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OUR MISSION

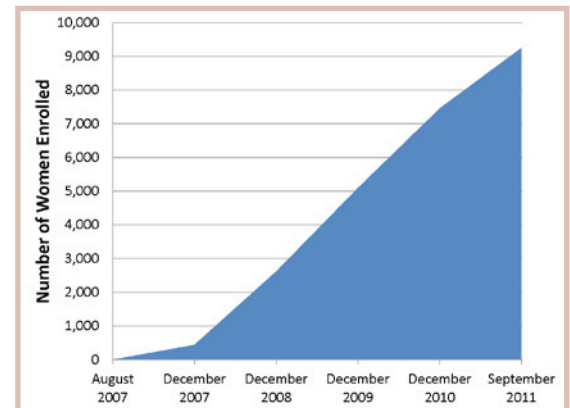
The Division of Clinical Research (DCR), Department of Obstetrics and Gynecology at Washington University School of Medicine provides specialized facilities and services to support clinical research in women's reproductive health.

Our mission is to foster collaborative, multidisciplinary research aimed at improving women's health.

The Contraceptive CHOICE Project Reaches Enrollment Goal of 9,250 St. Louis-area Women

In August of 2007, Dr. Peipert and colleagues launched the CHOICE Project, a prospective cohort study of women 14-45 years designed to promote the use of long-acting reversible contraceptive methods (e.g., IUDs and implant) to reduce unintended pregnancy at the population level. In September of 2011, the last participant was enrolled. The ability to recruit the cohort in four years was the result of a successful collaboration between research staff, St. Louis area community health clinics, and private providers. Our partners included Reproductive Health Services, Planned Parenthood, Hope Clinic for Women, Grace Hill Neighborhood Health Centers, Family Care Health Centers, Barnes, and the SPOT. Seventy percent of participants enrolled at the research clinic located at the Division of Clinical Research through provider referrals and word-of-mouth. The remaining 30% were enrolled on site at our partner clinics.

Women enrolled in CHOICE undergo standardized contraceptive counseling regarding all methods of reversible birth control. Women select a method and can change methods during the study if dissatisfied. Participants are followed for up to three years with telephone surveys to measure continuation and satisfaction and to identify pregnancy. All women are offered free sexually transmitted disease testing and treatment at enrollment and on an annual basis.



Thus far, the Project has published 15 peer-reviewed manuscripts and presented 22 peer-reviewed oral and poster presentations at 7 scientific conferences. Lead authorship has included faculty, staff, family planning fellows, OB/GYN residents, and medical and undergraduate students. Important study findings include:

- Nearly 75% of women selected the most effective forms of contraception, 58% IUD and 17% implant.
 - Among teens 14 to 17 years, 28% chose an IUD and 50% chose the implant.
 - Among young women 18 to 20 years, 44% chose an IUD and 24% chose the implant.
- Long-acting reversible contraception users had higher 12-month continuation rates (86%) than oral contraceptive pill users (55%). LARC continuation rates were: levonorgestrel intrauterine system (88%), copper IUD (84%) and implant (83%).
- Only 30% of women who use the pill, patch, or ring repeatedly fill their monthly prescription on time.
- In a randomized trial of 12-month chlamydia and gonorrhea screening, women assigned to home-based were twice as likely to complete testing as women assigned to clinic-based testing. These findings remained when women were not randomized and able to choose their testing method (home versus clinic).

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Research Staff Highlights



Gina Secura, PhD, MPH
Senior Scientist/Epidemiologist
Department of Obstetrics and Gynecology
Division of Clinical Research
Washington University School of Medicine

Gina Secura, PhD, MPH is a Senior Scientist/Epidemiologist at Washington University in the Department of Obstetrics and Gynecology in St. Louis Missouri.

She received her Bachelor of Arts degree in biology from the University of California at Santa Barbara in 1987 and her master of public health degree from Saint Louis University in 1996. From 1997 through 2002 she was employed as an epidemiologist at the Centers for Disease Control and Prevention (CDC) conducting HIV risk behavior and prevalence studies in adolescent populations. In 2002, she served as a consultant to the World Health Organization in Nepal and provided technical assistance to their Expanded Program on Immunization and Polio Eradication. Also in 2002, she served as a consultant to the CDC's Global AIDS Program in Malawi, Africa where she provided technical assistance in implementing an HIV seroprevalance and risk behavior survey. Dr. Secura completed her Ph.D. in public health studies at Saint Louis University in 2006.

Dr. Secura's current role at Washington University is the Project Director for the Contraceptive CHOICE Project. The objective of this prospective cohort study is to reduce the barriers to obtaining the most effective methods of contraception (e.g., intrauterine contraception and subdermal implant) to reduce unintended pregnancy rates in the St. Louis region. The study enrolled 9,250 women from the St. Louis region over a four-year period and follows participants up to three years. The study will measure contraceptive method satisfaction, side effects, and continuation among participants and unintended pregnancy rates at the population level. Additionally, the project seeks to reduce sexually transmitted infections (STI), particularly chlamydia and gonorrhea.

Dr. Secura's research interests are best described as sexually transmitted infections among adolescents, affordable contraception and international public health. Dr. Secura's previous research included: HIV prevalence and risk among young men who have sex with men, young women of color in New York City, and male bathhouse attendees in Los Angeles.

