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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.

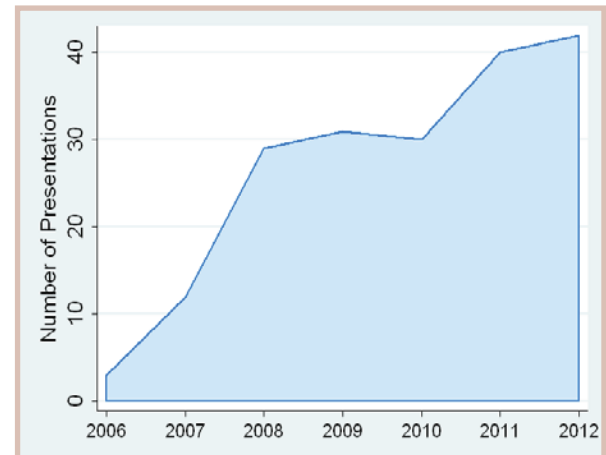
Washington University School of Medicine in St. Louis

Washington University Obstetrics DELIVERS at the Society for Maternal-Fetal Medicine Annual Meeting

The 32nd annual meeting of the [Society for Maternal Fetal Medicine](#) was held in Dallas this past February. This meeting, called the 'The Pregnancy Meeting', is an international conference for Maternal-Fetal Medicine physicians and staff. Activities included post-graduate courses and research presentations. Throughout the week WashU physicians moderated post-graduate courses and scientific forums and presented both oral and poster presentations.

This year 1,423 abstracts were submitted from all over the world, of which 800 were selected for oral and poster presentations. In all, 40 abstracts (6 oral and 34 poster presentations) were accepted from WashU.

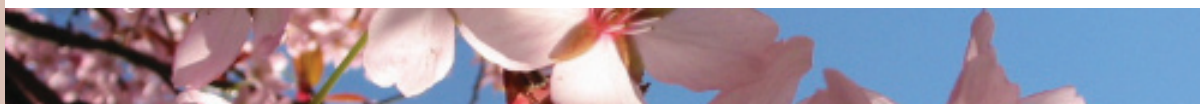
Additionally, WashU researchers continued in their many national collaborations as co-authors of an oral presentation from the University of Pittsburgh, as well as poster presentations from SLU, Oregon, and Northwestern. This was the second largest number of presentations from a single institution at the meeting.



The following were oral presentations from WashU:

- Pregnancy after LEEP: results of a multicenter study - Dr. Macones
- First-trimester prediction of preterm birth using ADAM12, PAPP-A, uterine artery Doppler and maternal characteristics - Dr. Goetzinger
- Prior preterm birth in first pregnancy and risk of small-for-gestational-age birth in second pregnancy: a population-based study - Dr. Chang
- The bladder flap at cesarean delivery-to create or not to create: a randomized controlled trial - Dr. Tuuli
- The pattern of labor preceding uterine rupture - Dr. Harper
- Predicting acidemia with intrapartum electronic fetal monitoring(EFM) patterns - Dr. Cahill

Many of these presentations have already been submitted for publication. Several of these were published in the April edition of *Obstetrics and Gynecology* (the green journal). The meeting was also an opportunity to brainstorm on future research ideas. We congratulate all our researchers and research staff on these achievements and look forward to a great year in the world of research. +



Research Staff Highlights



Sarah England, PhD

Professor

*Department of Obstetrics and Gynecology
Washington University School of Medicine*

Dr. Sarah K. England is a Professor of Obstetrics and Gynecology in the Basic Science Division. She joined the Washington University School of Medicine Faculty in July 2011. Dr. England attended the Medical College of Wisconsin in Milwaukee, after graduating from Carleton College in Northfield, Minnesota. She completed her Postdoctoral Fellowship in the Department of Molecular Physiology and Biophysics at Vanderbilt University. Prior to accepting her position at Washington University, Dr. England was on faculty for 14 years in the Department of Molecular Physiology and Biophysics at The University of Iowa. Besides her duties within Obstetrics and Gynecology, Dr. England also serves as a Professor in the Department of Cell Biology and Physiology and is a member of the Division of Biology and Biomedical Sciences at Washington University.

Dr. England's long-term research interest lies in the role of ion channels in smooth muscle as they pertain to women's health. Uterine dysfunction during pregnancy is a significant healthcare problem that has long-term medical and financial consequences. One focus of her research is to determine how calcium-activated K⁺ channels in the myometrium modulate uterine excitability and contractility during gestation and parturition.

