



2020 ANNUAL REPORT

DEPARTMENT OF
PHARMACEUTICAL
OUTCOMES AND
POLICY

LETTER FROM THE CHAIR

Dear POP family and friends,

This past year was marked with so much interruption that it is truly amazing to see what our group has accomplished. Despite the COVID-19 pandemic, which left many of us expanding our virtual world of data into other aspects of our professional lives, we have enjoyed a year full of exciting news. POP has continued its growth in terms of faculty, trainees, research and training and has made an even greater impact on public health. Please check out the faculty profiles of Hui Shao and Laura Happe, who joined us this past academic year. I am also pleased to report that Silken Usmani has transitioned from her fellowship into a research faculty position with Scott Martin Vouri, raising our total faculty count to 14. We had a great new cohort of Ph.D. and residential M.S. students join us this past year and several graduated and departed for exciting careers in academia and industry. Our online M.S. program, with more than 130 students, has a new leader in Laura Happe, who is planning to expand our specializations — more to come!

Areas of research continue to build strongly around several areas of excellence: the opioid epidemic, pain and mental health; drug use and drug safety and effectiveness in geriatrics; infections and cancer; and pregnancy and pediatrics. New faculty are adding diabetes into this mix, and our Consortium for Medical Marijuana Clinical Outcomes Research, which now involves nine universities in the state, has created another exciting focus. Our collaboration with colleagues in clinical pharmacology and pharmacogenomics is showing exciting results around evaluations of drug-drug interactions and effect modifiers of drug effectiveness and safety. Our work, with a total of more than 100 peer-reviewed publications this past academic year, was recognized with a number of press releases, some featured in this report, editorials and literature awards. Congratulations to Hui Shao for the CDC Kaafee Billah Early Career Award and to Jenny Lo-Ciganic for receiving the UF Excellence Award for Assistant Professors as well as the college's Best Clinical Paper Award this academic year. Our faculty have continued to increase POP's research funding, with \$2.5 million this year directly under POP faculty's control (up from \$2.1 million). Finally, the Center for Drug Evaluation and Safety, or CoDES, has started to involve more researchers on campus in an effort to share and further advance our big data research infrastructure. Both POP and CoDES will move to the new Data Science and Informatics Building, planned to be completed in early 2023 — check out the first plans for the building in this report.

I hope you agree this is exciting news and you have the opportunity to hear about some of these directly from our "POPers." I sure have missed meeting many of you at ICPE and other venues where we used to get together. I hope you stay close to our department, and if you have not been in Gator country for a while, please consider visiting us, virtually of course.

Sincerely,



ALMUT WINTERSTEIN, R.PH., PH.D., FISPE
Dr. Robert and Barbara Crisafi Chair and Professor
Director, Center for Drug Evaluation and Safety (CoDES)



PUBLIC HEALTH IMPACT SPANNING OVER 30 YEARS
OF GRADUATE TRAINING, RESEARCH AND SERVICE

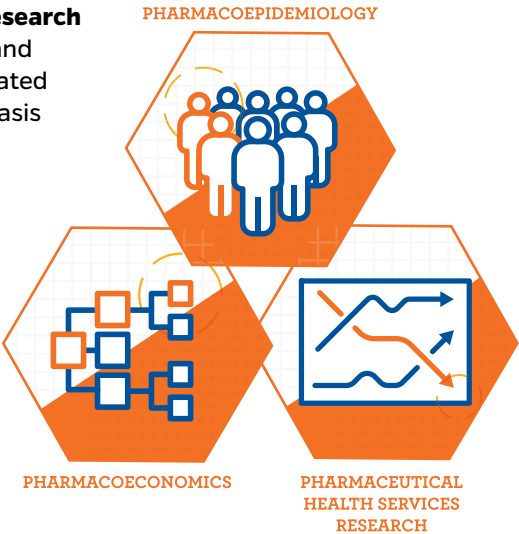
WHAT IS POP ABOUT?

The department of pharmaceutical outcomes and policy excels in three areas of specialization in both research and training. Each area employs its own set of methodological approaches, but all utilize the vast array of big data sources available in the department.

1. **Pharmacoepidemiology and Safety Sciences** applies epidemiologic methods and knowledge to the study of uses and effects of drugs in populations after drug approval. Important research areas include postmarketing safety studies, comparative effectiveness studies and predictive models of drug outcomes and use.
2. **Pharmacoeconomics and Outcomes Research** assesses the value (clinical and economic) of pharmaceutical products and related services in the delivery of health care. It aims to provide patients, providers and payers with evidence to inform decision-making. Important research areas include economic evaluations, budget impact analysis, multicriteria decision analysis and policy evaluations related to drug formulary, reimbursement and pricing.

3. **Pharmaceutical Health Services Research**

examines the quality, accessibility and delivery of pharmaceuticals and related services. The program places emphasis on vulnerable populations, such as children, elderly, minorities and persons with high-burden diseases and disabilities. Examples of research include the development of quality measures or assessment of determinants of appropriate therapy.



In this report, Dr. Amie Goodin shines a spotlight on the department’s Pharmaceutical Health Services Research area of specialization.

