEHAVIOR

To date, the effect of teen passengers on driving performance was reported in only one study (McKenna et al, 1998), which was conducted with drivers ages 20 years and older in England. Prevention Research Branch investigators evaluated this issue among teen drivers—a population at high risk for accidents. Investigators observed vehicles leaving high school parking lots, at the end of the school day, and recorded the presence and sex of the passengers, the vehicle speed, and the frontal headway allowed once the vehicles emerged onto a nearby main road and got into traffic. Results indicated that, on average, teen passengers drove faster and allowed less frontal headway than other drivers in the same situation. Risky driving behavior was greater among both male and female teen drivers in the presence of a teen passenger, particularly among male teen drivers with male teen passengers. These findings will be incorporated into future teen driving interventions.

THE EFFECTS OF EXPERIENCE ON TEEN DRIVING PERFORMANCE

Research has shown that crash rates for teen drivers are extremely high immediately after licensure, and decline rapidly for about six months post licensure. This study is designed to test the effects on driving performance of driving experience of six or more months and greater than 1,000 miles. Investigators recruited a sample of newly licensed teens and a comparison group of experienced drivers and assessed their driving performance on a test track at baseline (within two weeks of licensure for the teens), and then again six or more months later. Results indicated differences between teens' and adults' intersection behavior; specifically, teens were more likely "run the light" when a traffic light is yellow.

THE WILLINGNESS OF TEEN DRIVERS TO USE ELECTRONIC DEVICES

The issue of driver distraction is of concern for all drivers and especially for teens who are at greatly elevated risk for motor vehicle crashes and who are frequent users of electronic devices. In this study, Branch researchers recruited licensed drivers in four age groups: 16- and 17-year-olds; 18- to 25-year-olds; 26- to 45-year-olds, and drivers age 60 years and older. Study participants drove a course on public roads and, at specified points, answered questions about their willingness to use cell phones and other electronic devices. The teen group scored nearly as

high on willingness as the other age groups, except the 60 and older group, which was least willing in all categories. Although all age groups had self-imposed rules about the use of electronic devices while driving, the teens reported being the most frequent users.

TEEN DRIVING RISK – ON-ROAD EVALUATION

This research will provide the first evaluation of novice teen driving that uses instrumented vehicles to examine the effects of inexperience, passengers, road conditions, and other factors. Branch investigators are recruiting a sample of teens to drive instrumented vehicles for up to 18 months, while the instruments record data on speed, lane management, rapid starting and stopping, and the like, under a variety of driving conditions and with varying in-vehicle distractions.

THE EFFECTS OF PRE-LICENSE, SUPERVISED PRACTICE DRIVING ON DRIVING PERFORMANCE

Statistics indicate that teen crashes are elevated during the first six months after licensure. Practice generally has a positive effect on driving outcome, and many states have recently increased the amount of parent-supervised practice driving that is required during the learner's permit period prior to licensure. However, it is unclear how much supervised practice driving teens actually get, and the extent to which supervised practice driving affects independent driving performance. This study will determine how much pre-license, supervised practice driving teens actually get and the effect of practice driving on driving performance upon licensure. Results are expected in 2009.

RESEARCH ON MANAGEMENT OF CHRONIC DISEASE IN CHILDHOOD

Branch investigators have developed a broad program of research on management of diabetes during childhood and adolescence. Some of the Branch's efforts in this area of research are described below.

Developmental Influences on Diabetes Management

This observational study examines the influence of family, social, and behavioral variables on diabetes self-management, with a particular focus on adolescent developmental transitions. The study integrates assessment of both youth and parent variables to better understand the potential interactive and dynamic nature of factors predicting adherence. Researchers will collect data at four time points over two years. Results are expected in 2006.

Diabetes Personal Trainer Study

This intervention study is designed to test the efficacy of an individualized, problem-solving intervention, delivered by specially trained lay staff, on diabetes management. Guided by principles of motivational interviewing and applied behavior analysis, the "trainers" met with youth for six structured sessions over approximately two months with the goal of improving one or more youth-selected areas of diabetes management. Follow up of youth for two years post-intervention is ongoing.

Family Management of Childhood Diabetes

Four clinical sites in Massachusetts, Florida, Illinois, and Texas are participating in this multi-site intervention study. The research seeks to determine the efficacy of a clinic-integrated intervention designed to facilitate adherence among youth with type 1 diabetes during the transition from parent-led management that occurs during late childhood, to youth-led management in early adolescence. The intervention, which is delivered in low intensity over time, is designed to promote problem-solving skills and to address child, parent, and dyadic factors that may influence management practices. Investigators will follow youth over two years. An abbreviated pilot study is currently in progress to help inform the full trial.