Dr. Secura enjoys gardening, cooking, entertaining friends, and traveling to Italy. She is married to Bob Nease and has two stepsons, two cats, one dog & three chickens. †

Questions or Comments?
Feel free to contact
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Special thanks to all those
who made this newsletter
possible. Your hard work
is appreciated!

- Monica Anderson
- Teresa Bieg
- Tracy Burger
- Kim Delli-Zotti
- Christine Kramer
- Lynne Lippmann
- Molly Meyer
- Linda Odibo
- Jeffrey Peipert
- Lyndsay Roy

New Faces

Welcome to all of our newest staff members.

Bridget Conlon
Research Assistant

Sarah England
Professor

Kathleen Fendler
Research Patient Coordinator

Andrea Hagemann
Assistant Professor

Colleen McNicholas
Clinical Fellow

Molly Stout
Clinical Fellow

Michele Wells
Research Patient Coordinator



Methodius Tuuli, MD, MPH

Assistant Professor

Department of Obstetrics and Gynecology

Division of Maternal Fetal Medicine

Washington University School of Medicine

Dr. Tuuli is an Assistant Professor of Obstetrics and Gynecology in the Division of Clinical Research (Maternal Fetal Medicine). He joined the Washington University School of Medicine Faculty in August of 2011. Dr. Tuuli attended the University of Ghana Medical School in Accra, Ghana. He subsequently earned a Master's degree in Public Health at the University of California, Berkeley, after which he returned to Ghana to work as a public health consultant. He completed his residency in Obstetrics & Gynecology at Emory University in Atlanta, Georgia. He came to Washington University for fellowship in Maternal Fetal Medicine. Besides his clinical duties, Dr. Tuuli serves as Women's Reproductive Health Scholar, devoting 75% of his time to research.

Dr. Tuuli's areas of clinical interest include general maternal medicine, preterm birth, operative obstetrics, hypertensive disorders in pregnancy, sickle cell disease, preconception counseling, maternal cardiac disease, fetal cardiac defects, abdominal wall defects, obstetric ultrasound, and prenatal diagnosis.

His research interests are primarily in the area of obstetric epidemiology. He utilizes various designs including randomized clinical trials, cohort and case-control studies to generate primary data and critically assess and synthesize available data using systematic reviews, meta-analysis, decision and cost-effectiveness analysis with the goal of providing quality evidence to guide clinical practice and health policy. Specific areas of current research endeavors include prediction and prevention of placenta-related syndromes, prevention of preterm births, evidence-based practices at cesarean delivery, optimal management of labor and sickle cell disease in pregnancy.

He has several peer-reviewed publications and invited reviews and has authored two book chapters.

Dr. Tuuli enjoys reading, traveling and country music. †

What's Happening at the DCR

Below is a list of current studies conducted within the Division.

OBSTETRICS

3D DOPPLER AND INTRAUTERINE GROWTH RESTRICTED

PI: *Katie Goetzinger, MD* • CRNC: *Linda Odibo, RN, BSc, MN*

A prospective cohort study to determine if IUGR fetuses are more likely to exhibit evidence of altered cerebral blood flow compared to normal fetuses when quantified using 3-D power Doppler studies. Recruitment will occur in the Obstetric Ultrasound department in the Center for Advance Medicine, and 300 patients will be enrolled: 150 IUGR and 150 controls.

ANTISEPTIC SKIN PREPARATION FOR PREVENTING SURGICAL SITE INFECTION AT CESAREAN DELIVERY

PI: *Methodius Tuuli, MD, MPH* • CRNC: *Patty Fogertey, RN, MSN*

This is a randomized controlled trial to determine the comparative effectiveness of chlorhexidine-alcohol and iodine-alcohol preoperative skin preparation for preventing surgical site infections at cesarean section. All women undergoing cesarean delivery at Barnes-Jewish Hospital will be eligible and will be randomized on a 1:1 ratio to the use of Chlorhexidine-alcohol or Iodine-alcohol. A total of 1200 women will be recruited.

BACTERIAL-HOST INTERACTIONS IN BLOOD AND AMNIOTIC FLUID

PI: *Amanda Lewis, PhD*

The aim of the study is to examine the impact of bacterial surface carbohydrate structures on mechanisms of survival in blood and amniotic fluid and the potential consequences of bacterial products on proinflammatory cytokine induction. Approximately 100 samples of each of the following specimens: blood, umbilical cord blood, and amniotic fluid, through the Women and Infant's Health Specimen Consortium over a 2-year period.

CERVICAL DOPPLERS IN PREGNANCY

PI: *Jeffery Dicke, MD* • RA: *Lyndsay Roy*

We hypothesize that cervical Doppler studies will reflect vascular remodeling during pregnancy and thus may be a useful tool to assess cervical softening and dilation in pregnancy. As the cervical artery undergoes vascular changes throughout gestation to enhance blood flow to the cervix, the intravascular resistance will decrease and the Doppler indices, including the S/D ratio and the PI ratio, will decrease. We hypothesize that cervical Doppler indices will progressively change throughout each trimester. A total of 100 women will be enrolled in the Obstetric Ultrasound department in the Center for Advance Medicine.