SPOTLIGHT ON PHARMACEUTICAL HEALTH SERVICES RESEARCH

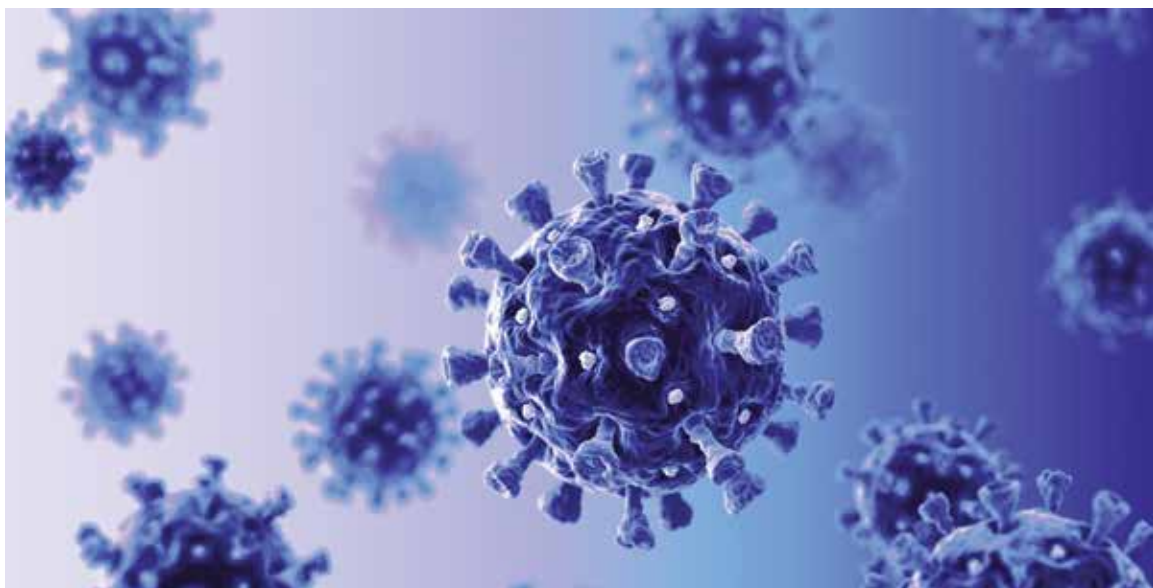


AMIE GOODIN, PH.D., M.P.P.
Assistant Professor and
PHSR Core Leader

Pharmaceutical Health Services Research, or PHSR, is a multidisciplinary field that studies how social factors, financing systems, organizational structures and processes, health technologies and personal behaviors affect access to medications, the quality and cost of pharmaceutical interventions, and ultimately, their effect on our health and well-being.

In the PHSR academic track within the pharmaceutical outcomes and policy graduate program, our goal is to arm students and trainees with the tools necessary to critically appraise drug policy and rigorously evaluate trends in the utilization of medications prescribed and dispensed within the context of health services. The PHSR curriculum is designed to draw on analytical skills conferred within foundational courses from epidemiology, biostatistics and bioinformatics and then applying these methodological skills toward practical research, public health and regulatory applications. Our research informs policymakers, consumers and clinicians regarding effectiveness of policies that shape medication access, use and reimbursement as well as medication-centered interventions that improve quality of care. Students training in this track have the opportunity to engage in timely research with faculty who specialize in diverse clinical and methodological focus areas, including, but not limited to; maternal and child health, geriatrics, substance use disorders, and legal epidemiology, using automated database analyses and mixed methods approaches. As faculty lead in the PHSR track, I look forward to further building our curriculum while our investigators and trainees inform improvements in pharmaceutical health services delivery, quality and resulting health outcomes.





POP'S COVID-19 RESEARCH

UF RESEARCHERS REPORT MIXED RESULTS IN SAFETY STUDY OF DRUGS SEEN AS POSSIBLE COVID-19 THERAPEUTICS

University of Florida College of Pharmacy researchers studying the safety of two classes of drugs touted as potential therapeutics for COVID-19 report mixed results. Their analysis of 13.3 million reports from the Food and Drug Administration's Adverse Event Reporting System showed antimalarial drugs hydroxychloroquine and chloroquine were not associated with the risk of abnormal heart rhythm either on their own or when prescribed with the antibiotic azithromycin. Azithromycin on its own, however, was associated with this safety concern.

Interest in treating COVID-19 patients with azithromycin and the antimalarial drugs rose in March when a small clinical study in France reported promising results. However, medical professionals have long cautioned against prescribing the two drugs together, due to safety concerns and a lack of evidence.

"Multiple ongoing trials are currently investigating the efficacy of antimalarials and azithromycin for COVID-19, but safety concerns are often not resolved in these small-scale clinical studies," said lead author Joshua Brown, Pharm.D., Ph.D. "Our study's goal was to verify that these potential treatments don't cause more problems than they cure."

The safety concerns are primarily centered on the risk of abnormal heart rhythm, specifically drug-induced QT interval prolongation, which can lead to tachycardias such as torsades de pointes and sudden cardiac death. Previous studies have not shown if the adverse effect is caused by the two classes of drugs interacting or if it's azithromycin's effect alone. Brown noted that the UF study in no way determines whether or not hydroxychloroquine or azithromycin are effective for treating COVID-19. Both drugs have demonstrated antiviral and immunosuppressive activity in test tube studies. These results have led to widespread hope for COVID-19 prevention and treatment, but real-world evidence among COVID-19-positive patients has yet to prove this.

ARE WE MOVING FORWARD IN OVERCOMING THE OPIOID EPIDEMIC?

UF STUDY EXAMINES TRENDS IN PRESCRIPTION OPIOID USE AND DOSE TRAJECTORIES

The current epidemic of opioid use and the ensuing morbidity and mortality, notably the growing burden of overdose deaths in the United States and other countries, has been well recognized in recent years—with the U.S. Centers for Disease Control and Prevention highlighting a daily toll of about 190 drug overdose deaths.