Feasibility and Acceptability of a Low Glycemic Index Diet in the Diabetes Camp Setting

In this unique effort, youth attending a diabetes summer camp were served standard diabetes camp menus and lower glycemic index diabetes camp menus in a daily, alternating cross-over design to determine how these meals impacted diabetes management outcomes. Analyses included youth satisfaction, food consumption, feasibility of mass preparation, cost, and safety. This pilot study is providing important preliminary data to guide development of the larger contract study.

Enhancing Carbohydrate Quality in Diabetes Management

A Branch contract seeks to investigate the efficacy of a family-based intervention for promoting consumption of lower glycemic carbohydrates from whole foods to facilitate management of type 1 and type 2 diabetes in youth. The study, currently in design, will assess both physiologic and behavioral outcomes.

FUTURE RESEARCH DIRECTIONS FOR DESPR

In determining its future research directions, DESPR begins by having each Branch hold an annual retreat, where staff discuss research results of the past year, review the status of current research projects, and consider both extensions of current research and new research directions. Each Branch then develops its future research agenda. These agendas are discussed at an annual retreat of the Branch chiefs and the Division Director, and, from this discussion, Division priorities are developed.

As an intramural Division, the DESPR portfolio is also reviewed every four years by the Board of Scientific Counselors; the most recent review was held in November 2004. These meetings and reviews provide an opportunity for peer review and critique of DESPR's progress and plans.

The Division will continue to identify critical data gaps that underlie reproductive, perinatal, and pediatric epidemiology that meet with its research expertise and mission, and to design epidemiologic studies responsive to these needs. This avenue of research includes the development of studies using state-of-the-art designs and methodologies—such as the inclusion of biomarkers of exposures, disease, or susceptibility—and attention to the contribution of genes and environment. This type of research is well suited to the conduct of methodologically orientated efforts, which impact all practicing investigators, particularly in terms of biospecimen

conservation approaches (for example, pooling specimens) and appropriate modeling of laboratory data given uncertainty in the measurement process for interpreting human health effects (for example, limits of detection).

With regard to reproductive epidemiology, Division investigators will continue to identify the environmental factors that impact human fecundity and related impairments that affect men and women. This research will continue to assess environmental chemicals to which a large percentage of the population is exposed, but in the context of lifestyle factors and stressors that also may impact human fecundity. Two planned initiatives include: physiologic and psychosocial stress and time-to-pregnancy; and persistent hormonally active environmental chemicals and gynecologic pathology, such as endometriosis and PCOS. A second (clinical) avenue of research will focus on pregnancies conceived with assisted reproductive technologies (ART) to address the growing concern that such treatments may adversely affect fetal growth and gestation among singleton pregnancies. The Division is also exploring methodologies for determining potential developmental toxicity associated with ART. This effort will require population-based research because of the relatively low prevalence (≈2 percent) of ART-conceived live births in the United States. Further, this research will build upon the Division's methods research in this area to address treatment versus underlying infecundity effects.

Future perinatal epidemiologic research initiatives will include the assessment of a host of environmental influences on fetal growth (as measured by birth size and gestation) and the impact of clinical treatment (for example, intrapartum clinical management) on fetal and newborn well-being. Division investigators are planning one intervention trial involving women with a history of miscarriage to evaluate the efficacy of aspirin treatment to prevent pregnancy loss. In addition, as weight of evidence continues to support a relation between urinary PIGF at mid-gestation and development of early onset preeclampsia, the Division will continue to assess the utility and feasibility of evaluating a urinary screening test for PlGF to enable health care providers to identify women at risk for preeclampsia. This study is in addition to continued etiologic research focusing on the angiogenic proteins and preeclampsia as potentially mediated by other (gravid) health conditions, such as diabetes mellitus, chronic hypertension, or multiple gestations. As noted previously, the Division will continue its research on the course of labor in the modern era by launching the Consortium on Safe Labor study. The study will use approximately 200,000 digitized labor records from several hospitals to improve the understanding of labor progression and to identify a meaningful cut point for operative intervention. The Division expects to award a contract for the data center to coordinate this effort in fiscal year 2006.

