THE ANNUAL CHARLES B. HAMMOND, MD RESEARCH DAY

Department of Obstetrics & Gynecology
Duke University Medical Center
Durham, North Carolina

Friday, May 20, 2022

Duke Obstetrics & Gynecology
Duke University School of Medicine

Foreword

Charles B. Hammond, MD, Research Day is a time to celebrate and honor Duke Obstetrics and Gynecology trainees for their exceptional achievements in research and their dedication to impacting the future of women's health. Dr. Hammond was an internationally recognized leader, educator, researcher and advocate for women's health. He was a mentor to many, me included. As Chair and Residency Program Director for more than 20 years, he was committed to ensuring that residents and fellows developed into well rounded academic obstetrician/gynecologists with outstanding clinical skills, a sharp scientific mind and a compassionate heart.

This year, more than ever, we will commemorate the impressive and tireless research efforts of our residents and fellows and honor the legacy of the renowned physician scientist whose commitment to research, education and patient care represents Duke Ob/Gyn's standard of excellence: the late Charles B. Hammond, MD.

Honoring Dr. Charles B. Hammond

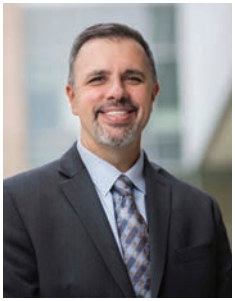
Dr. Hammond was the E.C. Hamblen Distinguished Professor of Reproductive Biology and Family Planning and Chair of the Department of Obstetrics & Gynecology from 1980 to 2002. He received his medical degree from Duke University in 1961. During the next nine years, he completed an internship in surgery, a residency in obstetrics and gynecology, a one-year training interval in the research training program, all at Duke, and two years as a clinical associate in the endocrinology branch at the National Cancer Institute in Bethesda, Maryland.

He joined the faculty at Duke in 1969 and had enormous impact on ob/gyn and women's health over more than 40 years in academia. A nationally recognized expert in menopause and hormone replacement therapy, Dr. Hammond was also a pioneer in the treatment of gestational trophoblastic disease and founded the Southeast Regional Trophoblastic Disease Center. Countless lives were saved because of his innovative research and the development of treatment regimens for this once life-threatening condition.

Dr. Hammond served as President of the North Carolina Society of Obstetricians and Gynecologists, the American Fertility Society (now ASRM), the American Association of Obstetricians and Gynecologists Foundation, the American Gynecological and Obstetrical Society, and the American College of Obstetrics and Gynecology. He received many honors throughout his career, including being named a National Association for Women's Health Lifetime Achievement Award recipient, a fellow of the Royal College of Obstetricians and Gynaecologists, and a member of the Institute of Medicine, now the Academy of Medicine. He was granted a Lifetime Achievement Award from the American College of Obstetrics and Gynecology in 2015.

Charles B. Hammond, MD, was honored by Duke Medicine in June 2011 as a Professor and Chairman Emeritus in the Department of Obstetrics & Gynecology. Watch a brief video about his legacy.

Hammond Research Day is a significant and impactful opportunity for our residents and fellows to demonstrate their accomplishments and dedication to their research in obstetrics and gynecology and is intended to advance medical knowledge, education and research in reproductive medicine. We are proud to present this event once again, and to honor the legacy of Dr. Hammond. Thank you for joining us.



Sincerely,

Matthew D. Barber, MD, MHS
E.C. Hamblen Professor and Chair
Duke Obstetrics & Gynecology

GRADUATING FELLOWS 2021-2022

Kateena L. Addae-Konadu, MD PhD MSc
Graduate School: Morehouse School of Medicine
Medical School: Morehouse School of Medicine
Residency: Case Western Reserve University
Fellowship: Duke University Medical Center
Division of Maternal-Fetal Medicine
Future Plans: Kaiser Southeast Permanente Medical Group
Atlanta, GA

Jerome J. Federspiel, MD PhD
Graduate School: University of North Carolina Chapel Hill
Medical School: University of North Carolina Chapel Hill School of Medicine
Residency: Johns Hopkins Hospital
Fellowship: Duke University Medical Center
Division of Maternal-Fetal Medicine
Future Plans: Duke University Medical Center
Durham, NC

Rafael Gonzalez, MD
Medical School: Warren Alpert Medical School of Brown University
Residency: Brigham and Women's Hospital
Fellowship: Duke University Medical Center
Division of Gynecologic Oncology
Future Plans: Tufts University
Boston, MA

Benjamin S. Harris, MD MPH
Graduate School: University of North Carolina at Chapel Hill
Medical School: University of North Carolina at Chapel Hill School of Medicine
Residency: Duke University Medical Center
Fellowship: Duke University Medical Center
Division of Reproductive Endocrinology and Infertility
Future Plans: Shady Grove Fertility
Richmond, VA

Emily S. Herfel, DO MS-GH

Medical School:	Ohio University Heritage College of Osteopathic Medicine
Residency:	Doctors Hospital OhioHealth
Fellowship:	Duke University Medical Center Duke Global Health
Future Plans:	Duke University Medical Center Durham, NC

Michele S. O'Shea, MD MPH

Graduate School:	University of Arizona College of Public Health
Medical School:	University of Arizona College of Medicine
Residency:	Northwestern University
Fellowship:	Duke University Medical Center Division of Female Pelvic Medicine and Reconstructive Surgery
Future Plans:	Rush University Chicago, IL

GRADUATING RESIDENTS 2021-2022

Caledonia K. Buckheit, MD
Medical School: Geisel School of Medicine at Dartmouth
Future Plans: Kamm McKenzie OBGYN
Raleigh, NC

Esther H. Chung, MD
Medical School: Harvard Medical School
Future Plans: Fellowship in Reproductive Endocrinology and Infertility
Stanford University
Stanford, CA

Mira L. Estin, MD PhD
Graduate School: University of Colorado
Medical School: University of Colorado School of Medicine
Future Plans: Fellowship in Maternal-Fetal Medicine
Duke University
Durham, NC

Victoria O. Fashakin, MD
Medical School: Columbia University College of Physicians and Surgeons
Future Plans: WakeMed Physician Practices
Raleigh, NC

Chelsea H. Feldman, MD
Medical School: Duke University School of Medicine
Future Plans: Maimonides Medical Center
Brooklyn, NY

Daniel L. Spinosa, MD
Medical School: University of California, San Diego, School of Medicine
Future Plans: Fellowship in Gynecologic Oncology
University of Colorado
Aurora, CO

2022-2023 FELLOWS

Female Pelvic Medicine and Reconstructive Surgery

Douglas H. Luchristt, MD MPH (2023)

Alejandro Gomez-Viso, MD (2024)

Abbigail K. Woll, MD (2025)

Gynecologic Oncology

Benjamin B. Albright, MD MS (2023)

Pamela N. Peters, MD (2024)

Angela C. Nolin, MD (2025)

Maternal-Fetal Medicine

Amanda M. Craig, MD (2023)

Luke A. Gatta, MD (2023)

Jennifer M. Cate, MD (2024)

Ronan P. Sugrue, MBBCh MPH (2024)

Miriam L. Estin, MD PhD (2025)

Virginia Y. Watkins, MD (2025)

Quality and Safety in Women's Health

Kathleen M. Zacherl, MD (2023)

Reproductive Endocrinology and Fertility

Jessica H. Selter, MD (2023)

Shilpi Agrawala, MD (2024)

Hilary S. Friedlander, MD (2025)