In a research paper published in the PLOS Medicine Special Issue, Yu-Jung “Jenny” Wei, Ph.D., M.S., co-authors a report on documented opioid prescriptions in a cohort of 227,000 adults with a diagnosis of opioid use disorder or overdose in the United States during the period 2005-16. Efforts to curb use of prescription opioids are generally focused on people receiving 90 mg of morphine equivalents per day or more. However, the authors found that about 35% of study participants received no prescription opioids in the year before diagnosis of opioid use or overdose, and two thirds received opioids at a level below the recognized threshold for risk. They comment that programs seeking to limit use of prescription opioids could be missing a growing proportion of people at risk of harm from opioid misuse.

NEW FLORIDA LAW LEADS TO DECLINE IN OPIOID USE, ACCORDING TO UF STUDY

A 2018 Florida law restricting opioid prescriptions for acute pain has led to a drop in opioid use, according to a study published by researchers at the University of Florida. UF researchers found the number of new opioid users per month dropped 16 percent immediately after the law was implemented, and the number of new users continues to decrease each month. Additionally, the average days’ supply fell from 5.4 days prior to the law to three days. The law was also associated with an immediate decrease in the use of hydrocodone, the most commonly used Schedule II opioid.

“The Florida law is among the most restrictive in the country by limiting patients to a three-day opioid supply for acute pain,” said Juan Hincapie-Castillo, Pharm.D., Ph.D., M.S., the study’s lead author. “We expected to find a decrease in opioid use following the law, but we did not anticipate the significant decline in the number of users.”

The law limits opioid prescriptions for acute pain to a three-day supply — with certain exceptions — and requires physicians and pharmacists to consult Florida’s state prescription drug monitoring database to review a patient’s prescription history.

“Our goal is to comprehensively evaluate this Florida law, because it does appear to have wide-ranging effects for patients and those working in health care,” said Amie Goodin, Ph.D., a co-author of the study.

GRANTS

DEPARTMENT FACULTY ARE STEADILY INCREASING THEIR EXTRAMURALLY FUNDED RESEARCH PORTFOLIO AND ARE ACTIVELY INVOLVED IN OVER 30 GRANTS AND CONTRACTS

Application of Physiologically Based Pharmacokinetic Models to Inform Dosing Recommendations for Hormonal Contraceptives Co-administered with Other Medications

Bill & Melina Gates Foundation (OPP118545)

Principal Investigator: Stephan Schmidt

Co-Investigators: Joshua Brown, Amie Goodin, Almut Winterstein 11/2017-10/2020

This project aims to develop pharmacological and pharmacoepidemiological evidence to inform treatment decisions for hormonal contraceptives and interacting medications by integrating real-world outcomes research, model-based meta analytic approaches and physiologically based pharmacokinetic modeling and simulations.

Quality of Care with Inferior Vena Cava Filters

UF Health Quasi-Endowment Fund Principal Investigator: Joshua Brown 10/2019-09/2020

This project aims to determine the scope of practice focused on a medical device, inferior vena cava filters, and aims to promote high-value, evidence-based practices within UF Health and collect preliminary data for future grant applications.

Characterizing Community and Physician-Level Factors Associated with Medical Marijuana Prescriber

Registration and Patient Access

Consortium for Medical Marijuana Clinical Outcomes Research

Principal Investigator: Joshua Brown Co-Investigator: Amie Goodin 12/2019-7/2020

This project will create a data resource and tool to understand the environmental factors related to use of cannabis in the state of Florida including community- and physician-level factors.

Sparking Advancements in Genomic Medicine

NIH/NHGRI U01HG007269 (U01)

Research Project-Cooperative Agreements Grant Award

Principal Investigator: Julie Johnson

Co-Investigators: Karam Diaby, Almut Winterstein

09/2018-06/2023

This project aims to address the significant burden of both pain and opioid use in the U.S. by testing the hypothesis that CYP2D6 genotype-guided pain management leads to improved patient reported outcomes for pain control and is cost-effective in a real-world setting.

Economic Evaluation of Rapid Whole Genome Sequencing (rWGS) in Critically Ill Children and Adolescents: The Case of Nicklaus Children's Hospital

Nicklaus Children's Hospital Principal Investigator: Karam Diaby 01/2020-12/2020

In this project, we will conduct a retrospective cohort study to assess the cost-effectiveness of rapid WGS compared to its omission in critically ill patients (0-18 years of age) using data from March 2018 to June 2020 from the Nicklaus Children's Hospital electronic health records.

Leveraging Social Media Data for Evaluation of Drug Use Trends After Opioid Policies

American Association of Colleges of Pharmacy

Principal Investigator: Juan Hincapie-Castillo

Co-Investigators: Amie Goodin, Wei-Hsuan "Jenny" Lo-Ciganic 03/2020-02/2021

The proposed study aims at exploring the feasibility of using consumer-generated data from social media to evaluate trends in prescription and illicit opioid use in the context of opioid-related policies.

Program Evaluation and Analytic Support Services for a Substance Use Disorders Recovery Community Center

Voices of Hope

Principal Investigator: Amie Goodin 08/2019-12/2020

This project aims to develop a measurement framework for, and then evaluate, participation and retention measures among programs offered within a recovery community center for persons with substance use disorders.

All-Cause Readmission Measures on Inpatient Psychiatric Facilities

UF Health Shands Hospital

Principal Investigator: Amie Goodin 03/2017-07/2020

This project aims to examine the individual and community-level factors predicting all-cause 30-day readmissions among patients discharged from inpatient psychiatric care.

Evaluating Learning Outcomes in Continuing Pharmacy and Medical Education

Creative Educational Concepts

Principal Investigator: Amie Goodin 04/2019-04/2020

This project applies a competency-based assessment strategy to evaluate a series of educational interventions and learning outcomes for health care professionals.