Dr. England's research is funded by both the National Institutes of Health, and the March of Dimes. She has written many research and review articles and has reviewed for multiple journals in both basic science and clinical fields. Dr. England has served on review committees for multiple funding agencies including the NIH, AHA, and the Howard Hughes Medical Institute. Dr. England was a 2005-2006 Robert Wood Johnson Health Policy Fellow. She worked in the office of Senator Hillary Rodham Clinton for one year on policies related to maternal child health issues, women's health and the healthcare workforce.

Dr. England enjoys playing tennis in her free time. +

*Questions or Comments?
Feel free to contact
Monica Anderson at:
andersonm@wudosis.
wustl.edu*

*Special thanks to all those
who made this newsletter
possible. Your hard work
is appreciated!*

- Monica Anderson
- Tracy Burger
- Kim Delli-Zotti
- Patty Fogertey
- Danielle Frueh
- Lynne Lippmann
- Linda Odibo
- Jeffrey Peipert
- Kristen Powers

New Faces

Welcome to all of our newest staff members.

Whitney Enlow
Research Patient Assistant

Michele Landeau
Research Patient Assistant

Suzanne Law
*Clinical Research Nurse
Coordinator*

Rondek Salih
Research Patient Assistant

Kirthika Vijayakumar
Research Patient Coordinator

Lauren Zeiter
Research Patient Assistant



Andrea Hagemann, MD

Assistant Professor

Department of Obstetrics and Gynecology

Division of Gynecologic Oncology

Washington University School of Medicine

Dr. Hagemann is an Assistant Professor of Obstetrics and Gynecology in the Division of Gynecologic Oncology. She joined the Washington University School of Medicine Faculty in July 2011, after completing her gynecologic oncology fellowship at the University of Pennsylvania. She is not entirely new to Washington University, however. After graduating cum laude from Princeton University with a degree in Molecular Biology and minor in French Language and Culture, she moved to St. Louis to complete medical school at Washington University School of Medicine. She remained at Barnes-Jewish Hospital for her residency in Obstetrics & Gynecology, and then went on to complete her fellowship at U Penn.

Dr. Hagemann's clinical interests include the surgical and medical management of gynecologic malignancies, complex pelvic surgery and minimally invasive surgery (laparoscopy and the da Vinci™ Surgical System). Research interests include treatment outcomes in gynecologic malignancies, including venous thromboembolism (VTE) prophylaxis in gynecologic malignancies. Recent efforts have also focused on translational aspects of cancer immunotherapy, including patient-specific vaccines for recurrent ovarian cancer. As a junior faculty member, she is hoping to complete her Masters in Clinical Investigation.

Dr. Hagemann is happy to once again call St. Louis home. She is an avid runner, and missed Forest Park during her fellowship. She is an accomplished pianist, though these days she mostly just plays for fun at home. She is back in St. Louis with her husband, Ian, currently a surgical pathology fellow at Barnes-Jewish, her two children, Sophie (4) and Oliver (1), and her yellow Labrador retriever. †

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.

BACTERIAL-HOST INTERACTIONS IN VAGINAL FLUIDS

PI: *Amanda Lewis, PhD*

This is a sub-study of the Women and Infant's Health Specimen Consortium Study using clinical samples from women with or without BV, to further characterize how sialidases may be involved in the initiation and complications of this infection using molecular, tissue culture and animal models.

CERVICAL DOPPLERS IN PREGNANCY

PI: *Jeffery Dicke, MD • CRNC Linda Odibo, RN, BSc, MN*

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 150 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 • CRNC Linda Odibo, RN, BSc, MN*

A prospective observational study aimed at assess 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). Secondary aim is to determine if maternal or fetal factors that weaken agreement between the measurements and to identify whether there is a minimal transabdominal length that sufficiently rules out shortened cervix and would make transvaginal assessment unnecessary. 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.

EARLY PREDICTION AND ASPIRIN FOR PREVENTION OF PREECLAMPSIA STUDY (THE EPAPP STUDY)

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

A prospective randomized control trial to estimate the efficacy of low dose aspirin for preventing preeclampsia in women identified as high risk from a first trimester preeclampsia prediction model. Women will be randomized on a 1:1 ratio to either placebo or low dose aspirin. A total of 220 women will be randomized. Recruitment will take place in the Center for Advance Medicine, BJH prenatal clinic and Missouri Baptist Medical center from women undergoing ultrasound examination at 9–13 6/7 weeks gestation.