RESIDENTS

CLASS OF 2023

Noor K. Al-Shibli, MD

Ryan Duggal, MD

Stephanie L. Lim, MD

Brianna E. Mastromarino, MD

Mary K. Montes De Oca, MD

Melissa N. Montoya, MD MA

Benjamin J. Peipert, MD

Julia R. Salinaro, MD

Gregory E. Zemtsov, MD

CLASS OF 2024

Carmen M. Avram, MD

Katherine E. Baumann, MD MPH

Kristen N. Carrillo-Kappus, MD MPH

Lauren E. Farmer, MD

Elizabeth P. Howell, MD

Meagan A. Kelly, MD

Sloane A. Mebane, MD

Ravyn S. T. Njagu, MD

Alexandra C. Sundermann, MD PhD

CLASS OF 2025

Susan M. Carlson, MD

Alice Darling, MD

Dayana M. Hernandez Calderon, MD

Colleen P. Judge-Golden, MD PhD

Bobby L. May, Jr., MD

Thao Nguyen, MD

Anna Shvygin, MD

Janice Wong, MD MS

Jenny Wu, MD

CLASS OF 2026

LaMani D. Adkins, MD

Maxwell E. Edmonds, MD PhD

Dayne L. Filer, MD PhD

Jessie Y. Li, MD

Alexandra E. Norton, MD MPH

Erica J. Odukoya, MD MPH

Jaxon C. Olsen, MD

Jennifer Talbott, MD MPH

Lester A. Watch, MD

CHARLES B. HAMMOND, MD RESEARCH DAY

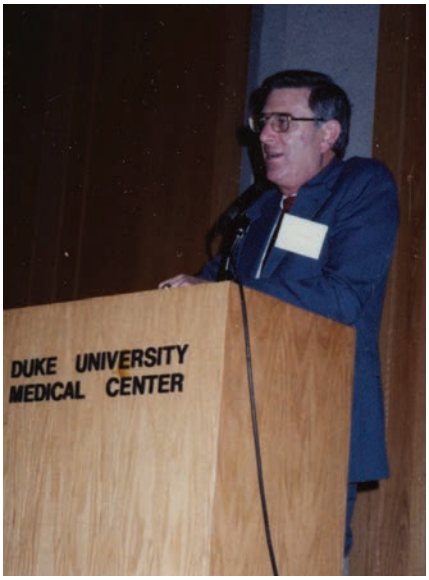
Charles B. Hammond, MD

1936-2021

Edwin Crowell Hamblen Distinguished Professor of Reproductive Biology

Chairman Emeritus, Department of Obstetrics and Gynecology
Duke University Medical Center

Dr. Charles Hammond



Previous Charles B. Hammond Lecturers

2004	Sterling B. Williams, MD
2005	William N. P. Herbert, MD
2006	David G. Mutch, MD
2007	John T. Queenan, MD
2008	Frank C. Miller, MD
2009	James R. Scott, MD
2010	Jennifer R. Niebyl, MD
2011	Michael T. Mennuti, MD
2012	Matthew D. Barber, MD MHS
2013	William C. Dodson, MD
2014	William A. Cliby, MD
2015	William T. Creasman, MD
2016	Barbara S. Levy, MD
2017	Alan H. DeCherney, MD
2018	Laura E. Riley, MD
2019	Geoffrey W. Cundiff, MD
2021	Laurel W. Rice, MD

FEATURED LECTURER AND DISTINGUISHED JUDGE

Emily S. Jungheim, MD MSCI

Edmond Confino, MD, Professor of Obstetrics an Gynecology
Chief of Reproductive Endocrinology and Infertility
Northwestern University, The Feinberg School of Medicine

Emily S. Jungheim, MD MSCI, is the Edmond Confino, MD, Professor of Obstetrics and Gynecology at Northwestern University Feinberg School of Medicine, and Chief of Northwestern's Division of Reproductive Endocrinology and Infertility. She has a busy clinical practice and conducts research focused on modifiable risk factors and reproductive health outcomes.

Outside of Northwestern, Dr. Jungheim is the incoming REI Division Chair and member of the Board of Directors of the American Board of Obstetrics and Gynecology. She also serves as an Associate Editor with *Fertility and Sterility Reports,* and on the editorial boards of *Fertility and Sterility Science,* and the *Journal of Assisted Reproduction and Genetics.*

Dr. Jungheim is a Midwesterner through and through, but she is grateful for the four formative years she spent in North Carolina as a Duke resident.

DISTINGUISHED JUDGE

Elizabeth N. Skinner, MD

Gynecologic Oncologist, Novant Health Cancer Institute
Consulting Associate in the Department of Obstetrics and Gynecology
Duke University School of Medicine

Elizabeth N. Skinner, MD, is a board-certified gynecologic oncologist. She received her undergraduate degree from Duke University and her medical degree from Emory University School of Medicine. She completed her residency training for obstetrics and gynecology and fellowship training for gynecologic oncology at the University of North Carolina, Chapel Hill in 2006.

As a gynecologic oncologist, Dr. Skinner is a huge proponent of minimally invasive surgery for gynecologic cancers, and was instrumental in developing the minimally invasive surgical program at the Novant Health Forsyth Medical Center and Novant Health Medical Park Hospital. In addition to providing medical and surgical care for women with gynecologic cancers, Dr. Skinner is committed to raising awareness about gynecologic cancers, and is the founder of Athena's Run for GYN Cancers, a nonprofit organization dedicated to raising awareness, funds and support for women battling gyn cancers.

Dr. Skinner is also extremely interested in decreasing the disparities in medical care that exist in developing countries. With this in mind, she has provided surgical/medical care for women in the Dominican Republic and recently has joined the Department of Ob/Gyn at Duke University School of Medicine as a consulting associate to continue the growing collaboration with the Kilimanjaro Christian Medical Center Ob/Gyn Residency Program in Tanzania.

DISTINGUISHED JUDGE

Alison C. Weidner, MD MMCi

2022 President, Bayard Carter Society
Professor, Department of Obstetrics and Gynecology,
Division of Female Pelvic Medicine
and Reconstructive Surgery
Duke University School of Medicine

Alison C. Weidner, MD MMCi, is a professor in the Duke Division of Urogynecology and bleeds Duke Blue, having completed her undergraduate and medical degrees at Duke prior to residency at Brigham and Women's Hospital in Boston, and returning to Duke for fellowship in urogynecology. Early in her career, she led innovative clinical research with broad-reaching impact on our knowledge of the mechanism of neuromuscular injury to the pelvic floor and its ultimate contribution to pelvic floor dysfunction. She is an active clinician/researcher treating women with various forms of pelvic floor disorders, and particularly excels at clinical and surgical education of learners at all levels in the medical setting.

Currently, her clinical research efforts are dedicated to implementing innovative studies with other investigators within the NICHD-funded Pelvic Floor Disorders Network. She is an associate editor for *Obstetrical and Gynecological Survey*. She is board certified in clinical informatics and supports the Department's Women's Health Data Sciences program developing data warehouse resources. A particular interest is enhancing care via patient-facing digital engagement applications and connected medical devices.

Duke Obstetrics & Gynecology
Duke University School of Medicine

The Annual Charles B. Hammond, MD, Research Day
Friday, May 20, 2022

ACADEMIC AGENDA

9:00 am	**Opening Remarks**
9:10 am	**Gregory E. Zemtsov, MD** Does acute funisitis predict worse neonatal outcomes among term newborns?
9:25 am	**Julia R. Salinaro, MD** Implementation of guidelines for risk-stratified thromboprophylaxis among gynecologic oncology patients receiving outpatient cancer-directed therapy: a quality improvement initiative
9:40 am	**Michele S. O'Shea, MD MPH** Standard restrictions versus expedited activity after pelvic organ prolapse surgery: a randomized non-inferiority trial
9:55 am	**Benjamin J. Peipert, MD** Utilization and perceived utility of home fertility tests among infertility patients and reproductive endocrinologists
10:10 am	**Mary K. Montes De Oca, MD** Cryocompression to reduce peripheral neuropathy in gynecologic cancer: a randomized controlled trial
10:25 am	**Emily S. Herfel, DO MS-GH** A stigma-responsive video to promote HPV-based cervical cancer prevention in Kisumu, Kenya
10:40 am	**Break**
10:50 am	**Melissa N. Montoya, MD MA** Assessing OB/GYN resident physician knowledge of state-specific parental involvement requirements for minors seeking abortions
11:05 am	**Brianna E. Mastromarino, MD** Diagnostic evaluation of recurrent pregnancy loss based on maternal age