CERVICAL LENGTH SCREENING STUDY

PI: *Jennifer McNamara, MD, Methodius Tuuli, MD, MPH* • RA: *Kristen Powers*

A prospective observational study aimed at assessing the agreement between transabdominal cervical length assessment to transvaginal cervical length assessment and to estimate if short cervical length in women with prior preterm birth who are on 17 OHP is predictive of therapeutic failure (recurrent preterm delivery). A total of 410 women will be recruited between 17 and 23 weeks gestation from the Obstetric Ultrasound department in the Center for Advanced Medicine and BJH.

CERVICAL FOLEY + CYTOTEC VS CYTOTEC FOR CERVICAL RIPENING AND LABOR INDUCTION

PI: *Jeanine Carbone, MD* • CRNC: *Patty Fogertey, RN, MSN*

A randomized controlled clinical trial to compare the efficacy of the combination of the cervical foley bulb and cervical misoprostol (Cytotec) to cervical misoprostol (Cytotec) alone for cervical ripening and induction of labor.

A total of 122 patients with Bishop's scores of ≤ 6 (unfavorable cervix) requiring induction of labor will be enrolled.

DIABETES STUDY

PI: *Alison Cahill, MD, MSCI* • CRNC: *Danielle Frueh, RN, BSN*

Sponsored by a Thrasher Grant

A prospective study aimed at assessing optimal predictors of fetal macrosomia, birth trauma, or combined neonatal morbidity outcomes in diabetic pregnant women. Recruitment occurs in the antepartum clinic, BJH and CAM. A total of 340 pregnant women will be enrolled over a four-year period.

EFFECT OF HYPOTHERMIA ON NEUTROPHINS IN NEWBORN INFANTS WITH ENCEPHALOPATHY

PI: Rakesh Rao, MD

This is a sub-study of the Women and Infant's Health Specimen Consortium study. Neurotrophins (NTs), particularly brain derived neurotrophic factor (BDNF) are trophic factors important in brain growth and development. BDNF has been shown to be neuroprotective in various forms of brain injury. This study is aimed at evaluating the change in BDNF and other NT's in newborn infants with encephalopathy particularly infants with hypoxic ischemic encephalopathy (HIE) after birth. Approximately 20 specimens will be collected through The Women and Infant's Health Specimen Consortium study.

ELECTRONIC FETAL MONITORING STUDY

PI: Alison Cabill, MD, MSCI • CRNC: Carla Chung RN; BSN, Danielle Frueh, RN, BSN

Sponsored by a Robert Wood Johnson Grant

A retrospective cohort study aimed at identifying which characteristics of fetal heart rate decelerations are associated with fetal acidemia at delivery. This is done by quantitatively analyzing electronic EFM recordings in the second stage of labor, and comparing these characteristics between women who deliver an infant with an umbilical cord pH ≤ 7.10 to those with a cord pH > 7.10 . A total of 5,000 charts will be reviewed over a three-year period.

GESTATIONAL WEIGHT GAIN IN THE OBESE GRAVIDA

PI: Lorie Harper, MD • CRNC: Patty Fogertey, RN, MSN

A prospective cohort study enrolling 245 women prior to 20 weeks gestation who have pre-pregnant BMI's > 30 . The aim of the study is to examine the impact of gestational weight gain on maternal and neonatal pregnancy outcomes. We will also investigate the relationship between serum biomarkers of adiposity and pregnancy outcomes. Patients will be enrolled through the WIHSC.

INTRAUTERINE GROWTH RETARDATION AND METABOLOMIC PROFILES

PI: Marwan Shinawi, MD

This is a sub-study of the Women and Infant's Health Specimen Consortium Study aimed at analyzing maternal serum metabolomic fingerprints and correlate them with fetal and newborn metabolomes. Although not a direct aim of this study, the fetomaternal metabolomic data can be correlated in long-term studies with developmental delays, cognitive disabilities, and behavioral abnormalities. The study will collect blood, urine, amniotic fluid, and umbilical cord blood from approximately 150 women with normal pregnancies and 30-50 women with fetal IUGR through the WIHSC.

INTRAUTERINE GROWTH RESTRICTION STUDY

PI: Anthony Odibo, MD, MSCE • CRNC: Linda Odibo, RN, BSc, MN

A prospective cohort study aimed at comparing the ability of two antepartum tests, (Doppler flow studies of fetoplacental vessels and biophysical profile), to optimally determine the timing of delivery of preterm intrauterine growth-restriction pregnancies. Recruitment occurs in the Obstetric Ultrasound department, BJH and the Center for Advanced Medicine. A total of 318 pregnant women will be enrolled.

MAGNETIC RESONANCE IMAGING AND SPECTROSCOPY OF THE HUMAN PLACENTA IN VIVO

PI: Michael Nelson, MD, PhD

The study aim is to optimize the magnetic resonance (MR) protocols for scanning human placentas in vivo in order to gain experience in studying human placental anatomy and metabolism using (MRI) and (MRS). Recent data indicate that fetal growth disorders are often better delineated as a result of MRI and MRS studies. Recruitment will occur from pregnant subjects who will undergo an MRI at Barnes Jewish Hospital. The aim is to recruit up to 65 women.