Consortium for Medical Marijuana Clinical Outcomes Research

State University System of Florida

Principal Investigator: Almut Winterstein

Co-Investigator: Amie Goodin 07/2019-06/2020

Faculty lead for the Medical Marijuana Clinical Outcomes Research Repository, or MEMORY. This state appropriation the establishes consortium for medical marijuana clinical outcomes research, charged to generate and disseminate evidence on the outcomes of the medical use of marijuana to inform clinical and policy decisions.

DR. JENNY WEI RECEIVES \$100,000 GRANT TO STUDY OPIOID-RELATED HOSPITALIZATIONS IN ELDERLY



Yu-Jung “Jenny” Wei, Ph.D., an assistant professor in the department of pharmaceutical outcomes and policy, has received a two-year, \$100,000 grant from the Agency for Healthcare Research Quality, or AHRQ. The grant funds Wei’s project to understand what risk factors predispose older adults to hospitalizations due to opioid dependence, abuse and poisoning.

Opioid-related hospitalizations among older adults have increased more than 50 percent over the past decade, according to AHRQ’s estimates from recent national inpatient data. AHRQ noticed this alarming increase and in 2018, issued a special emphasis notice focused on addressing opioid epidemic in various populations, including older adults.



Developing a Real-Time Trajectory Tool to Identify Potentially Unsafe Concurrent Opioid and Benzodiazepine Use Among Older Adults

NIH/NIA AGO60308 (R21)
Exploratory/Developmental Research Grant Award
Principal Investigator: Wei-Hsuan “Jenny” Lo-Ciganic
Co-Investigator: Almut Winterstein, Juan Hincapie-Castillo
05/2019-01/2021
This project aims to develop an innovative, real-time “Predicting Risky Opioid-Benzodiazepine Trajectory e-Care Tool (PROTECT)” for identifying and predicting subgroups of older adults with potentially unsafe patterns of concomitant use of opioids and benzodiazepines, in order to better guide clinical care and inform related policies and interventions.

Enhancing Active Learning of a Root Cause Analysis on a Medication Error in the Patient Safety and Quality in Pharmacy Course

UF College of Pharmacy PROSER Teaching Innovation Award
Co-Investigators: Scott M. Vouri, Amie Goodin and Juan Hincapie-Castillo
06/2019-12/2019
This funding was used for the development of a series of immersive video vignettes to teach concepts of medication error in the Pharm.D. curriculum. We used a multi-pronged approach for evaluating learning outcomes and attitudes towards medication errors.

Machine Learning and Opioid Overdoses in Allegheny County

Richard King Mellon Foundation
Multi-PI: Wei-Hsuan “Jenny” Lo-Ciganic/Walid Gellad/Julie Donohue
07/2018-06/2020
This project aims to apply advanced analytics to develop prediction and risk stratification algorithms that can identify patients at high risk of opioid overdose in the residents in Allegheny County in Pittsburgh, Pennsylvania.

Using Machine Learning to Predict Problematic Opioid Use

NIH/NIDA 1R01DA044985 (R01)
Research Project Grant Award
Consortium Principal Investigator: Wei-Hsuan “Jenny” Lo-Ciganic
09/2017-06/2020

The purpose of this study is to apply machine learning to develop two distinct prediction algorithms that can identify patients at high risk of problematic opioid use and overdose among Medicaid beneficiaries in Pennsylvania and Arizona.

Safety of Gadolinium-Enhanced MRI Exposure During Pregnancy on Adverse Fetal Outcomes

U.S. Food & Drug Administration
HHSF223201810083C
Principal Investigator: Almut Winterstein
09/2018-09/2020
This proposal has the primary aim to provide robust evidence on the safety of GBCA-enhanced MRI during pregnancy regarding adverse fetal outcomes to support regulatory decision-making. It will further establish enhanced capacity to evaluate emerging safety questions in pregnancy.

Using Machine Learning to Predict Direct-Acting Antiviral Treatment Failure in Patients with Chronic Hepatitis C Virus Infection

University of Florida, Translational Science Institute (CITI)
Principal Investigator: Haesuk Park
Co-Investigators: Wei-Hsuan “Jenny” Lo-Ciganic
04/2019-03/2020
To develop a predictive model using machine learning approaches for patients with chronic hepatitis C virus at higher risk of treatment failure with direct-acting antiviral therapy.

Trajectories of Apixaban for Extended Treatment of Recurrent Venous Thromboembolism: a Retrospective Cohort Study

American Thrombosis Investigator Initiated Research Program (ARISTA)
Principal Investigator: Haesuk Park
Co-Investigators: Wei-Hsuan “Jenny” Lo-Ciganic, Joshua Brown
04/2020-03/2022
To investigate the effects of extended use of apixaban or warfarin beyond six months of initial treatment on the risk of recurrent venous thromboembolism and major bleeding events among patients with a history of venous thromboembolism.

A Behavioral Economic Intervention to Reduce Marijuana Use in Truant Youth

NIH/NIDA K23DA046565 (K23)
Research Project Grant Award
Principal Investigator: Ali Yurasek
Co-Investigators: Haesuk Park
04/2019-03/2024
The aim of this proposal is to adapt a brief behavioral economic intervention to reduce marijuana use that involves truant youth and their parents. This project will examine the acceptability, feasibility, and initial efficacy of this intervention with adolescents referred for services as part of a juvenile specialty (truancy) diversion program.