11:20 am	**Stephanie L. Lim, MD** Outcomes and complications for concurrent hernia repair among women undergoing hysterectomy
11:35 am	**Benjamin S. Harris, MD MPH** Markers of ovarian reserve as predictors of future fertility
11:50 am	**Marquita N. Kilgore-Nolan, MD** A state-level analysis of maternal morbidity from hypertensive disorders of pregnancy by race/ethnicity and geography
12:05 pm	**Department Photo**
12:25 pm	**Lunch** **Afternoon Session Begins**
12:55 pm	**Emily S. Jungheim, MD MSCI** **Featured Lecturer and Distinguished Judge** U.S. Fertility Care in 2022: A Tale of Two Cities
1:45 pm	**Jerome J. Federspiel, MD PhD** Projected impact of guidelines on incidence of venous thromboembolism after Cesarean delivery in the United States
2:00 pm	**Ryan Duggal, MD** Increasing prevalence of risk factors for Placenta Accreta Spectrum (PAS) and associated maternal and neonatal morbidity
2:15 pm	**Rafael Gonzalez, MD** Cost-effectiveness analysis comparing "PARP inhibitors-for-all" to the biomarker-directed use of PARP inhibitor maintenance therapy for newly diagnosed advanced stage ovarian cancer
2:30 pm	**Noor K. Al-Shibli, MD** Erythropoietin levels in pregnant patients with anemia and pyelonephritis
2:45 pm	**Kateena L. Addae-Konadu, MD PhD MSc** Serum sFLT-1/PIGF ratio as a biological marker of preeclampsia in individuals with rheumatic disease
3:00 pm	**Closing Remarks** **Reception**
3:15 pm	**Awards Presentation**

ABSTRACTS

Title: Does acute funisitis predict worse neonatal outcomes among term newborns?

Resident: Gregory E. Zemtsov, MD

Faculty Mentor: Sarah K. Dotters-Katz, MD MMHPE

Objective: To evaluate the association between acute funisitis (AF) and neonatal morbidity in neonates born at term to patients with a clinical diagnosis of intraamniotic infection (IAI).

Methods: We carried out a retrospective cohort study of pregnant patients with clinically diagnosed IAI at term who delivered vaginally at a single tertiary institution from 2013-2019. Patients with intrauterine fetal demise or missing neonatal/placental pathology data were excluded. The primary outcome was a neonatal sepsis composite, defined as culture-positive bacteremia, neutropenia (ANC<3500/μL), or immature-to-total (I/T) neutrophil ratio >0.2. Secondary outcomes included composite neonatal morbidity, defined as neonatal intensive care unit (NICU) admission, 5-minute Apgar score <7, bacteremia, endotracheal intubation or need for continuous positive airway pressure, intraventricular hemorrhage (IVH) (grade 3 or 4), necrotizing enterocolitis (NEC) (stage 3 or 4), umbilical artery pH<7.1, umbilical artery base excess > 12, and neonatal mortality. Components of these composites and Kaiser early-onset sepsis (EOS) score were also measured. Neonates with AF on placental pathology were compared to those without AF using bivariate statistics.

Results: Of 184 included cases, AF was present in 109 (59%) of placental specimens. Composite neonatal sepsis was higher among neonates with AF (RR 1.85, 95% CI 1.13, 3.03). As a marker for sepsis, AF has a specificity of 78.7%, and positive predictive value (PPV) of 72.9%. I/T ratio > 0.2 (RR 1.83, 95% CI 1.09, 3.08) was also significantly associated with AF. Neonatal morbidity composite, IVH, NEC, NICU admission, higher Kaiser EOS scores, and other examined outcomes were not associated with AF.

Conclusion: In term deliveries complicated by IAI, AF was associated with increased neonatal sepsis. Current approaches for estimating neonatal sepsis risk are limited by their reliance on indirect maternal factors such as maximum maternal temperature and intrapartum antibiotic use. AF may serve as a biomarker that could be utilized to augment risk stratification at birth.

Title: Implementation of guidelines for risk-stratified thromboprophylaxis among gynecologic oncology patients receiving outpatient cancer-directed therapy: a quality improvement initiative

Resident: Julia R. Salinaro, MD

Faculty Mentor: Brittany A. Davidson, MD

Objective: Malignancy increases the risk of venous thromboembolism (VTE). Guidelines recommend thromboprophylaxis for oncology patients with a Khorana VTE risk score (KS) ≥ 2 receiving outpatient cancer treatment. We aim to describe the impact of a quality improvement (QI) initiative designed to standardize VTE risk assessment and increase compliance with guidelines for risk-stratified thromboprophylaxis among patients with gynecologic malignancies initiating outpatient cancer-directed therapy.

Methods: Key drivers of compliance with newly implemented thromboprophylaxis guidelines included provider awareness and standardized documentation of VTE risk assessment and KS eligibility. Starting May 2021, a KS calculator and thromboprophylaxis algorithm were incorporated into clinic documentation templates. Patients with gynecologic malignancies initiating treatment from January – December 2021 were eligible. Process measures included percentages of patients with KS eligibility documentation each month during the baseline (Jan – Apr) versus implementation (May – Dec) periods, rate of appropriate thromboprophylaxis initiation, and incidence of VTE. Rates of adverse bleeding events served as a balancing measure. Descriptive statistics, chi-squared test, and Fisher's exact test were employed.

Results: 337 patients accounted for the initiation of 383 treatment regimens, including 128 in the baseline period and 255 in the implementation period. KS documentation increased significantly between the baseline and implementation periods (7% vs 62.4%, $p < 0.001$). Of the 383 new treatment regimens, 177 (166 unique patients) were eligible for thromboprophylaxis (46.2%). Of these, 73 had appropriate documentation (44.0%) and 57 initiated thromboprophylaxis (78.1%). There was no difference in VTE rates or adverse bleeding events between eligible patients who initiated thromboprophylaxis compared with those who did not (12.3% vs 15.6%; p=0.65 and 7.0% vs 8.2%; p=1.0, respectively).

Conclusion: This QI initiative resulted in higher rates of VTE risk assessment and appropriate prescription of risk-stratified thromboprophylaxis. There was no difference in VTE rates or adverse bleeding among patients initiating thromboprophylaxis. Larger studies addressing efficacy, safety, and adherence are needed.

Title: Standard restrictions versus expedited activity after pelvic organ prolapse surgery: a randomized non-inferiority trial

Fellow: Michele S. O'Shea, MD MPH

Faculty Mentor: Matthew D. Barber, MD MHS

Objective: To evaluate whether expedited activity results in non-inferior anatomic and symptomatic outcomes when compared to standard activity restrictions after pelvic organ prolapse (POP) surgery.

Methods: This was a randomized controlled non-inferiority trial of patients undergoing apical reconstructive surgery for POP. Patients were randomized to receiving standard restrictions versus expedited post-operative activity instructions. Outcomes were assessed 3 months after surgery. Co-primary outcome was maximum support loss (SLmax), measured by the most distal point of pelvic organ support loss, and the Pelvic Organ Prolapse Distress Inventory (POPDI) symptom score. Secondary outcomes included subjective and objective measures of physical function, return to work, and health-related quality of life.