METABOLIC CONDITIONS AND PREGNANCY

PI: Marwan Shinawi, MD

This is a sub-study of the Women and Infant's Health Specimen Consortium Study aimed at analyzing the newborn metabolomes and correlate this with maternal serum metabolomic fingerprints in health and diseases (IUGR and metabolic conditions). Approximately 200 subjects will be collected through the WIHSC and the Predicting Adverse Pregnancy Outcomes study.

OCCULT INFECTIONS AND PRETERM DELIVERY

PI: Indira Mysorekar, PhD • RT: Rebecca Gunkel • RA: Bridget Conlon, Michele Landeau

Sponsored by Burroughs Wellcome

A prospective study aimed at determining which pathogenic bacteria are present as occult, intracellular reservoirs in endometrial/placental tissues in women with preterm birth and to evaluate whether pre-existing infection disrupts placental development. Recruitment will occur on Labor and Delivery at BJH through the WIHSC.

PANORAMA: PREDICTING NEONATAL ACIDEMIA AND NEUROLOGIC INJURY WITH INTRAPARTUM FETAL HEART RATE MONITORING

PI: Alison Cahill, MD, MSCI • CRNC: Monica Anderson, RN, BSN; Carla Chung, RN, BSN; Danielle Frueh, RN, BSN; Tracy Burger RN, BSN

Sponsored by a NIH/NICHHD RO1 grant

A prospective study aimed at determining which fetal heart rate deceleration characteristics, are associated with an infant umbilical cord arterial pH ≤ 7.10 . The study also aims to develop and validate a clinical predictive index to identify specific fetuses at high risk for acidemia based on characteristics of EFM recordings. Recruitment will occur at Barnes-Jewish Hospital with a total of 7,150 mothers and 200 babies over a five-year period.

PLACENTAL FUNCTION STUDY

PI: Methodius Tuuli, MD, MPH • CRNC: Linda Odibo, RN, BSc, MN

This is a prospective cohort study of pregnant women between 18-22 weeks gestation who are undergoing their second trimester fetal anatomy scan. The study aims to determine if a single parameter of placental structure, blood flow, or analyte secretion in the second trimester predicts sub-optimal pregnancy outcome and to determine if combination of first trimester and second trimester placental assessment and analyte secretion improve the predictive value of the model to predict adverse pregnancy outcome. A total of 1,500 women will be recruited from the Obstetric Ultrasound department, and the CAM.

POLYMICROBIAL SYNERGISM IN ADVERSE PREGNANCY OUTCOMES

PIs: Anthony Shanks, MD, Amanda Lewis, PhD, Jenifer Allsworth, PhD

This is a longitudinal study in order to examine whether combinations of bacterial inhabitants in the reproductive and urinary tracts are associated with higher risks of adverse pregnancy outcomes. Urine and vaginal swabs collected during prenatal visits will be obtained through the WIHSC.

PREDICTING ADVERSE PREGNANCY OUTCOMES

PI: Anthony Odibo, MD, MSCE • CRNC: Linda Odibo, RN, BSc, MN

This is a prospective cohort study of pregnant women between 11-14 weeks gestation undergoing their first trimester aneuploidy scan. The aim of the study is to determine if a single parameter of placental structure, blood flow, or analyte secretion predicts sub-optimal pregnancy outcome. The study includes doppler evaluation of uterine arteries, assessment of placental volume, maternal serum for free beta-hCG and PAPP-A, with the addition of ADAM12s, PP13 and PIGF levels. A total of 1,500 women will be recruited from the Obstetric Ultrasound Department, Center for Advanced Medicine over a three-year period.

THE ROLE AND REGULATION OF MAXI-K CHANNELS DURING PREGNANCY

PI: Sarah England, PhD

Sponsored by an NIH grant

This is a prospective study looking at the control of muscle contractions of the uterus during labor by looking at channel proteins in the uterine muscle. These channel proteins are involved in muscle functions. Approximately 1000 women will be recruited from Barnes Jewish Hospital who are undergoing cesarean delivery or hysterectomy at Barnes Jewish Hospital.

SLEEP DEPRIVATION DURING PREGNANCY

PI: George Macones, MD, MSCE, Jen Jen Chang, PhD • RA: Molly Meyer

A longitudinal prospective cohort study to ascertain the prevalence and risk factors of chronic sleep deprivation during pregnancy and its effects on postpartum depression and spontaneous preterm delivery. A total of 356 nulliparous women will be recruited from the antenatal clinic in BJC and the Center for Advanced Medicine over a three-year period.

TUPAC: TREATMENT UTILITY OF POSTPARTUM ANTIBIOTICS IN CHORIOAMNIONITIS

PI: Anthony Shanks, MD • CRNC: Patty Fogertey, RN, MSN

A randomized controlled clinical trial to determine if prophylactic antibiotics are required post-cesarean delivery for pregnancies with treated chorioamnionitis. Enrollment is 398 laboring patients with chorioamnionitis who require delivery via cesarean section.

THE ST. LOUIS NEONATAL GUT MICROBIOME INITIATIVE

PI: Barbara Warner, MD • CRC: Christine Kramer

Sponsored by the Children's Discovery Institute of St. Louis Children's Hospital

A twin birth cohort study aimed at testing the relative roles of host genotype versus early environmental exposures (mother, diet, etc) on gut microbial ecology. This will compare how similar the microbial community is for identical twins to non-identical twins in the first year of life. Recruitment will occur at the CAM, Labor and Delivery at BJC, and Missouri Baptist Hospital. The study aims to enroll 100 mothers and 25 monozygotic twin pregnancies over 34-weeks gestation.