Improving Medication Adherence with Telehealthcare Medication Therapy Management to Change Health Outcomes in Adolescents and Young Adults with Asthma (MATCH)

NIH/NHLBI R01HL136945 (R01)
Research Project Grant Award
Principal Investigator: Kathryn Blake (Nemours Children’s Clinic)
Co-Investigators: Haesuk Park, Almut Winterstein
5/2018-3/2023
This project aims to use video telemedicine to improve medication adherence in adolescents and young adults with poorly controlled asthma by monitoring improvements in asthma outcomes through adherence counseling with a pharmacist via telehealth in a convenient and private location.

Medicaid Prior Authorization Policies for Chronic Hepatitis C Treatment in Vulnerable Populations

NIH/NIDA K01DA045618 (K01)
Research Scientist Development Award
Principal Investigator: Haesuk Park
Mentor: Almut Winterstein
5/2018-4/2023
This award supports the PI’s career development in viral hepatitis and health policy for individuals with substance use disorders and HIV co-infection. The project will advance the understanding of the consequences of Medicaid policies for hepatitis C treatment on accessibility, quality of care, and clinical outcomes critical to improving access to care and health equality in underserved and vulnerable populations.

UF STUDY FINDS EXCESS USE OF LOOP DIURETICS FOLLOWING INITIATION OF DIHYDROPYRIDINE CALCIUM CHANNEL BLOCKERS



One in five adults in the United States take dihydropyridine calcium channel blockers to treat hypertension, which have long been viewed as safe and effective. However, one disadvantage of using this type of calcium channel blocker is the risk of leg swelling, or edema. To resolve the swelling, the suggested treatment includes reducing or stopping the calcium channel blocker.

A new study published in JAMA Network Open found a substantial number of patients are being prescribed a loop diuretic for leg swelling induced by calcium channel blocker. “When I was a geriatric clinical pharmacist, I frequently identified unnecessary loop diuretic use among patients prescribed calcium channel blockers, and this led to preventable adverse events. Treating a drug side effect unnecessarily with another drug, is called prescribing cascade,” said Scott Martin Vouri, Pharm.D., Ph.D., BCGP, who led this work as part of his UF Claude D. Pepper Scholar Scholarship. “Unfortunately, this problematic prescribing is not well documented. Therefore, we planned to quantify the magnitude of this prescribing cascade using a pharmacovigilance approach called prescription sequence symmetry analysis.”

Vouri estimated nearly one in nine patients who developed swelling may have experienced this prescribing cascade. Given time restriction during clinic visits, especially in very medically complex patients, it may be difficult for clinicians to identify all cases of swelling that result from the calcium channel blocker.

“The use of too many medications especially in elderly patients suffering from multiple chronic conditions is a well-recognized problem, but we oftentimes struggle to discern which medication is essential and which could be safely removed,” said Almut Winterstein, R.Ph., Ph.D., FISPE, a co-author of the study. “Dr. Vouri’s work in devising methodological approaches that can flag for clinicians when inappropriate prescribing occur can make a substantial contribution to care for these most vulnerable patients.”

Community Health Workers Practice Improvements

Florida Department of Health
Principal Investigator: Richard Segal
04/2019-09/2021

The overall goal of this project is to develop a critical mass of medication therapy management workforce who will effectively address medication therapy disparities in Florida.

Florida Minority Cancer Research and Training Center: Feasibility Studies

NIH/NCI P20CA192992 (P20)
Exploratory Grant

Principal Investigator: Folakemi Odedina

Co-Investigator: Richard Segal
09/2014-08/2019

This project aims to develop a Florida Minority Cancer Research & Training Center that will expand cancer research and training opportunities for underrepresented minority, or URM, faculty and students at UF and Florida A&M University and ultimately grow the number of URM scientists and clinical investigators in biomedical research.

Comparing Cardiovascular Benefits Between GLP-1RA and SGLT2 Inhibitor Agents

University of Florida 2020 PROSPER Award

Principal Investigators: Hui Shao, Christina DeRemer

Co-Investigator: Scott M. Vouri
1/2020-1/2021

This study will compare the risk for cardiovascular complications between GLP-1RA and SGLT2i users who have T2DM and are commercially insured by large health plans. We will emulate the SUSTAIN-8 diabetes trial by following its trial protocol and applying an instrumental variable to adjust for selection bias.

Mapping the Change of Cost-Sharing for Glucose-Lowering Drugs Between 2003-2019

CDC 20IPA2008335DPG

Principal Investigator: Hui Shao
6/2020-6/2021

This project seeks to understand the change of total payment for glucose-lowering drugs between 2003 and 2019, and what proportion of the total payment change was directly transferred to the patient's cost-

sharing amount. We will also explore how cost-sharing changes influence patients' medication adherence.

Prescription Opioid Use Trajectories and Risk Factors Associated with Opioid-Related Hospitalizations in Older Adults

AHRQ 1R03HS027230-01 (R03)
Award

Principal Investigator: Yu-Jung "Jenny" Wei

9/2019-8/2021

This study aims to assess elderly high-risk prescription opioid use patterns and risk factors that are associated with opioid-related hospitalizations among older adults.

Etiology and Mechanism of Opioid Overdoses — A Pilot Study of Interactions of Pain and Substance Use in a New Era of Reduced Access to Prescription Opioids and Increasing Overdose Rates

University of Florida Center for Research to Investigate Substance Use and Pain (UF-CRISP)

Principal Investigator: H Young

Co-Investigators: Almut Winterstein
6/2019-5/2020

This project will serve as pilot study for a larger initiative that will recruit a geographically dispersed group of emergency departments to implement a surveillance system that evaluates the circumstances of opioid overdoses.