Results: Of 123 participants who were randomized, 108 completed 3-month follow-up. Participants were mean 62.7±10 years of age, and 56% underwent vaginal native tissue repair. At 3 months, SLmax was -1.8±1.4cm in the expedited group and -1.5±1.4cm in the standard group (p=0.4). In a linear regression model adjusting for baseline SLmax, the maximum support loss was 0.18cm higher in the vaginal canal in the expedited compared to standard activity group (SLmax -0.18, 95% CI: -0.68 to 0.32), which did not exceed the pre-specified non-inferiority margin of 1.0cm. The co-primary outcome of 3-month POPDI score was 23.6±41.4 in the expedited group vs. 25.7±39.3 in the standard group (p=0.8), with higher scores indicating more distress. In a linear regression model adjusting for baseline scores, POPDI scores were 5.96 points lower after expedited compared to standard activity (POPDI -5.96, 95% CI: -20.45 to 8.54), and also did not exceed the pre-specified non-inferiority margin of 34.3 points. Postoperative complications, physical function, time off work, and quality of life outcomes were not significantly different between groups.

Conclusion: Expedited activity after prolapse surgery results in non-inferior anatomic and symptomatic prolapse outcomes.

Title: Utilization and perceived utility of home fertility tests among infertility patients and reproductive endocrinologists

Resident: Benjamin J. Peipert, MD

Faculty Mentor: Thomas M. Price, MD

Objective: To characterize the utilization of home fertility tests (HFTs) among infertility patients and the perceived utility of HFTs among patients and reproductive endocrinologists (REIs).

Methods: We conducted a cohort analysis of new infertility patients visiting the Duke Fertility Center between December 2020-2021. Patients were identified via ICD 10 code and sent an electronic invitation to participate. HFTs were defined as tests not ordered by a physician nor performed at a physician's office. Patients and REIs were asked to rate how likely they were to recommend a given HFT on a 0-10 Likert scale. Scores were compared between patients and REIs using Wilcoxon Rank Sum tests at a significance level of $p<.05$. Multivariable logistic regression was used to assess potential factors associated with patient utilization and positive utility scores among REIs, controlling for potential confounders.

Results: In total, 425 patients (response rate =50%) and 178 REIs (response rate = 21%) completed the survey. Commonly used HFTs among patients included calendar methods of ovulation prediction (85%), urinary ovulation prediction (79%), basal body temperature monitoring (31%), hormone analysis (e.g., TSH) (14%), semen analysis (10%), and ovarian reserve testing (e.g., AMH) (9%). REIs rated the utility of all HFTs significantly lower than patients (average discordance -4.2 [range -2.4 to -5.9], $p<.0001$), except for urinary ovulation prediction, which REIs gave a significantly higher score (discordance +1.0, $p<.0001$). Prior pregnancy was significantly associated with home ovulation prediction utilization among patients (OR 3.21 [95% CI 1.2-9.83]). No REI characteristics were consistently associated with utility scores.

Conclusion: Significant discordance exists in the perceived utility of HFTs between patients and REIs. Other than urinary ovulation prediction kits, REIs gave significantly lower utility scores for all HFTs compared to patients. HFTs represent an accessible first step for many patients struggling with infertility. Education and guidelines are needed to better inform patients considering HFTs.

Title: Cryocompression to reduce peripheral neuropathy in gynecologic cancer: a randomized controlled trial

Resident: Mary K. Montes De Oca, MD

Faculty Mentor: Laura J. Havrilesky, MD MHSc

Objective: To investigate the efficacy of cryocompression therapy to prevent chemotherapy-induced peripheral neuropathy during gynecologic cancer treatment.

Methods: This is a single institution randomized, self-controlled trial of cryocompression in women with gynecologic cancer and being treated with a plan for 6 cycles neurotoxic chemotherapy. Exclusion criteria are prior neurotoxic chemotherapy or baseline peripheral neuropathy. Subjects are randomized to cryocompression applied to the dominant versus non-dominant hand and foot, with no intervention on opposite side. Compression socks and ice bags are applied to the hand and foot 15 minutes prior to chemotherapy, throughout infusion, and 15 minutes after completion. Outcome measures: Patient Neurotoxicity Questionnaire [PNQ], Functional Assessment of Cancer Therapy -Taxane [FACT-NTX], tactile disturbance using the monofilament test. Sixty completing subjects were necessary to detect a 70% reduction in the odds of PNQ ≥ C peripheral sensory neuropathy.

Results: Seventy-three subjects enrolled from January 2021-February 2022: 3 withdrew prior to intervention, 14 discontinued after 1-3 cycles. At interim descriptive analysis, 23 subjects have completed all study procedures and 33 remain on-study. The average age is 64.8 years, 68.5% are White, 93% Non-Hispanic/Latino, 60.3% with ovarian cancer, and 98.5% receiving paclitaxel. With each cycle, more subjects have sensory PNQ grade ≥ C on the control compared to the cryocompression side: 2.8% versus 2.8% at baseline; 20% vs 4% at final assessment. More subjects have a motor PNQ grade ≥ C on the control versus cryocompression side with subsequent cycles: 1.4% versus 0%-baseline and 3.0% vs 0%- cycle 5. FACT-NTX scores on the control side are consistently better than on the cryocompression side: 1.4 and 1.2-baseline; 4.7 and 3.0-final visit. Monofilament scores are near zero in each group throughout the study.

Conclusion: Cryocompression therapy appears to reduce subjective measures of chemotherapy-induced peripheral neuropathy in patients receiving paclitaxel or cisplatin for gynecologic cancer; statistical comparison is forthcoming.

Title: A stigma-responsive video to promote HPV-based cervical cancer prevention in Kisumu, Kenya

Fellow: Emily S. Herfel, DO MS-GH

Faculty Mentor: Megan J. Huchko, MD MPH

Objective: Despite increasing availability of preventative HPV vaccines and screening strategies, uptake of these effective measures in Kisumu, Kenya is limited by cultural and logistical barriers. Limited understanding and societal perceptions of HPV and cervical cancer are potential sources of stigma that could negatively impact screening behavior. By designing and implementing a stigma-responsive educational intervention, we sought to improve understanding and risk perception and increase the likelihood cervical cancer screening.

Methods: We carried out focus group discussions (FGDs) to explore experiences with HPV and cervical cancer screening, messaging and potential stigma sources. Qualitative analysis of the FGD informed the development of a stigma-responsive educational video. Four facilities were randomized to either watch the video or receive standard HPV and cervical cancer education, after which participants at both sites completed a survey to measure HPV- and cervical cancer stigma. Stigma scores were compared between control and intervention groups using linear regression.

Results: Thirty women participated in the FGDs. Drivers of stigma included concerns about confidentiality and disclosure of HPV results, fears of cancer or implications of a sexually transmitted infection diagnosis. Anticipated outcomes included illness or death, financial hardship or family abandonment. The FGD findings informed development of the educational video. Twenty-eight women, 109 in the intervention group, completed the stigma survey. Mean HPV and cervical cancer scores were statistically lower in the intervention arm, with Dholuo language associated with higher stigma levels in both arms.

Conclusion: This multi-step study explored knowledge and attitudes specific to HPV and cervical cancer health messaging in western Kenya in order to develop and test a stigma-responsive education strategy. The video demonstrated a quantitative decrease in stigma survey response means for those who watched the video. The pre-pilot will drive a larger pilot study to examine the effect of the educational video on HPV self-sampling.

Title: Assessing OB/GYN resident physician knowledge of state-specific parental involvement requirements for minors seeking abortions

Resident: Melissa N. Montoya, MD MA

Faculty Mentor: Jonas J. Swartz, MD MPH

Objective: To assess obstetrics and gynecology (OB/GYN) resident knowledge of state-specific legislation of parental involvement in minors' abortions and overall abortion laws.

Methods: OB/GYN resident physicians in the United States were sent invitation e-mails via program coordinators, ACOG program representatives, and a complex family planning national listserv. Our survey assessed demographics, general OB/GYN knowledge, and state-specific abortion legislation. Knowledge was scored by awarding 1 point for correct answers. The relationship between knowledge of parental consent for minors and resident characteristics was assessed using a test of two independent proportions. A multivariable model was used to analyze the relationship between knowledge scores for overall state-specific abortion laws and resident characteristics at a significance value of $p<.05$.