With regard to pediatric epidemiologic research, the Division will continue to identify risk factors for birth defects. Innovative large-scale genotyping techniques allow researchers to identify and confirm genetic variants associated with birth defects. They can then test these variants for phenotypic expression using material already in place, including DNA samples, exposure data, and blood samples already collected for a large normal population. When a genetic variant of interest is found, researchers can genotype the DNA from this normal population for the variant and can compare those with the variant to those without the variant for the biochemical factors of interest. Additional samples are already available to measure other analytes of interest.

Other planned pediatric research initiatives include: following children/families with developmental disabilities to assess long-term growth patterns of affected members and to capture the occurrence of injuries; and longitudinally following girls to better identify the natural history of gynecologic conditions such as PCOS. Work will continue on the effect(s) of nutrition and other lifestyle factors (for example, prenatal alcohol consumption) on children's cognitive functioning and other psychosocial dimensions.

The U.S. HBSC survey has provided valuable information on adolescent health behaviors and their determinants. These data have identified successful public health efforts as well as informed new intervention efforts targeting aggression and bullying. The Division plans to continue to support U.S. participation in this project.

In the area of adolescent problem behavior, the Division recently initiated an intervention study that focuses on the prevention of aggressive behavior and the promotion of school engagement among inner-city, low-income early adolescents. This very challenging area of research will demand considerable attention and resources over the next several years.

In the area of young drivers, the Division expanded its intervention research into new arenas, with randomized trials under way in driver education and routine MVA settings. In addition, Division staff are planning a study to evaluate various approaches to improving intervention effectiveness. The Division has extended its research in teen driving risk and plans for the world's first study of teen drivers using instrumented vehicles are now under way. The instrumented vehicle study will allow observation of driving performance under a wide range of driving conditions over an 18-month period starting at licensure.

Finally, Division research in the area of family management of childhood diabetes is rapidly expanding. The pilot study for its first multi-site randomized trial, now nearing completion, was successful and instructive, and will guide the main trial expected to start by the end of 2005. Also within this area, the Division has developed a thoughtful study that focuses on the use of low-glycemic diet in the management of childhood diabetes, scheduled to start in 2006. Further, Division investigators are developing a study to examine the transition from pediatric to adult care for youth with diabetes.

FIGURES AND TABLES

TABLE 1: DESPR STAFFING

Office of the Director

Positions Requiring Full-Time Employees (FTEs)	Number of FTEs
Director	1
Staff Scientist	0.5
Secretary	1
Collaborative Studies Unit	2
National Children's Study	7
Positions Not Requiring FTEs	**Number of FTEs**
Pre/Postdoctoral Fellow	2
National Children's Study	5.75

Biometry and Mathematical Statistics Branch

Positions Requiring FTEs	Number of FTEs
Chief	1
Senior Investigator	1
Investigator	2 (1 position filled, 1 position vacant)
Positions Not Requiring FTEs	**Number of FTEs**
Postdoctoral Fellow	2

Epidemiology Branch

Positions Requiring FTEs	Number of FTEs
Chief	1
Senior Investigator	2
Investigator	3
Research Fellow	1
Staff Clinician	1
Staff Scientist	1
Biologist	1
Information Technology Specialist	1
Positions Not Requiring FTEs	**Number of FTEs**
Pre/Postdoctoral Fellow	6

Prevention Research Branch

Positions Requiring FTEs	Number of FTEs
Chief	1
Investigator	1
Staff Scientist	1.5
Positions Not Requiring FTEs	**Number of FTEs**
Pre/Postdoctoral Fellow	4 (2 positions filled, 2 positions vacant)

TABLE 2: CONTRACT DOLLARS BY DESPR COMPONENT, FISCAL YEARS 2001 THROUGH 2004

Fiscal Year	Office of the Director Biometry and Matehmatical Statistics Branch Epidemiology Branch Prevention Research Branch	National Children's Study	Total
2001	$ 5,017,000	--	$ 5,017,000
2002	$ 5,294,000	$ 2,000,000	$ 7,294,000
2003	$ 6,173,000	$ 6,500,000	$ 12,673,000
2004	$ 9,485,000	$ 7,500,000	$ 16,985,000
Total:	**$ 25,969,000**	**$ 16,000,000**	**$ 41,969,000**

APPENDIX A: DESPR PERSONNEL

OFFICE OF THE DIRECTOR (OD)

Mark A. Klebanoff, M.D., M.P.H., is a pediatrician and epidemiologist who joined DESPR's Epidemiology Branch in 1983. He has been director of DESPR since 1999. His research interests span a broad range of topics in the epidemiology of maternal and child health, but focus mainly on factors associated with preterm birth and fetal growth, as well as with genital tract infections.