Reduction of inpatient hypoglycemia rates using EHR-based risk score stratification for prioritized care by diabetes management teams

NIH/NCATS UL1TR001427

UF Health-CTSI Learning Health System Initiative Subaward

Principal Investigator: Almut Winterstein

11/2019-11/2020

This study will refine a previous electronic health record, or EHR, -based hypoglycemia prediction algorithm, implement the algorithm in the UF Health EHR system and plan clinical roll-out of diabetes management care team's response to algorithm-prioritized high-risk patients.

Together: Transforming and Translating Discovery to Improve Health

NIH/NCATS UL1TR001427

Principal Investigator: David Nelson

Co-Investigators: Almut Winterstein
7/2019-6/2024

The University of Florida and Florida State University Clinical and Translational Science Awards hub will work within Florida to improve human health by accelerating the translation of scientific discoveries and the implementation of evidence-based best practices for the diagnosis, treatment, prevention and cure of human diseases across the lifespan.

Advancing Personalized Hypertension Care through Big Data Science

NIH/NHLBI K01HL138172 (K01)

Research Scientist Development Award

Principal Investigator: Steven Smith
Mentor: Almut Winterstein
07/2018-06/2023

This award supports providing mentorship on the principal investigator's project, which seeks to better understand how antihypertensive drugs are prescribed in routine practice and to aid in making personalized recommendations for antihypertensive drug selection based on an individual patient's clinical profile using electronic health records data, pharmacoepidemiological methods, biomedical informatics and prediction modeling.

Pharmacological Management of Pain in Alzheimer's Disease and Related Dementia (ADRD)

NIH/NIA 1K01AG054764-01A1

(K01) Mentored Research Scientist Development Award

Principal Investigator: Yu-Jung "Jenny" Wei

Mentor: Almut Winterstein
08/2017-06/2022

This project aims to provide preliminary data that improve our understanding of current pain medication prescribing and potential discrepancies between practices and pain guidelines, and to formulate hypotheses for future research regarding the role of pain control in reducing mental health problems in ADRD.



Collaboration on Joint Research to Train the Next Generation of Pharmacoepidemiologists

Merck and Company Inc
Principal Investigator: Almut Winterstein

12/2019-12/2021

In collaboration with Merck epidemiologists, UF will nominate senior graduate students to conduct pharmacoepidemiologic research on specific topics identified by Merck.

Developing the Capability of Using National Medicaid data for FDA Post-Marketing Surveillance to Assess Medication Safety During Pregnancy — Harvard FDA

U.S. Food & Drug Administration
HHSF223201400043I

Principal Investigator: Almut Winterstein

9/2017-9/2020

This study will develop and validate Medicaid-specific algorithms to estimate gestational age for live birth pregnancies, explore methods to identify non-live birth

pregnancy outcomes and estimates for the gestational length of these pregnancies, if deemed feasible, and develop analytic tools to assess the impact on relative risk estimates of exposure misclassification, outcome misclassification, selection bias and residual confounding.

Observational External Comparator Cohorts as Control for Long-Term Uncontrolled Clinical Trials

International Society for Pharmacoepidemiology
Principal Investigator: Almut Winterstein

05/2019-09/2019

This funding is part of the International Society for Pharmacoepidemiology manuscript initiative and supports the development of a series of manuscripts focused on methodological issues related to the use of observational external comparator cohorts as control for long-term uncontrolled clinical trials.

Epidemiology and Cost of RSV Infections in Infants and Toddlers

Merck and Company Inc

Principal Investigator: Almut Winterstein

5/2020-6/2021

This study will estimate the number and proportion of children less than 5 years of age with respiratory syncytial virus, or RSV, -associated inpatient admissions or outpatient visits, and estimate RSV-related costs, considering relative contributions of RSV infections to the overall burden of lower-respiratory tract infections and variation in disease incidence and cost across strata defined by chronological and gestational age, key risk conditions, plan type, and RSV season and geographic region.

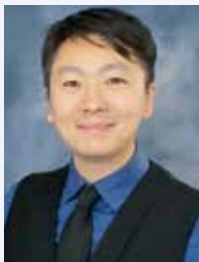
NEW FACULTY IN 2019-20



LAURA E. HAPPE, PHARM.D., M.S.

Clinical Associate Professor, Director of the POP Online M.S. Program

Laura Happe is an editor, professor and author who specializes in using data to aid in decision-making. Happe leads the online master’s degree program with approximately 150 students and 50 graduates annually. She is also the Editor-in-Chief of the Journal of Managed Care and Specialty Pharmacy, the official peer-reviewed journal of the Academy of Managed Care Pharmacy. Her first book, If You Give an Ox an Oxy, is an educational resource for parents to teach their adolescents about the hazards of opioid use.



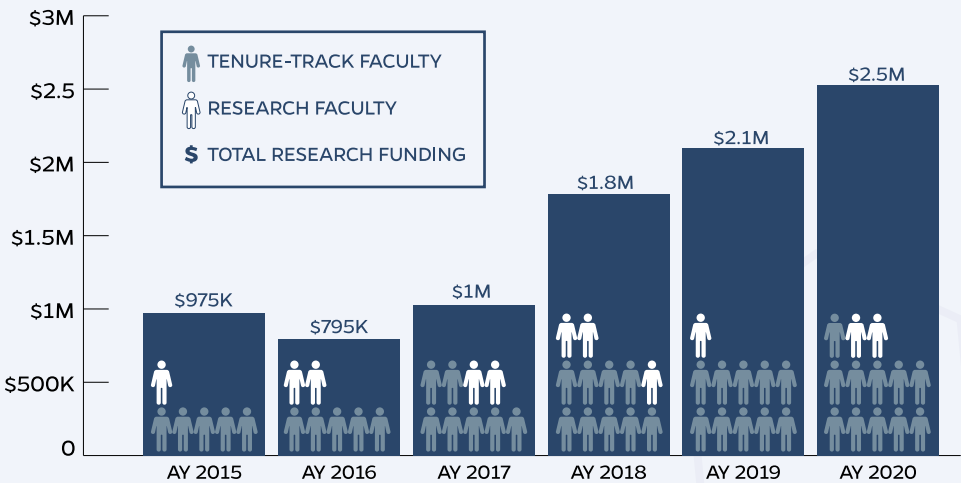
HUI SHAO, M.D., PH.D.