Results: In total, 331 residents from 26 states and the District of Columbia completed our survey (Response rate=21.2%). Overall, 152 residents (55.3%) correctly responded to the question on parental consent for minors in their state. The question on parental consent had the third lowest number of correct responses among all questions about state-specific abortion laws. Lower-level residents were less likely to provide a correct response, but this trend was not statistically significant (OR 0.63 [95% CI 0.39-1.02], $p=0.06$). OB/GYN knowledge was not significantly associated with a correct response to parental consent for minors nor overall abortion laws ($p>.2$). Knowledge scores for overall state-specific abortion laws were significantly associated with prior experience providing abortions (adjusted point difference +1.58), a correct response to parental consent for minors (+1.42), and participation in a Ryan Program (+0.72) ($p<.001$).

Conclusion: Experience with and exposure to providing abortions is associated with improved resident knowledge of state abortion laws; however, residents are less familiar with regulation of minors seeking abortions than they are with other areas of abortion legislation. The availability of abortion training is essential to promoting understanding of legal barriers to abortion care.

Title: Diagnostic evaluation of recurrent pregnancy loss based on maternal age

Resident: Brianna E. Mastromarino, MD

Faculty Mentor: Kelly S. Acharya, MD

Objective: To assess whether the likelihood of finding an abnormal result in the diagnostic evaluation of recurrent pregnancy loss differs based on maternal age.

Methods: We conducted a retrospective cohort study of patients within the Duke University Health System with a diagnosis of recurrent pregnancy loss who underwent at least a partial diagnostic evaluation of recurrent pregnancy loss, including thyroid screening, diabetes screening, parental karyotypes, antiphospholipid antibody testing, and uterine cavity evaluation. The likelihood of having an abnormal result was compared for two age cohorts (age <35 and age ≥35) using a logistic regression model. These results were stratified by number of pregnancy losses and presence or absence of a prior euploid loss. Lastly, we assessed which components of the diagnostic evaluation were most likely to be abnormal for both age cohorts.

Results: Out of 352 patients identified, only 61 patients had a complete diagnostic evaluation of recurrent pregnancy loss, and 121 patients had a complete maternal evaluation (complete work up excluding paternal karyotype). There was no difference in the likelihood of having an abnormal result for patients age > 35 years compared to patients age < 35 years (RR 1.08, 95% CI 0.75-1.56). No difference was found between the age groups when stratified by number of pregnancy losses. There was a trend towards increased likelihood of an abnormal result for patients with a prior euploid loss (RR 1.33, 95% CI 0.95-1.95; P = NS). The most common abnormal test results were thyroid testing (29%) and uterine cavity evaluation (45.2%). Patients age < 35 years were more likely to have an abnormal parental karyotype (17.3%) than patients age > 35 years (4.9%), though not statistically significant.

Conclusion: The likelihood of having an abnormal result in the diagnostic evaluation of recurrent pregnancy loss is not affected by maternal age.

Title: Outcomes and complications for concurrent hernia repair among women undergoing hysterectomy

Resident: Stephanie L. Lim, MD

Faculty Mentor: Rebecca A. Previs, MD MS

Objective: The aim of this study was to determine if concurrent hernia repair (hysterectomy + hernia) is associated with an increased complication rate compared to hysterectomy alone.

Methods: Patients who underwent hysterectomy alone or hysterectomy+hernia were queried using the American College of Surgeons National Surgical Quality Improvement Program participant use file. Propensity score matching was performed. Outcomes were operation time (OT), length of stay (LOS), major and minor complications. A secondary analysis of patients who underwent hysterectomy for malignant indications was performed.

Results: From 2005-2019, 369,010 patients underwent hysterectomy, and 5,071 patients had a concurrent hernia repair. Cohorts were matched 1:1 with respect to pre-operative and operative characteristics, resulting in 5,071 patients in each arm. Hysterectomy+hernia had a longer OT by 46 minutes (95% Confidence Interval [CI] = 42.6, 49.6; $p < 0.001$) and increased LOS by 0.71 days (95% CI = 0.59, 0.84; $p < 0.001$). Hysterectomy+hernia was associated with 22% higher risk (95% CI = 1.11, 1.34; $p < 0.001$) of a major complication and 34% higher risk (95% CI = 1.16, 1.56; $p < 0.001$) of a minor complication. In subgroup analyses, there was no significant effect on major complications for subjects with a body mass index (BMI) <40 kg/m2, age <40 or >60 years, tobacco use, diabetes, or a minimally invasive approach. In the malignant cohort, hysterectomy+hernia was associated with a longer OT by 32 minutes (95% CI = 25.2, 38.8; $p <0.001$) and 0.35 days increased LOS (95% CI = 0.04, 0.67; $p = 0.027$) but no significant difference in major and minor complications.

Conclusion: Hysterectomy+hernia is associated with increased OT, LOS, and risk of major and minor complications compared to hysterectomy alone. Based on subgroup analyses, concurrent hernia repair can be safely considered in select patient populations, such as those with BMI <40 kg/m2 and in patients with known malignancy.

Title: Markers of ovarian reserve as predictors of future fertility

Fellow: Benjamin S. Harris, MD MPH

Faculty Mentor: Anne Z. Steiner, MD MPH*

Objective: Ovarian reserve biomarkers have been shown to be poor predictors of current reproductive capacity. However, their value predicting future reproductive capacity is uncertain. This study sought to determine the association between ovarian reserve biomarkers and future fertility among late reproductive-age women.

Methods: This community-based cohort study included participants enrolled in Time to Conceive (TTC), a time-to-pregnancy cohort study of ovarian reserve biomarkers. Participants were 30-44 years old, without a history of infertility, and recruited from 2008-2016. Participants that provided blood samples at enrollment and agreed to future follow-up completed a web-based questionnaire between October 2020 and February 2021 on pregnancy attempts following TTC. Primary outcomes were probability of achieving a live birth > 3 years following TTC enrollment, diagnosis of infertility, and time to pregnancy in future pregnancy attempts.

Results: Women with diminished ovarian reserve (DOR), defined as AMH < 0.7 ng/mL or FSH > 10 mIU/ml, did not have lower probability of future live birth (Relative Risk [RR] 1.32; 95% CI, 0.95-1.83 and RR 1.28; 95% CI, 0.97-1.70, respectively) compared to women with normal ovarian reserve after adjusting for age at blood draw, race, obesity, use of hormonal contraception, and year of enrollment in original study. Among women in the cohort that attempted to conceive, there was not a significant association between DOR as measured by AMH or FSH and risk of future infertility (RR 0.65; 95% CI, 0.21-2.07 and RR 1.69; 95% CI, 0.86-3.31, respectively). Similarly, there was no association between DOR as measured by AMH and FSH and future fecundability (Fecundability Ratio [FR] 0.97; 95% CI, 0.59, 1.60; and FR 0.86; 95% CI 0.55-1.36, respectively).

Conclusion: Diminished ovarian reserve is not associated with reduced future reproductive capacity. Women should not use biomarkers of ovarian reserve as predictors of their current or future reproductive capacity.

**formerly at Duke*

Title: A state-level analysis of maternal morbidity from hypertensive disorders of pregnancy by race/ethnicity and geography

Resident: Marquita N. Kilgore-Nolan, MD

Faculty Mentor: Maria J. Small, MD MPH

Objective: Hypertensive disorders of pregnancy (HDP) are leading causes of global maternal mortality (MM) and severe maternal morbidity (SMM). Both Blacks and Hispanics appear to have higher SMM than whites. Racial disparities exist despite controlling for social determinants of health (SDH). Rural geography is associated with higher SMM. This study aims to: (1) determine SMM related to HDP by race/ethnicity and geography in NC, and (2) to examine differences in prevalence of HDP subtypes and related SMM by race/ethnicity and geography in NC.