VDAART: VITAMIN D ANTENATAL ASTHMA REDUCTION TRIAL

PI: Robert Strunk, MD • CRNC: Danae Larson, RN, BSN • RA: Jennifer Byers, Yvonne Burrage

Sponsored by a NIH Grant

A multi-centered randomized double blind controlled trial to determine whether sufficient vitamin D supplementation in the pregnant mother is associated with reduced incidence of asthma in the child during the first three-years of life. Our primary outcomes will be doctor's diagnosis of asthma and/or recurrent wheeze in the child at age three-years. A total of 290 patients at Washington University will be recruited over two years.

GYNECOLOGY

BMI: CHANGE IN BMI AND CONTRACEPTION STUDY

PI: Jeffrey Peipert, MD • RA: Jennifer Wade

As a retrospective sub-study of the Contraceptive CHOICE Project (CHOICE), our goal is to measure the change in body weight and body mass index (BMI) between baseline and 12 months in women who use the ENG implant, LNG-IUC, or depot medroxyprogesterone acetate for at least 11 months and to compare these measures to users of the copper IUC. We plan to enroll 100 participants in each group.

BACTERIAL-HOST INTERACTIONS IN VAGINAL FLUIDS

PI: Amanda Lewis, PhD • Co-PI's: Jenifer Allsworth, PhD, Tessa Madden, MD, MPH

We have shown that sialidase activity can have a profound impact on the physical properties of proteins involved in mucosal immunity that are modified with sialic acid residues. Using clinical samples from women with or without BV, we aim to further characterize how sialidases may be involved in the initiation and complications of this infection using molecular, tissue culture, and animal models. Approximately 800 vaginal swabs will be collected through the VAST study over a 3 year period.

THE CONTRACEPTIVE CHOICE PROJECT

PI: Jeffrey Peipert, MD, PhD • Project Director: Gina Secura, PhD, MPH

Sponsored by an anonymous foundation

The study aim is to reduce the number of unintended pregnancies in the St. Louis area by providing no cost contraception of a woman's choice for three years, including STD and HIV testing and STD treatment. Recruitment occurs at the Division of Clinical Research, as well as multiple family planning clinics in the St. Louis region. A total of 10,000 women will be enrolled over a four-year period with follow-up for three-years after enrollment.

DEVELOPMENT OF A CONTRACEPTIVE DECISION MAKING TOOL

PI: Tessa Madden, MD, MPH • Project Director: Gina Secura, PhD, MPH

Sponsored by a Society of Family Planning (SFP) Grant

The study will conduct the formative research necessary to develop a computerized decision-making tool that incorporates the social and cultural factors that influence women's contraceptive decisions; and therefore increase satisfaction, knowledge, and decision certainty with the contraceptive decision-making process. Through focus groups, surveys and initial assessments among women and clinicians, a web-based interactive computerized tool will be developed and pilot tested among participants of the Contraceptive CHOICE Project.

DXA: WEIGHT CHANGE AND CONTRACEPTION STUDY

PI: Jeffrey Peipert, MD, PhD • RA: Danielle Grunloh

As a prospective sub-study of the Contraceptive CHOICE Project (CHOICE), our goal is to measure the change in body weight, body mass index (BMI), and body composition measured by dual-energy x-ray (DXA) technology between baseline and 12 months in women using the ENG implant, LNG-IUC, or depot medroxyprogesterone acetate and to compare these measures to users of the copper IUC. We will also examine whether appetite and physical activity change during this time period. Enrollment began in December 2010; 115 participants will be enrolled in each group. In addition, among the first 40 participants, we will compare body composition results of the DXA scan to results using a bioelectric impedance scale.

FACT (FERTILITY AFTER CONTRACEPTION)

PI: Amy Stoddard, MD • Co-PI: Jeffrey Peipert, MD, PhD • CRA: Hanna Xu

The FACT Study will assess time to pregnancy (fertility) after IUD removal, and compare this group to women discontinuing other contraceptive methods. Eligible participants will be between 18 and 35 years old and will have discontinued their contraceptive method within the past 60 days. Following enrollment, women will be followed-up with phone interviews at 6, 12, 18 and 24 months after method discontinuation.

A PHASE 3, RANDOMIZED, MULTI-CENTER, OPEN-LABEL STUDY OF A LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEM AND MIRENA® FOR LONG-TERM REVERSIBLE CONTRACEPTION

PI: David Eisenberg, MD, MPH • RA: Kristen Powers

Sponsored by Medicine 360

A Phase III, multi-center, randomized study aimed at evaluating whether the safety and effectiveness of LNG 20 intrauterine contraceptive system compared to the Mirena. A total of 150 women will be recruited at the Division of Clinical Research.