Kaye Beall joined the federal government and DESPR in June 2003, from an academic background at Georgetown University and George Washington University. She provides secretarial support for the entire Division.

Rebecca M. Brotman, M.P.H., is a doctoral candidate in epidemiology at the Johns Hopkins Bloomberg School of Public Health, who joined OD as a predoctoral fellow in 2005. Her main research interests include the epidemiology of bacterial vaginosis and the use of vaginal hygiene products.

Maurice Davis, M.P.A.-M.H.S.A., is a health scientist administrator in DESPR's OD. He joined the NICHD in 2002 and assists with the DC Initiative to Reduce Infant Mortality in Minority Populations. His research interests include health disparities issues that affect minority populations, specifically minority children's perceptions of health careers.

Anusha H. Hemachandra, M.D., M.P.H., is a postdoctoral Intramural Research Training Award (IRTA) fellow who joined DESPR in 2004 to work with Dr. Klebanoff. She is a practicing neonatologist whose research interest lies in the developmental origins of adult disease, with an emphasis on the perinatal determinants of hypertension.

Michele Kiely, Dr.P.H., is a pediatric and perinatal epidemiologist who joined DESPR's OD in 2001. She is chief of the Collaborative Studies Unit and serves as the project officer of the DC Initiative to Reduce Infant Mortality in Minority Populations.

COMPUTER SCIENCES SECTION

Ann Trumble, Ph.D., head of the Computer Sciences Section, has been with DESPR for more than 13 years. She is responsible for organizing computer support for the 33 scientists and visiting researchers in the Division and serves as an analyst on several projects in DESPR. She is also project officer for two contracts, one that provides Division computer support, and the other that provides repository services to the NICHD for storage of biological samples.

Patricia Moyer has worked in DESPR for more than 14 years as a computer/information technology (IT) specialist. She is a statistical programmer who supports epidemiologic research using various computer languages and packages for a variety of platforms. She also provides assistance to DESPR staff, using state-of-the-art solutions to resolve problems.

NATIONAL CHILDREN'S STUDY

Peter C. Scheidt, M.D., M.P.H., is a medical officer and the director of The National Children's Study. His research has focused on environmental exposure to radiation in children, behavioral pediatrics, and the epidemiology and prevention of injuries and violence in children.

Marion J. Balsam, M.D., is the Research Partnerships Program director and the executive secretary of the Federal Advisory Committee for the National Children' s Study.

Leni Buff is the Education Program manager at the Smithsonian Institution, National Portrait Gallery. She is on an interagency detail to the National Children's Study as the program analyst responsible for all aspects of the logistical support contract, and for the e-updates that are provided to the Study listserv under a communication support contract.

Richard L. Callan, M.P.H., is an Association of Schools of Public Health Fellow at the National Center for Environmental Research at the U.S. Environmental Protection Agency and is working in the program office for the National Children's Study.

Elizabeth Ann Davis serves as the program assistant for the National Children's Study program office. Ms. Davis has worked for the NICHD since 2003.

Alan R. Fleischman, M.D., is chair of the Federal Advisory Committee of the National Children's Study, ethics advisor to the Study, and senior advisor at The New York Academy of Medicine. He is at the NICHD on an intergovernmental personnel act (IPA) detail. He has written extensively in the field of neonatal and fetal physiology with a research emphasis on nutrition and about many aspects of the field of bioethics, emphasizing the rights of individual patients and the responsibilities of health care providers.

Warren Galke, M.S.P.H., Ph.D., is an environmental epidemiologist who joined the Study program office in September 2003. Dr. Galke is a well-known expert in childhood lead poisoning research. He focuses on the residential housing environment and is working with other Study staff on issues related to environmental exposure assessment, laboratory analyses of biological and environmental samples, and quality assurance and quality control.

Sarah A. Keim, M.A., M.S., is the Study coordinator for the National Children's Study. She works on the strategic planning, contracts management, personnel planning, project management, and budget functions.

Sarah S. Knox, Ph.D., senior scientist, is a behavioral epidemiologist who joined the National Children's Study in 2003. Her research focuses on mechanisms mediating the effects of psychosocial factors on health and includes the area of behavioral genetics. She is also project officer of the Study Data Coordinating Center.

Cynthia A. Moore, M.D., Ph.D., of the Office of Genomics and Disease Prevention at the Centers for Disease Control and Prevention (CDC), spends a portion of her time working in the National Children's Study program office. She is involved in protocol development, with a special emphasis on genetic issues. Her research activities focus on mechanisms of morphogenesis, classification of birth defects and genetic syndromes, and genetic and environmental risk factors for birth defects.