Methods: We performed a retrospective, cross-sectional case control study from 2016-2019 using a state-wide inpatient hospitalization database. Inclusion criteria were delivery discharges for NC females ages 12 to 55 having a diagnosis of any subtype of HDP. Exclusion criterion was eclampsia as a type of SMM, given that it was included as a subtype of HDP. Independent variables were: race/ethnicity, geography (rural vs. urban) and subtypes of HDP. Dependent variables were SMM (defined by Alliance for Innovation on Maternal Health (AIM) criteria using ICD-10 diagnosis codes and procedure notes). We used frequencies to compare HDP diagnosis rates and chi-squared tests to assess differences in SMM.

Results: Of 441,739 deliveries, HDP occurred in 17%. Of those with HDP, 32%, 50%, and 10% were Blacks, whites, and Hispanics, respectively; also, 36% were from rural areas. Blacks had highest rates of diagnosis for every HDP subtype. Hispanics had higher diagnosis rates of preeclampsia than whites. SMM occurred in 1.7% of those with HDP. Compared to whites (128.1 per 10k delivery discharges), significantly higher rates of SMM were experienced by Blacks (232.2) and Hispanics (155.1). Diagnosis of eclampsia was significantly higher in rural areas.

Conclusion: Similar to national data, SMM and HDP subtypes were highest in Blacks, and Hispanics had higher SMM than whites. Eclampsia was higher in rural areas of NC.

Title: Projected impact of guidelines on incidence of venous thromboembolism after cesarean delivery in the United States

Fellow: Jerome J. Federspiel, MD PhD

Faculty Mentor: Andra H. James, MD MPH

Objective: To estimate the impact of adoption of venous thromboembolism (VTE) prevention guidelines on receipt of VTE pharmacologic prophylactic therapy and VTE incidence after cesarean delivery in the United States.

Methods: We used data from the 2015-2019 National Readmissions Database (NRD) to identify cesarean deliveries and rates of VTE, stratified by risk factors that would lead to different prophylactic strategies based on several national guidelines. We then used additional input parameters from the literature to construct a hybrid decision tree / Markov model to project the implications of guideline adoption on VTE rates for the first 6 weeks following delivery.

Results: Among a sample of 2.3 million cesarean delivery hospitalizations in the NRD dataset, we found an overall incidence of VTE postpartum as 1.8 per 1,000 deliveries; we calibrated the VTE rates used in modeling to be concordant with a recent meta-analysis at 4.3 per 1,000 deliveries (95% confidence interval: 1.4-8.4). Adoption of either the 2011 American College of Obstetricians and Gynecologists or the 2018 American Society for Hematology guidelines would avert a relatively small proportion (7%) of VTE cases, albeit with little use of LMWH (86-115 doses per 1,000 cesarean delivery patients). The 2012 American College of Chest Physicians guidelines were predicted to be more effective at averting VTE (27.8% reduction) with more LWMH usage (570 doses per 1,000 deliveries). The 2015 Royal College of Obstetricians and Gynaecologists guidelines and universal use of 6 weeks of LMWH would avert an even larger proportion of cases (42.6% and 61.1%, respectively), at the cost of significantly higher rates of LMWH utilization (7,233 doses per 1,000 patients and 38,648 per 1,000 patients, respectively).

Conclusion: Adoption of different guidelines has varying implications for clinical practice and potential for alteration of the national rate of VTE following cesarean delivery.

Title: Increasing prevalence of risk factors for Placenta Accreta Spectrum (PAS) and associated maternal and neonatal morbidity

Resident: Ryan Duggal, MD

Faculty Mentor: Evan R. Myers, MD MPH

Objective: To update the prevalence of risk factors for PAS disease and associated maternal and neonatal morbidity in US birth certificate data from 2010-2020.

Methods: We used US birth certificate data from 2010-2020 from the National Center for Health Statistics to analyze known risk factors for PAS included in the data set. We included singleton pregnancies who had multiple cesarean sections and assisted reproductive technology (ART) complicating their pregnancies. We calculated the incidence of maternal transfusion, unplanned hysterectomy, and ICU admission and NICU admissions by number of prior C-sections and receipt of infertility treatment. Additionally, the distribution of gestational age at delivery was calculated. We calculated relative risks and 95% CIs for women by number of prior C-sections and receipt of infertility treatment using women with no prior C-sections or infertility treatment as the reference.

Results: There was an overall increase in both the number and proportion of singleton births with risk for PAS disease between 2010 (409,938, 13.8% of singleton births) and 2020 (572,147, 16.4%). Receipt of ART alone was associated with a risk of complications associated with PAS, comparable to having 3 prior C-sections.

Conclusion: Risk factors for PAS disease increased over the last decade with an associated increased risk for complications associated with PAS, with ART having an association as high as 3 prior C-sections.

Title: Cost-effectiveness analysis comparing "PARP inhibitors-for-all" to the biomarker-directed use of PARP inhibitor maintenance therapy for newly diagnosed advanced stage ovarian cancer

Fellow: Rafael Gonzalez, MD

Faculty Mentor: Haley A. Moss, MD MBA

Objective: Clinical trials evaluating universal PARP inhibitor (PARPi) frontline maintenance therapy for advanced stage ovarian cancer have reported progression-free survival (PFS) benefit. It is unclear whether PARPi maintenance therapy will universally enhance value (clinical benefits relative to cost of delivery). We compared a "PARPi-for-all" to a biomarker-directed frontline maintenance therapy approach as a value-based care strategy.

Methods: The cost of two frontline PARPi maintenance strategies, PARPi-for-all and biomarker-directed maintenance, was compared using modified Markov decision models simulating the study designs of the PRIMA, VELIA, and, PAOLA-1 trials. Outcomes of interest included overall costs and incremental cost-effectiveness ratios (ICERs) reported in US dollars per quality adjusted progression-free life-year (QA-PFY) gained.

Results: PARPi-for-all was more costly and provided greater PFS benefit than a biomarker-directed strategy for each trial. The mean cost per patient for the PARPi-for-all strategy was $166,269, $286,715, and $366,506 for the PRIMA, VELIA, and PAOLA-1 models, respectively. For the biomarker-directed strategy, the mean cost per patient was $98,188, $167,334, and $260,671 for the PRIMA, VELIA, and PAOLA-1 models. ICERs of PARPi-for-all compared to biomarker-directed maintenance were: $593,250/QA-PFY (PRIMA), $1,512,495/QA-PFY (VELIA), and $3,347,915/QA-PFY (PAOLA-1). At current drug pricing, there is no PFS improvement in a biomarker negative cohort that would make PARPi-for-all cost-effective compared to biomarker-directed maintenance.

Conclusion: This study highlights the high costs of universal PARPi maintenance treatment, compared with a biomarker-directed PARPi strategy. Maintenance therapy in the front-line setting should be reserved for those with germline or somatic HRD mutations until the cost of therapy is significantly reduced.

Title: Erythropoietin levels in pregnant patients with anemia and pyelonephritis

Resident: Noor K. Al-Shibli, MD

Faculty Mentor: Sarah K. Dotters-Katz, MD MMHPE

Objective: To measure erythropoietin (EPO) levels in pregnant patients at diagnosis of acute pyelonephritis. Secondary outcomes include markers of iron deficiency and hemolysis. We hypothesized that EPO levels in pregnant pyelonephritis will be significantly lower due to renal inflammation when compared to non-infected pregnancy EPO levels established in the literature. Additionally, we hypothesized that iron and hemolysis labs will be normal, as we believe the anemia is primarily due to hypoerythropoietinemia.

Methods: Prospective cohort study of pregnant people age ≥ 18 years diagnosed with pyelonephritis defined as presence of UTI symptoms plus flank pain, fever, or nausea/vomiting. Blood samples including EPO, iron, transferrin, lactate dehydrogenase, and haptoglobin were obtained within 72 hours of diagnosis. Patient demographics, pregnancy information, and prior lab studies were abstracted from the medical record. Data analysis was completed using descriptive statistics. Wilcoxon Signed Rank test and one-sided T-test were used to compare study EPO levels to non-infected pregnancy values established in the literature.