MISTIC: MIRENA INTRAUTERINE SYSTEM TIMING OF INSERTION CONTROLLED TRIAL

PI: Lorie Harper, MD • Co-PI: David Eisenberg, MD, MPH

This substudy of the CHOICE Contraceptive Project is a randomized control trial with the aim of determining the timing of Mirena® insertion that results in the greater proportion of women with a Mirena in place at 6 months post-partum. Women requesting the Mirena for post-partum contraception will be enrolled at CHOICE sites at 36 weeks gestation or greater and will be randomized at the time of vaginal delivery to receive the Mirena immediately post-placenta or at 4-8 weeks post-partum. Approximately 200 women will be randomized.

mtDNA ON FERTILITY

PI: Kelle Molle, MD

This is a sub-study of the Women and Infant's Health Specimen Consortium study. The purpose of this study is to identify heteroplasmic mitochondria (mt) DNA mutations at the level of a single oocyte that can lead to decreased IVF efficiency and fertility.

NK CELLS AND IVF OUTCOME

PI: Joan Riley, PhD

This is a sub-study of the Women and Infant's Health Specimen Consortium Study aimed to determine if the percentage of NK (natural killer) cells, their cell surface phenotype, or their cytokine production profile in follicular fluid can be used to predict pregnancy outcome. Specimens will be collected through the Women and Infant's Health Specimen Consortium study from approximately 50 women.

OVARIAN RESERVE AND JUVENILE/ADULT RHEUMATOID ARTHRITIS & SPONDYLOARTHRITIS

PI: Amber R. Cooper, MD • CRNC: Mary Koenig, RN

Sample analysis supported by Beckman Coulter, Inc.

This is a prospective study aimed at evaluating ovarian reserve in females 4-50 years of age with the diagnosis of RA, JRA/JIA, or SPA (spondyloarthritis). The purpose is to evaluate the effects of disease severity and biologic/cytotoxic therapies on ovarian function. Recruitment of patients is at SLCH and the Rheumatology Clinic at the Center for Advanced Medicine and will continue until 300 patients are enrolled.

REPRODUCTIVE OUTCOMES IN OBESE WOMEN WITH INFERTILITY

PI: Emily Jungheim, MD

A prospective cohort study of obese versus non-obese women undergoing in-vitro fertilization with the objective to study potential contributions of leptin, and adiponectin to poor reproductive outcomes among obese women. Recruitment will occur in the Department of Reproductive Endocrinology and Infertility. Approximately 450 IVF cycles and seven patients will be recruited from each group through WIHSC.

THE VARIANT HOOK EFFECT IN OVER-THE-COUNTER hCG DEVICES

PI: Ann Gronowski, PhD • CRC: Christine Kramer

The objective of this study is to investigate whether very high concentrations of one variant form of hCG (hCG beta core fragment) would produce falsely negative hCG results in five commonly used qualitative OTC hCG devices and to also demonstrate the temporal nature of this effect in early pregnancy.

THE VAST STUDY

PI: Jenifer Allsworth, PhD • CRNC: Linda Odibo, RN, BSc, MN • RA: Molly Meyer

A prospective cohort study nested within the Contraceptive CHOICE Project that seeks to evaluate the role of genomic variation in Human Leukocyte Antigens in susceptibility to bacterial sexually transmitted infections (*Chlamydia trachomatis* and *Neisseria gonorrhoeae*). A total of 1,000 women between the ages of 18 and 45 years will be recruited.

VITAMIN D AND VAGINAL FLORA

PI: Jenifer Allsworth, PhD • Danae Larson, RN, BSN

A substudy of the Vitamin D Antenatal Asthma Reduction Trial that will evaluate the impact of Vitamin D supplementation during pregnancy on vaginal flora. Up to 150 women will be recruited.

WIHSC: WOMEN AND INFANT'S HEALTH SPECIMEN CONSORTIUM

PI: Ann Gronowski, PhD; Kelle Moley, MD; Jenifer Allsworth, PhD; Marwan Shinawi, MD • CRC: Christine Kramer • RAs: Lyndsay Roy, Kim Townsend, Laura Hanneken, Bridget Conlon, Michele Landeau

Sponsored by a Children's Discovery Institute Grant

The study aim is to create a structure to facilitate the collection of patient specimens for women and infant's health research. The bank will provide specimen collection, specimen storage and processing, as well as the maintenance of a comprehensive database of outcomes data for five hypothesis driven projects. This process will be completed by working together with the LTP (Laboratory Translational Pathology). Recruitment will occur at Washington University Reproductive Endocrinology and Infertility Center, the Center for Advanced Medicine, Barnes Jewish Women's Health Clinic and Labor and Delivery. Approximately 2000 women and 350 infants will be enrolled.

ONCOLOGY*

A RANDOMIZED PHASE III TRIAL OF EVERY-3-WEEKS PACLITAXEL VERSUS DOSE DENSE WEEKLY PACLITAXEL IN COMBINATION WITH CARBOPLATIN WITH OR WITHOUT CONCURRENT AND CONSOLIDATION BEVACIZUMAB (NSC #704865, IND #7921) IN THE TREATMENT OF PRIMARY STAGE III OR IV EPITHELIAL OVARIAN, PERITONEAL OR FALLOPIAN TUBE CANCER