GESTATIONAL WEIGHT GAIN IN THE OBESE GRAVIDA : MATERNAL/FETAL OUTCOMES

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

This sub study of the Women and Infant's Health Specimen Consortium studies gestational weight gain in obese (pre-pregnant BMI >30) in relation to adverse maternal and fetal/neonatal outcomes. Maternal and infant blood samples are being collected to measure adipokine levels. Patients are enrolled between 15-22 weeks gestation with a target enrollment of 238.

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: Carla Chung, RN, BSN; Danielle Frueh, RN, BSN; Tracy Burger RN, BSN; Suzanne Law RN • RA: Whitney Enlow

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 Recruitment: Patty Fogertey, RN, MSN

Sponsored by an NIH grant and March of Dimes

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.

THE STAGE AND ORGAN – SPECIFIC TRANSCRIPTOME OF THE HUMAN EMBRYO

PI: Kelle Moley, MD

This is a sub-study of the Women and Infant's Health Specimen Consortium Study aimed to use available otherwise discarded, miscarried and ectopic pregnancies to develop a database of spatio-temporal gene expression in the organs and tissues of the human embryo. Using laser microdissection methods, frozen tissues from these nonviable conceptuses will be used to extract RNA, amplify as cDNA and then use as templates for next-generation sequencing (RNA-seq). These data would be made available to WU investigators involved in the study of specific organs or tissues.

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. Women with treated chorioamnionitis undergoing cesarean delivery at Barnes-Hospital are eligible and are randomized on a 1:1 ratio to no postpartum antibiotics or postpartum antibiotics. Recruitment goal is 238 patients. Multi-center trial with Washington University as coordinating site.

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.

VAGINAL MICROBIOME AND PRETERM BIRTH

PI: George Macones, MD

This is a sub-study of the Women and Infant's Health Specimen Consortium Study aimed to identify novel microbes which constitute the vaginal microbiome of pregnancy and identify specific patterns which may be linked to preterm birth. Second and third trimester vaginal swabs will be selected from 30 cases of preterm births less than 37 weeks and 90 controls will be selected based on gestational age of delivery > 37 weeks.

GYNECOLOGY

BMI: CHANGE IN BMI AND CONTRACEPTION STUDY

PI: Tessa Madden, MD, MPH • 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: Tessa Madden, MD, MPH • Co-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.

EFFECTIVENESS OF PROLONGED USE OF IUD/IMPLANT FOR CONTRACEPTION

PIs: Jeffrey Peipert, MD, PhD, Colleen McNicholas, DO • RA: Meghan Proehl

Sponsored by a Family Planning Fellowship Grant

This research study is looking to evaluate the use of the Implant or the hormonal intrauterine device (IUD) for contraception past the FDA approved duration of use. This study will provide essential information to inform patients, their clinicians and the field. Through phone surveys information will be collected regarding extended use.

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.

THE FUNCTIONAL SIGNIFICANCE OF INSULIN IN TESTES AND SPERM

PI: Kelle Moley, MD

This is a sub-study of the Women and Infant's Health Specimen Consortium Study aimed to investigate glucose transportation and insulin signaling in sperm from both diabetic and non-diabetic men and to evaluate how they may be impacted by diabetes. Semen will be obtained from 10 non-diabetic men from the Reproductive and Infertility Clinic.

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

[Click here to learn more about this study.](#)

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.

LEVONGESTREL INTRAUTERINE SYSTEM FOR EMERGENCY CONTRACEPTION

PI: Colleen McNicholas, DO

This research study is evaluating the hormonal intrauterine device as a form of emergency contraception as compared to the current most common oral levonorgestrel regimen. Increasing the use of intrauterine contraception as a method of emergency contraception, and as a result, providing long term reversible contraception, has the potential to significantly reduce unintended pregnancy and abortion rates. Information regarding efficacy and satisfaction of the hormonal intrauterine device will be collected through clinic visit and phone surveys.

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.

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.