James Quackenboss, M.S., is an environmental scientist for the National Exposure Research Laboratory at the U.S. Environmental Protection Agency (EPA), is an EPA member of the Study Interagency Coordinating Committee, and has been working part-time in the Study program office since July 2003. He is working with other staff on issues related to environmental exposure assessment, laboratory analyses of environmental samples, sampling design and measurement errors, and quality assurance and quality control.

Kenneth C. Schoendorf, M.D., M.P.H., is a pediatrician and medical epidemiologist at the National Center for Health Statistics within the CDC. Dr. Schoendorf is also a part-time member of the Study program office, on detail from CDC, and works primarily on the Study's protocol development. His primary research focus is disparities in pregnancy outcomes within the United States, but has also researched a broad array of maternal and child health issues.

Sherry G. Selevan, Ph.D., is an epidemiologist whose specialty is the relationship between toxic exposures, both environmental and occupational, on reproduction and development. She currently works at the EPA and is a member of the Interagency Coordinating Committee for the National Children's Study.

BIOMETRY AND MATHEMATICAL STATISTICS BRANCH (BSMB)

Kai Fun Yu, Ph.D., is the chief and a senior investigator in the BMSB, where he has worked since 1990. Dr. Yu has broad interests in the theory, methodology, and applications of statistics and probability. He has worked in many areas, including sequential analysis, longitudinal data analysis, categorical data analysis, neural network, clustering and classification, non-parametric statistics, and adaptive sampling. Recent emphases include on sequential clinical trials, longitudinal data analysis, and non-parametric procedures.

Aiyi Liu, Ph.D., is a tenure-track investigator who has been a member of the BMSB since 2002. His research interests include: general statistical estimation theory, sequential methodology and applications to clinical trials, adaptive designs for medical studies, linear models and regression analysis, analysis of repeated measurements and longitudinal data, multivariate data analysis and related topics, diagnostic biomarkers and ROC curve analysis, statistical methods for pooled assessments, and measurement errors.

James F. Troendle, Ph.D., is a tenured investigator who has been a member of the BMSB since 1992. His research interests include multiple hypothesis testing, non-parametric tests, and computational statistical procedures.

Albert Vexler, Ph.D., is postdoctoral fellow who joined the BMSB in 2004. His research interests include asymptotic methods of statistics, change point problems, sequential analysis, renewal theory, and regression models.

Chengqing (Alan) Wu, Ph.D., visiting postdoctoral fellow, is a statistician who joined the Branch in 2003. Dr. Wu's primary research interests include: sequential design and secondary analysis, non-parametric and semi-parametric inference, change point, ROC curve, and AUC.

EPIDEMIOLOGY BRANCH

Germaine M. Buck Louis, Ph.D., has been a senior investigator and chief of DESPR's Epidemiology Branch since 2000. Dr. Buck Louis' research interests primarily focus on the interplay between environmental exposures, behavior, and human reproduction and development.

Michael Bloom, Ph.D., is a postdoctoral fellow in reproductive epidemiology who joined the Epidemiology Branch in 2004. His main interests include fertility, epidemiologic methods, and chronic environmental exposures.

Ruth A. Brenner, M.D., M.P.H., tenure-track investigator, is a pediatrician/epidemiologist who joined the Epidemiology Branch in 1991. Dr. Brenner's research focus is in the epidemiology and prevention of childhood injuries, with a special emphasis on childhood drowning. She is currently on leave of absence to lead the development of the Study protocol, procedures, and related procurements for the National Children's Study.

Mary Conley, M.A., is an IT specialist who has worked in the Epidemiology Branch since 1991. Her research interests include analysis of the biochemistry and genetics of birth defects.

Penelope Howards, Ph.D., is a postdoctoral fellow in reproductive epidemiology who joined the Epidemiology Branch in 2004. Her research interests include methodological issues in the study of reproductive epidemiology, miscarriage, fertility, and fecundity.

Mary L. Hediger, Ph.D., (Biological Anthropologist), has published widely in the areas of fetal, infant, and child growth and currently serves as president of the Society for Pediatric and Perinatal Epidemiologic Research. Her research interests include fetal, child and adolescent growth, perinatal epidemiology, and growth and nutrition.