PI: David G. Mutch, MD • Coordinator: Lynne Lippmann, CCRP

Sponsored by Gynecologic Oncology Group (NCI), GOG 262 / ACRIN 6695

A Phase III randomized study for the treatment of Stage III (and some Stage II) suboptimal or Stage IV primary ovarian, peritoneal or fallopian tube cancer. Patients who have received prior neoadjuvant chemotherapy with interval cytoreduction are eligible for this study as well. Patients are randomized to Carboplatin/Paclitaxel on Day 1 versus Carboplatin Day 1 and Paclitaxel Days 1, 8 and 15 of a 21 day cycle. Each patient may choose whether she wants to receive Bevacizumab in combination with her chemotherapy as well as maintenance therapy with Bevacizumab. There is an imaging component using perfusion CT scans available to those patients who opt to participate as Washington University is an ACRIN (American College of Radiology Imaging Network) site. Target accrual group-wide: 625

A PHASE II RANDOMIZED DOUBLE-BLIND TRIAL OF A POLYVALENT VACCINE-KLH CONJUGATE (NSC 748933 IND# 14384) + OPT-821 VERSUS OPT-821 IN PATIENTS WITH EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PERITONEAL CANCER WHO ARE IN SECOND OR THIRD COMPLETE REMISSION

PI: David G. Mutch, MD • Coordinator: Lynne Lippmann, CCRP

Sponsored by Gynecologic Oncology Group (NCI), GOG 255 - Cooperative Group

This is a Phase II vaccine study for patients who have achieved a 2nd or 3rd complete response (CR) defined as CA125 level within normal limits, negative physical, exam and CR or MRI showing no evidence of disease. Patient must have undergone cytoreductive surgery and at least one platinum-based treatment as part of their primary therapy. Treatment includes the immunologic adjuvant OPT-821 given subcutaneously +/- polyvalent vaccine. Treatment is given on weeks 1, 2, 3, 7 and 11 and then every 3 months for a total of 11 vaccines. Target accrual group-wide: 164

A RANDOMIZED TRIAL OF BUFFERED VS NON-BUFFERED LIDOCAINE WITH EPINEPHRINE FOR CERVICAL LOOP EXCISION

PIs: Nora Kizer, MD; L. Stewart Massad, MD • Coordinator: Lynne Lippmann, CCRP

Sponsored by Gynecologic Oncology Group (NCI)

A randomized 2 arm study comparing two different lidocaine solutions commonly used in the performance of a LEEP. At the time of their procedure, patients who have consented to participate in the study receive their local anesthesia for the LEEP with either buffered or non-buffered lidocaine. The physician is blinded as to which lidocaine is being used. At the end of the procedure, patients are asked to score the pain they felt during the procedure using a visual scale on a paper questionnaire. Study participation ends once their pain score is completed. Target accrual group-wide: 54

A LIMITED ACCESS PHASE I/II TRIAL OF PACLITAXEL, CISPLATIN AND CTEP SUPPLIED AGENT ABT-888 (VELAPARIB) (IND #77840, NSC #737664) IN THE TREATMENT OF ADVANCED, PERSISTENT, OR RECURRENT CARCINOMA OF THE CERVIX

PI: David Mutch, MD • Coordinator: Lynne Lippmann, CCRP

Sponsored by Gynecologic Oncology Group (NCI), GOG 0076HH - Cooperative Group

This is a Phase II study with a Phase I lead-in which will also be performed at Washington University to determine the final dose to be used in the Phase II study. Patients will receive the chemotherapy drugs paclitaxel (given on day 1) and cisplatin (given on day 2), given intravenously, in addition to the investigational drug ABT-888, a PARP inhibitor available as an oral capsule twice daily on days 1-7. Cycles are repeated every 21 days. There is a translational research component to this study involving tumor tissue taken from a previous biopsy or surgery as well as additional blood draws for those patients entered in the Phase I portion of the study. Treatment will continue unless there is evidence of disease progression, there are side effects prohibiting further therapy, or the study is stopped. Target accrual group-wide: 111

A PHASE II EVALUATION OF IXABEPILONE (IND #710428) IN THE TREATMENT OF RECURRENT OR PERSISTENT CARCINOSARCOMA OF THE UTERUS

PI: David Mutch, MD • Coordinator: Lynne Lippmann, CCRP

Sponsored by Gynecologic Oncology Group (NCI), GOG 130F - Cooperative Group

This is a Phase II study exploring the use of Ixabepilone, an epothilone drug. Epothilones are similar to paclitaxel but have the potential to work on cells that are resistant to paclitaxel. Patients are treated on day 1 of each 21-day cycle and are given the drug intravenously. There is a translational research component to this study involving tumor tissue taken from a previous biopsy or surgery. Treatment will continue unless there is evidence of disease progression, there are side effects prohibiting further therapy, or the study is stopped. Target accrual group-wide: 34

**A RANDOMIZED PHASE III EVALUATION OF DOCETAXEL (NSC#628503)
AND GEMCITABINE (NSC#613327) PLUS G-CSF WITH BEVACIZUMAB (NSC #704865, IND#7921) VERSUS
DOCETAXEL (NSC#628503) AND GEMCITABINE (NSC#613327) PLUS G-CSF WITH PLACEBO IN THE
TREATMENT OF RECURRENT OR ADVANCED LEIOMYOSARCOMA OF THE UTERUS**