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, 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 *

PHASE I STUDY OF IV CARBOPLATIN/PACLITAXEL OR IV AND IP PACLITAXEL/CISPLATIN IN COMBINATION WITH CONTINUOUS OR INTERMITTENT ABT-888 AND BEVACIZUMAB IN NEWLY DIAGNOSED PATIENTS WITH PREVIOUSLY UNTREATED EPITHELIAL OVARIAN, FALLOPIAN TUBE AND PRIMARY PERITONEAL CANCER

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

Sponsored by Gynecologic Oncology Group (NCI), GOG 9923

Phase I study to determine the MTD and dose-limiting toxicities of the oral PARP inhibitor ABT-888 given BID when administered using continuous (days 1-21) versus intermittent (Days -2-5) dosing with IV carboplatin, paclitaxel and bevacizumab (2 different regimens) or IP cisplatin and IV/IP paclitaxel and IV bevacizumab in this patient population. Cycles are every 21 days with bevacizumab beginning at cycle 2 for 6 cycles. Bevacizumab is then continued as maintenance for cycles 7-22. As this is a Phase I study, dosing cohorts will open and close quickly.

Target accrual group-wide: Minimum 145, maximum 474

RANDOMIZED PHASE II EVALUATION OF SINGLE-AGENT BEVACIZUMAB AND COMBINATION BEVACIZUMAB WITH FOSBRETABULIN TROMETHAMINE (CA4P) IN THE TREATMENT OF RECURRENT OR PERSISTENT EPITHELIAL OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CARCINOMA

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

Sponsored by Gynecologic Oncology Group (NCI), GOG 0186I

Short description: A randomized 2 arm study comparing bevacizumab to bevacizumab + fosbretabulin tromethamine for the treatment of recurrent/persistent disease in women with ovarian, fallopian tube or primary peritoneal cancer. Bevacizumab blocks vascular endothelial growth factor and fosbretabulin tromethamine recognizes abnormal blood vessels in the cancer cells and sticks to the inside walls of these blood vessels, causing cell death. Both drugs are considered investigational for this study and are provided by the study. Treatment on both arms is every 3 weeks given intravenously until disease progression, unacceptable toxicity, closure of study, or physician or participant decision to discontinue.

Target accrual group-wide: 53-110

PHASE II EVALUATION OF BIBF 1120 IN THE TREATMENT OF RECURRENT OR PERSISTENT ENDOMETRIAL CARCINOMA

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

Sponsored by Gynecologic Oncology Group (NCI), GOG 229K

Short description: A Phase II study of the investigational drug BIBF 1120 for the treatment of endometrial cancer in the recurrent per persistent setting. Participants must have received at least one prior chemotherapeutic regimen and one additional chemotherapeutic regimens but no prior non-cytotoxic therapy. BIBF 1120 stops 3 proteins from working: VEGFR, PDGFR and FGFR, thus preventing the growth of tumor blood vessels and tumor cells. This is an oral drug given BID until disease progression, unacceptable toxicity, closure of study, or physician or participant decision to discontinue.

Target accrual group-wide: 32-52

**Sampling of current studies*

GRANTS AWARDED

Center for Women's Infectious Disease Research

PI: Drs. Jeffrey Peipert and Jenifer Allsworth | Award Period: 11/01/11 – 08/31/12
Fertility After Intrauterine Device Removal (FAIR)

National Institute of Health National Institute of Environmental Health Sciences F32 / NRSA Fellowship

PI: Kenan Omurtag, MD | Award period: 01/01/12 – 12/31/13
The Effect of Dioxins on Glucose Homeostasis in Murine Testes

Barnes Jewish Hospital Foundation (Poetting Fund)

PI: David Mutch, MD | Award period: 01/01/12 – 12/31/12
Support for Gynecologic Oncology Research

Society of Family Planning

PI: Colleen McNicholas, MD | Award Period: 01/09/12 – 06/28/13
Effectiveness of Prolonged use of IUD/Implant for Contraception (EPIC)

CIMED Pilot & Feasibility Program

PI: Sarah England, PhD | Award Period: 02/01/12 – 01/31/13
Role of K_{ATP} Channels in Regulating Gestational Timing

March of Dimes

PI: Sarah England, PhD | Award Period: 03/01/12 – 02/28/15
Mechanisms Underlying Myometrial Smooth Muscle Relaxation During Pregnancy

National Institute of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development

PI: Tessa Madden, MD | Award Period: 03/08/12 – 01/31/15
Evaluation and Testing of a Decision Support Aid in Contraceptive Decision Making

Transdisciplinary Research on Energetics and Cancer (TREC)

PI: Joan Riley, PhD | Award Period: 06/01/12 – 05/31/13
The Effects of Obesity on Breast Cancer Development and NK Cell-Mediated Antitumor Immune Responses



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

Altered mitochondrial apoptotic pathway in placentas from undernourished rat gestations.