Assistant Professor

Hui Shao’s research interests include predictive modeling, using advanced machine learning, microsimulation and econometrics method to build valid predictive models to resolve real-world issues. He is one of the original developers of the Building, Relating, Assessing, and Validating Outcomes, or BRAVO, diabetes model, which is the first person-level microsimulation model predicting the progression of diabetes based on individuals’ characteristics and treatment regimen in the U.S. Hui is currently working with the Centers for Disease Control and Prevention on multiple projects and oversees the development process of several national diabetes and prediabetes predictive models.

A GROWING DEPARTMENT

The department of pharmaceutical outcomes and policy has experienced significant growth in its faculty and total research funding in the last six years.



CURRENT FACULTY IN 2019-20



ALMUT WINTERSTEIN, R.PH., PH.D., FISPE
Dr. Robert and Barbara Crisafi Chair and Professor
Almut Winterstein’s research program focuses on the evaluation and prediction of drug safety and effectiveness in real-world populations and on devising ways to improve medication use. Clinical areas of interest include pediatrics and pregnancy, psychopharmacology and treatment and prevention of infectious disease.



JOSHUA BROWN, PHARM.D., PH.D., M.S.
Assistant Professor and Associate Graduate Program Director
Joshua Brown’s research is in the field of comparative effectiveness and safety research focusing on anticoagulants, hematology and cardiology and in health care policy evaluation. His research also focuses on medication effects on mobility and aging in older adults and developing real-world evidence for generic drugs and biosimilars.



KARAM DIABY, PH.D., M.SC.
Assistant Professor
Karam Diaby’s research interests are in the field of economic evaluation, decision analytic modeling, health technology assessment and priority setting using multi-criteria decision analysis.



AMIE GOODIN, PH.D., M.P.P.
Assistant Professor
Amie Goodin’s research focuses on policy evaluation through the lens of health services research, incorporating mixed-method approaches to assess the impact of policy changes on populations that face health disparities. Specific interests include substance use disorders, particularly opioids and tobacco cessation during pregnancy.



JUAN HINCAPIE-CASTILLO, PHARM.D., M.S., PH.D.
Assistant Professor
Juan Hincapie-Castillo’s research interests include the study of drug utilization and safety in the area of pain management, the evaluation of the effects of state and federal laws on patient outcomes (legal epidemiology) and the assessment of patient safety and quality for inpatient pain management.

CURRENT FACULTY IN 2019-20



WEI-HSUAN “JENNY” LO-CIGANIC, PH.D., M.S., M.S. PHARM
Assistant Professor

Wei-Hsuan “Jenny” Lo-Ciganic’s research program focuses on evaluation of treatment effectiveness and safety, application of advanced predictive analytics, and improvement of prescribing quality and health disparity, especially among vulnerable populations. Areas of research interests include medication adherence, prescription drug abuse, treatment for substance use disorders, chronic diseases management and oncology.



HAESUK PARK, PH.D.
Associate Professor

Haesuk Park’s research program focuses on the evaluation of economic and health outcomes of medication and pharmaceutical care services, as well as policy associated with the use of pharmaceuticals.



RICHARD SEGAL, R.PH., PH.D., M.S.
Associate Dean, Professor, and Graduate Program Director

Richard Segal’s research focuses on improving the quality and safety of the medicines use process, with a particular emphasis on improving prescribing practices and in creating collaborative practice models to improve medication use by patients.



STEVE SMITH, PHARM.D., M.P.H.
Assistant Professor

Steve Smith’s research program focuses on understanding risk associated with common cardiometabolic risk factors, especially high blood pressure, and how pharmacotherapy modifies that risk. He is also focused on improving methods for optimizing electronic health record data in comparative effectiveness research.



SCOTT MARTIN VOURI, PHARM.D., PH.D., BCGP
Clinical Assistant Professor and Assistant Director of Pharmacy Services-UF Health Physicians

Scott Martin Vouri’s research interests include pharmaco-epidemiology and pharmaceutical health services research related to the fields of inappropriate medication prescribing/deprescribing, geriatrics, urology and medication utilization following bariatric surgery.



YU-JUNG “JENNY” WEI, PH.D., M.S.
Assistant Professor

Yu-Jung “Jenny” Wei’s research programs focus on questions surrounding the effectiveness, safety and quality of medication use in elderly patients with chronic conditions, especially those in nursing home settings.

POSTDOCTORAL FELLOWS & RESEARCH FACULTY



HYERIM KANG, PH.D.

Postdoctoral Fellow

Kang is a postdoctoral fellow and works with Haesuk Park.



**RACHEL REISE,
PHARM.D.**

Postdoctoral Fellow

Reise is a postdoctoral fellow and works with Scott Martin Vouri.



**HAMED KIANMEHR,
PH.D.**

Postdoctoral Fellow

Kianmehr is a postdoctoral fellow and works with Hui Shao.



HYUN JIN SONG, PH.D.

Postdoctoral Fellow

Song is a postdoctoral fellow and works with Haesuk Park.



**SABINA NDUAGUBA,
PH.D.**

Postdoctoral Fellow

Nduaguba is a postdoctoral fellow and works with Almut Winterstein.