Leila Jackson, Ph.D., M.P.H., is a postdoctoral fellow in reproductive epidemiology who joined the Epidemiology Branch in 2003. Her main research interests include the effect of hormonally active compounds on fecundity, puberty, and menstrual cycle characteristics. Dr. Jackson left DESPR in August 2005, to join the faculty at Case Western Reserve University.

Richard J. Levine, M.D., M.P.H., joined DESPR in 1991 and is a senior investigator in the Epidemiology Branch. His current research interests focus on the pathogenesis of preeclampsia, with particular emphasis on the role of angiogenic factors.

Feng-Ying (Kimi) C. Lin, M.D., M.P.H., is a physician epidemiologist whose research interests focus on seroepidemiology of neonatal GBS disease and evaluations of pediatric vaccines. She joined DESPR in 1993.

Courtney Denning-Johnson Lynch, Ph.D., joined the Epidemiology Branch in January 2001 as an IRTA predoctoral fellow. She served as a postdoctoral fellow for one year before accepting a position as a staff scientist. Her research interests include the identification of modifiable risk factors for infertility, and follow-up of children conceived with the help of ovulation induction and ART.

James L. Mills, M.D., M.S., is a senior investigation and chief of the Pediatric Epidemiology Section in DESPR's Epidemiology Branch. He joined DESPR in 1979. His primary research interest is the etiology of birth defects. He has worked for the last decade on genetic and biochemical risk factors for NTDs and other folate-related birth defects.

Neil Perkins, M.S., is a predoctoral fellow in statistics, who joined the Epidemiology Branch in 2003. His research interest and dissertation involve epidemiological methods, specifically, receiver operating characteristic curves, summary measures of the ROC, and measurement error.

Gitanjali Saluja, Ph.D., joined DESPR in 1991 as a postdoctoral fellow and became a research fellow in the Epidemiology Branch in 2004. Much of her research focuses on the epidemiology and prevention of child and adolescent injuries, particularly drowning. She is also interested in developmental disabilities, mental health, and parent and child behaviors as they relate to health and injury.

Enrique Schisterman, Ph.D., is a tenure-track investigator who was recruited to the Epidemiology Branch in March 2002 for his expertise in epidemiologic methods. His current research interest focuses on exposure assessment, with emphasis on the use of biomarkers. Dr. Schisterman has a long-standing interest in issues related to oxidative stress and its impact on general health, and particularly as it relates to women's health (i.e., endometriosis, infertility, and menstrual cycle function). Dr. Schisterman has worked to develop new analytical tools that are closely tied to etiological questions.

Caroline Signore, M.D., M.P.H., is a postdoctoral fellow in the Epidemiology Branch who joined DESPR in 2004. She is interested in the identification of genetic, nutritional, and biochemical risk factors for birth defects and other pregnancy complications.

Brian Whitcomb, B.A., is a predoctoral fellow pursuing a doctorate in epidemiology at the University of Maryland, Baltimore, who first came to the Epidemiology Branch as a summer IRTA in 2002 and joined the Branch in 2004. His main research interests include early pregnancy failure, determinants of fertility, and health effects of hormonally active environmental agents.

Jun (Jim) Zhang, M.D., Ph.D., is a tenure-track investigator in perinatal epidemiology who joined the Epidemiology Branch in 1997. His main research interests include early pregnancy failure, preeclampsia, fetal growth, and labor and delivery.

PREVENTION RESEARCH BRANCH

Bruce Simons-Morton, Ed.D., M.P.H., is senior investigator who joined the Branch in 1992, and who was appointed chief of the Prevention Research Branch in 1997. His primary research interests are early adolescent problem behavior prevention and the prevention of motor vehicle crashes among novice young drivers. His research focuses on both risk assessment and the development and evaluation of effective interventions.

Denise Haynie, Ph.D., M.P.H., is staff scientist in the Prevention Research Branch and has been with the branch since 1993. Her primary research interests are early adolescent problem behavior prevention and positive youth development. Her current research is focused on the development and evaluation school based interventions to enhance school engagement and reduce problem behavior among adolescents.

Ronald J. Iannotti, Ph.D., joined the Prevention Research Branch in August 2001 as a senior research fellow and was appointed a staff scientist in April 2005. Dr. Iannotti assists the OD in a variety of administrative areas. His research interests are in the development and maintenance of health behaviors, children's management of acute and chronic illness, and the influence of families and peers on these processes.

Kantahyanee W. Murray, M.A., is a predoctoral fellow who joined the Prevention Research Branch in 2004. Her main research interests include adolescent parenting practices and adolescent reproductive health.