Results: The study cohort included 16 pregnant patients with pyelonephritis and comprised of 2nd and 3rd trimester pregnancies. Anemia was present on admission in 37.5% (6/16) of patients. Over half of patients had a positive urine culture with E. coli ≥100,000 cfu/ml (56.3%, 9/16). When compared to mean EPO levels established in the literature in non-infected pregnant cohorts, study EPO levels were significantly higher in pyelonephritis patients during the 2nd trimester (P=0.0002) (Table 2). Secondary analysis demonstrated low iron and haptoglobin levels in most patients, and normal LDH levels in all patients (Table 3).

Conclusion: In our pilot study, EPO levels in pregnant pyelonephritis were significantly higher compared to normal pregnancy levels established in the literature. Evaluation of iron and hemolysis studies showed inconsistent results. Further investigation is necessary to elucidate the relationship between erythropoietin, anemia, and inflammation in this patient population.

Title: Serum sFLT-1/PIGF ratio as a biological marker of preeclampsia in individuals with rheumatic disease

Resident: Kateena L. Addae-Konadu, MD PhD MSc

Faculty Mentor: Jennifer B. Gilner, MD PhD

Objective: Individuals with preexisting rheumatic conditions are disproportionately affected by preeclampsia. In patients with lupus and APLS, angiogenic factors soluble fms-like tyrosine kinase 1 (sFLT-1) and placental growth factor (PIGF) have predictive value for adverse pregnancy outcomes. However, it is unclear if sFLT-1/PLGF ratio can serve as a marker of preeclampsia in individuals with any rheumatic disease. The primary objective of this study was to assess the utility of sFLT-1/PLGFF ratio as a maker of preeclampsia in individuals with any preexisting rheumatic condition.

Methods: A retrospective cohort analysis of prospectively collected data and frozen serum from individuals with rheumatic disease from a single tertiary care center was preformed between July 2008-January 2021. Serum from 101 individuals collected during the second(n = 101) and third(n = 96) trimesters were thawed once and assayed for sFLT-1 and PIGF by multiplex ELISA. Descriptive statistic estimated differences in baseline demographics and sFLT-1/PLGF ratio for individuals with and without preeclampsia.

Results: Preeclampsia was diagnosed in 13 patients(12%); with associated preterm delivery in this group (36.2wga). Lupus was the most common rheumatic diagnosis(46%) for individuals with preeclampsia. While obesity was more frequent among individuals diagnosed with preeclampsia(62% vs 28%), there was no difference in mean maternal age at delivery, mean BMI, anti-hypertensive medication and aspirin use, or maternal race. The median sFlt-1/PIGF ratio was significantly higher in individuals diagnosed with preeclampsia compared to individuals without preeclampsia in the 2nd trimester(67.9 pg/mL [IQR: 47-115] vs. 47.6 pg/mL [IQR: 22– 95]; p = 0.04) and 3rd trimester(319.9 pg/mL [IQR: 84-510] vs 32.4 pg/mL [IQR: 12–64]; p = 0.0003).

Conclusion: Serum sFLT-1/PLGF ratio is positively associated with preeclampsia diagnosis among individuals with rheumatic disease. In this population of individuals at high risk for preeclampsia, early detection may allow for targeted interventions to decrease the impact of preeclampsia and associated preterm delivery.

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PGY2 Research

Project Title: A cost-effectiveness analysis of postpartum bilateral tubal ligation versus salpingectomy after vaginal delivery

Resident: Carmen M. Avram, MD

Faculty Mentor: Jonas J. Swartz, MD MPH

Research Question: What are the outcomes and costs of postpartum bilateral tubal ligation versus salpingectomy for postpartum sterilization following vaginal delivery?

Methods: A Markov model will be designed using TreeAge Pro Software to compare tubal ligation versus salpingectomy with a vessel-sealing device or suture ligation among women desiring postpartum sterilization following vaginal delivery in the United States. After being stratified into a strategy, women will alternate between health states including unintended pregnancy, ectopic pregnancy, living without ovarian cancer, and living with ovarian cancer until they have experienced death from ovarian cancer or other causes. This analysis will be performed for non-Hispanic white, Hispanic, Asian, and Black race/ethnicity to account for differences in ovarian cancer incidence and mortality. Model inputs including probabilities, costs, and utilities will be obtained from literature. We will evaluate the total costs and quality-adjusted life years (QALYs) to calculate the incremental cost-effectiveness ratio (ICER). An ICER of $100,000/QALY or less will be considered cost-effective. We will also calculate outcomes including surgical complications, unintended pregnancy, ectopic pregnancy, ovarian cancer cases and ovarian cancer deaths for each strategy in our model.

Progress Made: We completed literature search for model inputs, received Hammond Grant for TreeAge access, received IRB exemption, and started to build our model.

Anticipated Challenges: Build Markov model and perform analysis, currently receiving active help from Dr. Swartz & Dr. Myers.

Project Title: Cost-effectiveness of pre-procedural pregnancy test administration

Resident: Katherine E. Baumann, MD MPH

Mentor: Evan R. Myers, MD MPH

Research Question: The purpose of this study is to quantify the number of pre-procedural pregnancy tests performed at Duke University Health System and cost of these tests. We will also identify patients who would have been excluded from pre-procedural pregnancy test administration had a Pregnancy Reasonably Excluded Guide (PREG) been implemented and the cost-savings had these tests not been performed.

Methods: This project utilizes the Patient Record Universe recently created in Duke Maestro by the Center for Women's Health Data Science Team. We have abstracted encounters for women aged 18-54 who underwent a surgery, procedure, or radiologic imaging in the past 5 years and for whom a urine or serum pregnancy test was performed within 1 week prior to that procedure. We have collected data about procedure type and timing, basic demographics, and information to identify patients who would have been excluded from pre-procedural pregnancy test administration had the PREG questionnaire been implemented (prior hysterectomy, prior tubal ligation, etc.).

Progress Made: Data extraction has been performed and we now have a data set upon which to perform the above analyses.

Anticipated Challenges: Our methods will identify some but not all of the patients who would have been excluded from pre-procedural pregnancy test administration had the PREG questionnaire been implemented as not all pregnancy reasonably excluded criteria are routinely documented.

Project Title: Examining unexpected gynecologic surgical hospitalizations in Medicaid expansion states and non-expansion states and the potential costs everted

Resident: Kristen N. Carrillo-Kappus, MD MPH

Mentor: Haley A. Moss, MD MBA

Research Question: Does Medicaid Expansion reduce the number of unexpected gynecologic surgical hospitalizations among nonelderly adult patients? In non-expansion states, what are the potential costs everted?

Methods: To answer these questions, we will use Healthcare Cost and Utilization Project (HCUP) Fast Stats database to calculate inpatient surgical hospitalizations and discharges involving an operating room and a gynecologic procedure for states of interest. We will then use CDC National Environmental Public Health Tracking Network databases to determine population surgical discharge rates, various relevant state-level variables, and uninsured population cohort's patient-level data compared to Medicaid and private coverage patients. To assess differences, we will employ Pearson's chi-square for categorical variables and analysis of variance for continuous variables. To compare outcomes in Expansion vs. Non-expansion states pre/post 2019, we will generate difference-in-differences estimates of the overall effect of Medicaid expansion. This difference will be used to estimate costs due to unexpected gynecologic surgical admissions.

Progress Made: I have completed HCUP online training and am awaiting approval of signed agreement for use of data. I have begun the process of IRB exemption. Identifying an appropriate statistician is essential for success of this project – this is an ongoing matter. I am in the process of applying to Hammond for research funding.

Anticipated Challenges: A major challenge will be obtaining recent years of data limited by cost; may have to use prior years. Once data is purchased and made available, critical next step will be to import data to appropriate software (SAS, STATA) to complete complex analysis.