Belkacemi L, Desai M, Nelson DM, Ross MG.

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Magnesium sulfate therapy for the prevention of cerebral palsy in preterm infants: a decision-analytic and economic analysis.

Cahill AG, Odibo AO, Stout MJ, Grobman WA, Macones GA, Caughey AB.

Am J Obstet Gynecol. 2011 Dec;205(6):542.e1-7. Epub 2011 Sep 16.

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Cahill AG, Roehl KA, Odibo AO, Zhao Q, Macones GA.

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Chiang CL, Hagemann AR, Leskowitz R, Mick R, Garrabrant T, Czerniecki BJ, Kandalaft LE, Powell DJ Jr, Coukos G.

PLoS One. 2011;6(12):e28732. Epub 2011 Dec 14.

Plan B, One Step not taken: politics trumps science yet again.

Cleland K, Peipert JF, Westhoff C, Spear S, Trussell J.

Contraception. 2012 Feb 1. [Epub ahead of print] No abstract available.

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Cooper AR, O'Neill KE, Allsworth JE, Jungheim ES, Odibo AO, Gray DL, Ratts VS, Moley KH, Odem RR.

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Reprod Sci. 2011 Aug;18(8):702-12. Review.

Treatment Strategies and Prognosis of Endometrial Cancer, Cancer of the Uterine Endometrium - Advances and Controversies

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J. Salvador Saldivar (Ed.), ISBN: 978-953-51-0142-0, InTech, 2012.

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Goetzinger KR, Tuuli MG, Odibo AO.

J Ultrasound Med. 2011 Oct;30(10):1415-23.

Effect of regional anesthesia on the success rate of external cephalic version: a systematic review and meta-analysis.

Goetzinger KR, Harper LM, Tuuli MG, Macones GA, Colditz GA.
Obstet Gynecol. 2011 Nov;118(5):1137-44. Review.

A phase I study with an expanded cohort to assess the feasibility of intravenous paclitaxel, intraperitoneal carboplatin and intraperitoneal paclitaxel in patients with untreated ovarian, fallopian tube or primary peritoneal carcinoma: A Gynecologic Oncology Group study.

Gould N, Sill MW, Mannel RS, Thaker PH, Disilvestro P, Waggoner S, Yamada SD, Armstrong DK, Wenzel L, Huang H, Fracasso PM, Walker JL.
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Am J Perinatol. 2011 Nov 21. [Epub ahead of print]

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More About the LNG20 Birth Control Study

In April 2010, Washington University launched the LNG20 birth control study, a Phase 3, randomized, multi-center trial studying the effectiveness and safety of a levonorgestrel-containing IUD. Our site's recruitment goal was 150. Given the number of women who needed and were interested in receiving free birth control, we quickly enrolled 61 women by July. Due to issues with the insertion device the study sponsor, Medicines360 Inc, decided to pause enrollment at all sites in July 2010. Those women already enrolled would keep their IUD and be followed according to protocol.

Those enrolled are in the study for a minimum of 2 years and up to 5 years. During this time, they are required to come to the clinic for in-person visits and complete phone and email surveys. In order for this drug to get FDA approval, it's incredibly important that women not only stay in the study, but complete all of these follow ups within their visit "window." Our site has been working hard to achieve this goal and has been very successful. Currently, we have a >90% in-window follow up rate for all visits and surveys done in the last 2 years. We have also managed to keep most of our original 61 enrolled active in the study. Washington University is in the top 25% retention-wise of the 26 sites open in the US.

Quite possibly the most difficult part in clinical research is keeping participants active and compliant with necessary study procedures. There are many factors that can lead to subjects dropping out or being non-compliant, and it's up to study staff to try to reduce as many of these reasons as they can to keep studies successful. The following are some tips that may help in keeping subjects interested and on board with being great participants!

- Take time to know your patients.
- Treat subjects as you would want to be treated!
- Be accommodating with their schedule and life.
- Listen and be available to talk to participants about any concerns or issues they are having.
- Personality is key!