Tonja R. Nansel, B.S.N., Ph.D., joined the Prevention Research Branch as a postdoctoral fellow in 1998 and has been a tenure-track investigator since 2001. Her primary research interest is in the management of diabetes in children and their families. Her research focuses on the integration of prevention and health promotion intervention within the health care setting.

Erik C.B. Olsen, Ph.D., has been a postdoctoral research fellow with the Prevention Research Branch since 2004. His primary research interests are driver safety and transportation human factors and ergonomics. His research focuses on collecting objective measures of driver performance, particularly of novice teen drivers.

Jessica Miller Rath, Ph.D., C.H.E.S., is a postdoctoral fellow who joined the prevention research branch in 2002. Her main research interests include the role of parenting in adolescent aggression prevention, community based participatory research, and adolescent health program evaluation. Dr. Rath left DESPR in August 2005 to join the faculty at the University of Maryland.

APPENDIX B: AWARDS AND CITATIONS FOR DESPR INVESTIGATORS, FISCAL YEAR 2000 THROUGH FISCAL YEAR 2005

AWARDS FOR 2000

- Feng-Ying (Kimi) Lin—Public Health Service (PHS) Outstanding Service Medal: *For outstanding efforts in the prevention of typhoid fever and neonatal streptococcal sepsis*
- Feng-Ying (Kimi) Lin—NIH Award of Merit: *For making landmark contributions to the design and conduct of clinical trials of typhoid vaccine effectiveness in complex field conditions*
- James Mills—NIH Director's Award: *For providing important insight into the relationship between folate metabolism and birth defects*

AWARDS FOR 2001

- Mark Klebanoff—NIH Director's Award: *For scientific accomplishments and vision in perinatal epidemiology and the pursuit of knowledge to ensure the health of mothers and infants*
- Feng-Ying (Kimi) Lin—U.S. Department of Health and Human Services (DHHS) Secretary's Award for Distinguished Service (Group Award): *For untiring efforts of the Typhoid Vaccine Team leading to a typhoid fever vaccine that, for the first time, protects young children*
- Courtney Johnson (Lynch)—Donald Cornely Outstanding Doctoral Student Scholarship, Johns Hopkins Bloomberg School of Public Health (Intramural Research Training Award [IRTA] Predoctoral Fellow)

AWARDS FOR 2002

- Mark Klebanoff—Johns Hopkins Society of Scholars
- Feng-Ying (Kimi) Lin—PHS Meritorious Service Medal: *For creative and untiring efforts in developing, maintaining, and directing the field evaluation site for the first typhoid vaccine effective in young children*
- Germaine Buck (Louis)—NIH Award of Merit: *For providing leadership and vision in epidemiologic research to the Institute and the epidemiologic community at large*
- Bruce Simons-Morton—NICHD Staff Recognition Award: *Research on Adolescent Problem Behavior – The Going Places Program*

- Ann Trumble—NIH Award of Merit: *For sustained, creative and tireless leadership in directing data management and computer programming support of epidemiologic, statistical and behavioral research*

AWARDS FOR 2003

- Courtney Johnson (Lynch)—Paul A. and C. Esther Harper Outstanding Dissertation Award, Johns Hopkins Bloomberg School of Public Health (IRTA Predoctoral Fellow)

AWARDS FOR 2004

- Kaye Beall—NIH Award of Merit: *For tireless, creative, effective support of the mission of DESPR*
- Tara Collins—Howard Hughes Medical Institute Scholar (continued medical school support following completion successful internship)
- Germaine Buck (Louis)—NIH Mentoring Award: *For exemplary performance while demonstrating significant leadership skill and ability in serving as a mentor for the Epidemiology Branch at NICHD*
- Erik C.B. Olsen—Outstanding Student Paper Award, Human Factors and Ergonomics Society
- Bruce Simons-Morton—Certificate of Recognition: Excellence and Commitment to Traffic Safety and Accident Prevention, 2003 Geico Public Service Award
- Bruce Simons-Morton—NIH Award of Merit: *For developing and testing innovative school-based interventions to prevent smoking, aggressiveness and other problem behaviors among middle school students*
- Anjel Vahratian—Student Prize Paper Award, Society for Pediatric & Perinatal Epidemiologic Research (IRTA Predoctoral Fellow)
- Brian Whitcomb—Student Award Prize, Society for Epidemiologic Research (IRTA Predoctoral Fellow)
- Kai Fun Yu—Elected to the International Statistical Institute
- Jun Zhang—Project nominated as one of the DHHS's *Women's Health Accomplishments 2001-2004: Epidural Analgesia in Labor and Delivery*
- Jun Zhang—NIH Award of Merit: *For accomplishments in advancing safe intrapartum care of women and excellence in obstetrical epidemiology*