Project Title: Patient experience with gender affirming hysterectomy, A qualitative study

Resident: Lauren E. Farmer, MD

Mentor: Beverly A. Gray, MD

Research Question: How do patients make decisions around proceeding with gender-affirming hysterectomy/bilateral salpingo-oophorectomy?

Methods: This project is a qualitative cross-sectional observational study to capture data on participants' experience seeking gender affirming care as Transgender and Gender Non-Conforming (TGNC), specifically related to gender affirming hysterectomy/bilateral salpingo-oophorectomy via in-depth interviews. We will utilize NVIVO to code interview transcripts and evaluate qualitative themes.

Progress Made: IRB approval was obtained. Thirteen patient interviews have been obtained and transcribed. A background literature review has been performed.

Anticipated Challenges: We plan to acquire additional funding this spring during the 2022 Hammond Research Grant funding cycle to support transcription and qualitative support through BERD. We have completed 13 interviews with a goal of completing 20-25 total interviews or until thematic saturation is reached.

Project Title: Healthcare access and disparities in ovarian cancer survival

Resident: Elizabeth P. Howell, MD

Mentor: Rebecca A. Previs, MD MS

Research Questions: Objective 1: To assess the extent to which three specific dimensions of healthcare access (HCA) – Affordability, Availability, and Accessibility – might partially explain racial and/or ethnic differences in survival among ovarian cancer patients.

Objective 2: To assess the relationships among receipt of guideline-adherent treatment, patient race/ethnicity, and overall survival, with adjustment for healthcare access.

Methods: This is a retrospective cohort study, utilizing the following datasets: SEER-Medicare data files, US Census Small Area Health Insurance Estimates Program, NCI Hospital File, Area Healthcare Resource File, and the Dartmouth Atlas of Healthcare. Descriptive analyses will examine the association between patient factors – race, ethnicity, and other demographics – and HCA scores. Kaplan-Meier plots will be created to assess differences in all-cause and cancer-specific mortality. Additional models will be run with adjustments for HCA to determine how each might affect associations between patient factors and mortality. Finally, a landmarked survival analysis will assess the association between patient demographics, receipt of guideline-concordant treatment, and all-cause mortality.

Progress Made: All relevant IRBs, access requests, and Data Use Agreements have been updated. A statistician has been engaged, and a Statistical Analysis Plan created. Our preliminary data analysis is complete, and discussions remain ongoing as to how to best interpret and present these data. Concurrently, manuscript drafting is underway.

Anticipated Challenges: Based on the data being utilized, this analysis is limited to patients aged 66+, which limits its generalizability. This analysis is also inherently limited by the availability and integrity of data within included databases.

Project Title: Prevalence and risk factors for postpartum psychological birth trauma in a high-risk population

Resident: Meagan Kelly, MD

Mentor: Sarah K. Dotters-Katz, MD MMHPE

Research Question: How many of our patients who deliver at the Duke Birthing Center would describe their births as traumatic? How can we identify women at highest risk for this?

Methods: We plan to identify postpartum women at our High-Risk Obstetrics clinic for study enrollment. Participants will complete a survey including the Modified Perinatal Post-Traumatic Stress Disorder (PTSD) Questionnaire, a validated tool for identifying mothers experiencing significant emotional distress postpartum. We will then correlate individual risk factors such as maternal age, race/ethnicity, gravida, gestational age at time of delivery, pre-existing mental health diagnoses, length of labor and mode of delivery to risk of developing postpartum psychological birth trauma. Participants who screen positive for trauma will be referred to Duke Perinatal Clinical Social Work who have agreed to be part of the project.

Progress Made: Our IRB is submitted and awaiting approval. We have a statistical plan. We aim to begin subject enrollment in the fall.

Anticipated Challenges: As with any survey-based study, we anticipate challenges with subject accrual. With a wide range of prevalence of birth trauma reported in the literature, it is challenging to estimate the number of participants needed to demonstrate an effect.

Project Title: A cross-sectional evaluation of patient satisfaction and financial cost of securing donor gametes according to desired race and ethnicity

Resident: Sloane A. Mebane, MD

Mentor: Shelby A. Neal, MD

Research Question: Is there a difference in donor gamete acquisition and financial cost based on the desired race and ethnicity of the gamete donor?

Methods: Following IRB approval, electronic medical records will be reviewed to identify patients who sought treatment utilizing donor gametes at Duke Fertility Center (DFC) between 2015-2020. Patients at DFC who presented for consultation and expressed an intent to pursue fertility treatment using donor oocytes or donor sperm will be eligible for inclusion in this study. Eligible patients will be contacted by twice by email and once by phone and invited to complete a questionnaire regarding their experience. The questionnaire will be administered through the REDCap platform. A $10 gift card will be provided as incentive for questionnaire completion. Data will be collected including demographic information, desired gamete donor traits, availability of donors meeting the desired criteria, ability to attain donor gametes of the desired ethnicity, cost of treatment and treatment outcome. Descriptive statistics will be used to compare characteristics of those who did and did not secure desired donor gametes.

Progress Made: IRB submitted, Hammond grant acquired, Statistical plan completed, RedCap Database in Process, Epic Query in Process, Questionnaire reviewed by survey methodology group and finalized.

Anticipated Challenges: The primary challenges in study completion center around patient recruitment for questionnaire completion. Given the small pool of eligible patients, maximizing recruitment is a priority. Providing incentives for questionnaire completion and contacting eligible patients both electronically and by telephone are the proposed mitigating steps to maximize response rate.

Project Title: Impact of Covid-19 on vaccination rates among pregnant patients

Resident: Ravyn S. T. Njagu, MD

Mentor: Sarah K. Dotters-Katz, MD MMHPE

Research Question: Did Covid-19 affect vaccination rates among pregnant patients?

Methods: This study will be a retrospective cohort study of Duke Perinatal patients between October 1, 2017 to August 31, 2021. Vaccination data will be extracted from Stork. Chart review will then be completed to specifically extract Tdap and Flu vaccination records in Duke Perinatal patients. Primary year of interest will be October 1, 2020 to August 31, 2021. Comparison years include October 1, 2017-August 31, 2018 and October 1, 2018-August 31, 2019.

Progress Made: This project is added to the existing IRB (Pro00105162). The project team has engaged BERD core who has provided access to data and will help analyze. Delivery data from the years of interest have been pulled using Stork and stored on Duke Box for review.

Anticipated Challenges: An anticipated challenge is analysis of large data volume to ensure accuracy.

Project Title: Delivery hospitalizations among patients with cancer diagnoses

Resident: Alexandra C. Sundermann, MD PhD

Mentor: Evan R. Myers, MD MPH

Research Question: What is the prevalence of concurrent cancer diagnoses at time of delivery and how have those trends changed over time? Do women with cancer diagnoses at time of delivery have higher rates of preterm deliveries, C-sections, VTE events, and maternal morbidity?

Methods: We will leverage data from the National Inpatient Sample to identify delivery-associated hospitalizations from 2007–2018. We will identify women with concurrent cancer diagnoses using ICD-9 and ICD-10 codes to estimate the prevalence of cancer diagnoses at time of delivery by cancer type. We will then compare delivery hospitalization outcomes between women with and without cancer including mode of delivery, gestational age at delivery, in-hospital mortality, and measures of maternal morbidity.

Progress Made: The National Inpatient Sample data between 2007–2018 has been previously secured by my team. We have identified 9,480,858 delivery-associated hospitalizations in that period. Data cleaning and operationalization of key variables is underway, including the development of code for generating equivalent cancer diagnoses categories under both ICD-9 and ICD-10. The project is approved under IRB.

Anticipated Challenges: There are limitations to the information available in the NIS data, including the absence of several maternal characteristics and the potential for misclassification if providers did not reliably code for cancer diagnosis. It will take time to perform data validation to ensure that the code for cohort identification and variable operationalization perform as expected.

THE ANNUAL CHARLES B. HAMMOND, MD RESEARCH DAY

Friday, May 20, 2022

Duke Obstetrics & Gynecology
Duke University School of Medicine