PI: David G. Mutch, MD • Coordinator: Lynne Lippmann, CCRP

Sponsored by Gynecologic Oncology Group (NCI), GOG 250 - Cooperative Group

This is a Phase III randomized, blinded, placebo controlled study with 2 arms: one arm involves the use of the combination of docetaxel and gemcitabine, G-CSF and Bevacizumab versus the other arm utilizing the combination of docetaxel and gemcitabine, G-CSF and placebo. Gemcitabine and docetaxel are the current commonly used drugs for the treatment of leiomyosarcoma and the use of Bevacizumab/placebo is the investigational portion of this study. If there is evidence of tumor progression, the investigator may request information regarding whether or not Bevacizumab was part of the original treatment regimen. Gemcitabine is given on Day 1 of a 21 day cycle along with the Bevacizumab/placebo. On day 8 patients receive docetaxel and gemcitabine. All drugs are given intravenously. G-CSF is given after Day 8, either utilizing Neupogen daily for 7 days or Neulasta given on Day 9 or 10. There is a translational research component to this study involving tumor tissue taken from a previous biopsy or surgery. Treatment will continue unless there is evidence of disease progression, there are side effects prohibiting further therapy, or the study is stopped. Target accrual group-wide: 130

**Sampling of current studies*

GRANTS AWARDED

Barnes Jewish Hospital Foundation

PI: George A. Macones, MD, MSCE | Award period: 07/01/11 – 06/30/12
In-Vitro Fertilization Program Endowed Fund

Barnes Jewish Hospital Foundation

PI: George A. Macones, MD, MSCE | Award period: 07/01/11 – 06/30/12
Faye Beth and S. Charles Baer Research Endowment Fund in Reproductive Medicine

Barnes Jewish Hospital Foundation

PI: George A. Macones, MD, MSCE | Award period: 07/01/11 – 06/30/12
Koven/Wasserman Research Endowed Fund

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PI: George A. Macones, MD, MSCE | Award period: 07/01/11 – 06/30/12
Dr. David Rothman Endowed Fund

Barnes Jewish Hospital Foundation

PI: George A. Macones, MD, MSCE | Award period: 07/01/11 – 06/30/12
Department of Obstetrics and Gynecology Patient Safety & Quality Improvement Initiative

Barnes Jewish Hospital Foundation

PI: David Mutch, MD | Award period: 07/01/11 – 06/30/12
Michael and Carol Staenberg Gynecologic Oncology Research Fund

Barnes Jewish Hospital Foundation

PI: David Mutch, MD | Award period: 07/01/11 – 06/30/12
Gynecologic Oncology Fund

Barnes Jewish Hospital Foundation

PI: David Mutch, MD | Award period: 07/01/11 – 06/30/12
J.G. Probstin Visiting Professorship in Surgery Endowed Fund

Barnes Jewish Hospital Foundation

PI: D. Michael Nelson, MD | Award period: 07/01/11 – 06/30/12
Virginia S. Lang Chair in Obstetrics and Gynecology

Society of Family Planning

PI: Amy Stoddard, MD | Award Period: 06/01/11 – 06/30/12
Fertility after IUD Removal: The FAIR Study

American College of Obstetricians & Gynecologists

PI: Katherine Goetzinger, M.D. | Award Period: 07/01/11 – 06/30/12
Three-Dimensional Power Doppler in the Evaluation of Intrauterine Growth Restriction

The Gynecologic Oncology Group

PI: David Mutch, MD | Award Period: 07/16/11 – 05/31/12
GOG - 8199 Coordinating Center

National Institute of Health R21

PI: Israel Zigelboim, MD | Award Period: 09/22/11 – 08/31/13
ATR Mutation in Endometrial Cancer

Society of Family Planning

PI: Tessa Madden, MD | Award Period: 10/01/11 – 09/30/13
Randomized Clinical Trial of a Computerized Contraceptive Decision Aid



If we missed your publication, please let us know and we will be happy to include it in the next issue of the newsletter.

Severity of bacterial vaginosis and the risk of sexually transmitted infection.

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The effects of body mass index on complications and survival outcomes in patients with cervical carcinoma undergoing curative chemoradiation therapy.

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Continued from Front Page:

As of September 2011, over 42,000 surveys have been completed and nearly 1,500 women have graduated the study. Follow-up rates at 12, 24, and 36-months are 89%, 85%, and 82% respectively. The Project will continue to follow women until September of 2014 and will measure population-based outcomes for repeat abortion and teen pregnancy.

In addition to the main study, investigators have recruited participants from the CHOICE cohort into 13 additional sub-studies investigating a range of research questions including home versus clinic-based STI testing, weight gain/change by contraceptive method, immediate versus delayed post-partum insertion of the IUD, fertility after contraceptive use, trial of lidocaine gel to reduce discomfort with IUD insertion, and the development of a computerized contraceptive decision making tool.

The Project has received local and national media attention and in January of 2011, it created a community engagement workgroup to develop a dissemination and translation plan beyond peer-reviewed channels. The Project has hosted multiple meetings with community partners, academics in translation and dissemination research, participants, and local stakeholders in women's health to better understand how best to share research findings that resonate with different audiences and eventually translate into clinical practice. In September the Project's [website](#) transitioned from a recruitment tool to a referral and resource site where St. Louis area women can locate area providers for contraception and STD testing. The website is also regularly updated to reflect current publications. †

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