AWARDS FOR 2005

- Kaye Beall—NIH Director's Award: *For outstanding support for DESPR and NIH with a pleasant work ethic which exemplifies the best of civil service support*
- Denise Haynie—NIH Undergraduate Scholarship Program Special Recognition Award: *For mentorship and training of scholars*
- Mark Klebanoff—2005 Advancing Knowledge Award: *From The Coalition for Excellence in Maternal and Child Health Epidemiology*
- Richard Levine—NIH Director's Award: *For scientific advances in understanding the pathogenesis of preeclampsia*
- Bruce Simons-Morton—Rockefeller Foundation Scholar-In-Residence, Awarded for February through March, 2005

In addition, five DESPR investigators are elected Fellows of the American College of Epidemiology (Drs. Klebanoff, Levine, Buck Louis, Mills, and Zhang), four are Fellows of the American Epidemiological Society (Drs. Klebanoff, Levine, Buck Louis, and Mills), one is a Fellow of the Infectious Diseases Society of America (Dr. Lin), one is a Fellow of the American Academy of Health Behavior and Distinguished Fellow, Society for Public Health Education (Dr. Simons-Morton), and one is a Fellow of the American Psychological Association (Dr. Iannotti). One Division investigator is also an elected member of the International Statistics Institute (Dr. Yu).

APPENDIX C: PUBLICATIONS BY DESPR STAFF, FISCAL YEAR 2001 THROUGH FISCAL YEAR 2005

(DESPR Staff Names Appear in Bold)

OFFICE OF THE DIRECTOR (OD)

2001

Branch, D.W., Sibai, B.M., Hogg, B., Lindheimer, M.D., **Klebanoff, M.A.**, vanDorsten, J.P., et al. (2001). Antiphospholipid antibodies in women at risk for preeclampsia. *American Journal of Obstetrics and Gynecology, 184*, 825-834.

Buekens, P., & **Klebanoff, M.A.** (2001). Preterm birth research: From disillusion to the search for new mechanisms. *Paediatric and Perinatal Epidemiology, 15*(S2), 159-161.

Buka, S.L., Tsuang, M.T., Torrey, E.F., **Klebanoff, M.A.**, Bernstein, D., & Yolken, R.H. (2001). Maternal infections and subsequent psychosis among offspring: a forty-year prospective study. *Archives of General Psychiatry, 58,* 1032-1037.

Buka, S.L., Tsuang, M.T., Torrey, E.F., **Klebanoff, M.A.**, & Yolken, R.H. (2001). Maternal cytokine levels during pregnancy and adult psychosis. *Brain, Behavior and Immunity, 15*, 411-420.

Carey, J.C., & **Klebanoff, M.A.** (2001). Bacterial vaginosis and other asymptomatic infections in pregnancy. *Current Women's Health Reports, 1*, 31-35.

Cohen, G.R., Levine, R.J., Ewell, M.G., Morris, C.D., Catalano, P.M., Clokey, D., & **Klebanoff, M.A**. (2001). Ethnicity, nutrition, and birth outcomes in nulliparous women. *American Journal of Obstetrics and Gynecology, 185*, 660-667.

Goldenberg, R.L., **Klebanoff, M.**, Carey, J.C., & MacPherson, C. (2001). Metronidazole treatment of women with a positive fetal fibronectin test result. *American Journal of Obstetrics and Gynecology, 185*, 485-486.

Klebanoff, M.A., Carey, J.C., Hauth, J.C., Hillier, S.L., Nugent, R.P., Thom, E.A., et al. (2001). Metronidazole to prevent preterm birth among asymptomatic pregnant women with *Trichomonas vaginalis*. *New England Journal of Medicine, 345*, 487-493.

Klebanoff, M.A., Levine, R.J., Morris, C.D., Hauth, J.C., Sibai, B.M., Curet, L.B., et al. (2001). Accuracy of self-reported cigarette smoking among pregnant women in the 1990s. *Paediatric and Perinatal Epidemiology*, 15, 140-143.

Longnecker, M.P., **Klebanoff, M.A.**, Brock, J.W., & Zhou, H. (2001). Polychlorinated biphenyl serum levels in pregnant subjects with diabetes. *Diabetes Care, 24*, 1099-1101.

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PREVENTION RESEARCH BRANCH

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