**SILKEN USMANI,
PHARM.D.**

Assistant Scientist

Usmani is an assistant scientist and works with Scott Martin Vouri.



FOR ALL DEPARTMENT NEWS IN THE PAST YEAR, VISIT

[POP.PHARMACY.UFL.EDU/CATEGORY/RECENT-NEWS/](https://pop.pharmacy.ufl.edu/category/recent-news/)

WHO WE ARE

14

FACULTY

7

STAFF

31

PH.D.
STUDENTS

6

POSTDOC
FELLOWS

7

RESIDENTIAL
MASTER'S STUDENTS

AWARDS, HONORS & APPOINTMENTS

DR. WEIHSUAN “JENNY” LO-CIGANIC WINS UF EXCELLENCE AWARD FOR ASSISTANT PROFESSORS



The University of Florida has honored Weihsuan “Jenny” Lo-Ciganic, Ph.D., M.S., M.S.Pharm., with the 2020 Excellence Award for Assistant Professors — one of the university’s top awards for a junior faculty member. As a pharmacoepidemiologist, her research interests involve drug safety, medication adherence, prescription drug abuse and the quality and value of prescribing, especially among vulnerable or minority populations. With machine learning and other advanced analytics, she develops and improves quality measures and risk prediction models. Lo-Ciganic has successfully secured more than \$2.6 million in funding as principal investigator or co-principal investigator and has published over 40 manuscripts in top research journals.

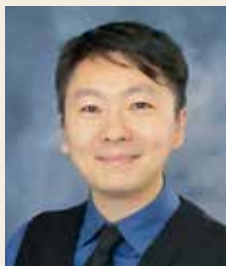
As an educator, Lo-Ciganic has excelled in the classroom while teaching in the college’s Pharm.D. and graduate programs. She leads several journal clubs in her department, advises Ph.D. students, serves on dissertation committees and supervises postdocs, interns and Pharm.D. student projects. As a mentor, she has helped graduate students and postdoctoral associates secure employment at pharmaceutical companies and academic institutions, as well as publishing in high-impact journals.

“Dr. Lo-Ciganic has been incredibly successful in her early career, a rising star,” said Julie Johnson, Pharm.D., dean and distinguished professor in the UF College of Pharmacy. “Her research and scholarship is addressing the nation’s opioid crisis by improving drug safety, patient care and health outcomes, and her teaching is advancing the training of the next generation of scientists.”

There are more than 500 tenure-track assistant professors at UF, and Lo-Ciganic is one of only 10 to receive a 2020 Excellence Award for Assistant Professors. The award comes with a \$5,000 stipend to support research-related expenses such as travel, books, equipment and graduate student salaries.

DR. HUI SHAO

EARNs EARLY CAREER AWARD FROM CDC



The Centers for Disease Control and Prevention, or CDC, Health Economics Research Group bestowed Hui Shao, M.D., Ph.D., an assistant professor of pharmaceutical

outcomes and policy, with the Kaafee Billah Early Career Award. The award was established in 2016 and recognizes an early career health economists for outstanding contributions in furthering economics and decision sciences at the CDC.

Shao is active in disseminating his research through publications and presentations at major international conferences. In his Ph.D. program and two-year fellowship at the CDC, Shao published 36 articles in leading professional peer-reviewed journals, which includes numerous first-author publications in Diabetes Care, Value in Health, and Pharmacoeconomics, all of which are top journals in each corresponding field. He has also published 30 conference papers and delivered 17 oral presentations as the presenting author at international conferences. He is the developer of the BRAVO diabetes model, which is deemed to be one of the most advanced diabetes microsimulation models in the world.

The Health Economics Research Group is a network of economists within the CDC and from other institutions that regularly collaborate with the CDC. Shao concluded a fellowship at the CDC in 2019, before joining the University of Florida College of Pharmacy. His CDC experience gave him a clear perspective on what issues need to be addressed to prevent diabetes and improve diabetes management.

JOSHUA BROWN, PHARM.D., PH.D., M.S.

Assistant Professor and Associate Graduate Program Director

- National Academy of Medicine, Emerging Leader, 2019
- Academy Health and AHRQ-HCUP Manuscript of the Year, Runner-Up, Policy Section, 2019
- Academy of Managed Care Pharmacy New Practitioner Award, 2019
- Elected co-chair (chair elect) of the Academic Council for the International Society for Pharmacoepidemiology (ISPE)

KARAM DIABY, PH.D., M.SC.

Assistant Professor

- Editor, PharmacoEconomics – Open, 2020
- Member, International Society for Pharmacoeconomics and Outcomes Systematic Reviews with Cost and Cost-Effectiveness Outcomes Good Practices Task Force, 2019
- Grant Peer-Reviewer, NOW Talent Programme — Veni Scheme ZonMw- The Netherlands, 2020

AMIE GOODIN, PH.D., M.P.P.

Assistant Professor

- Outstanding Contribution in Reviewing, Journal of American Pharmacists Association, 2020
- Editorial Advisory Board, Pain Medicine, Opioids & Substance Use Disorders Section, 2019

JUAN HINCAPIE-CASTILLO, PHARM.D., M.S., PH.D.

Assistant Professor

- Emerging Leader Award, International Society for Pharmacoepidemiology, 2020
- New Investigator Award, American Association of Colleges of Pharmacy, 2020
- 2018 Best Reviewer, Pharmacoepidemiology and Drug Safety, 2019

WEI-HSUAN “JENNY” LO-CIGANIC, PH.D., M.S., M.S. PHARM
Assistant Professor

- University of Florida College of Pharmacy Outstanding Clinical Science Publication Award, 2020
- University of Florida Excellence Awards for Assistant Professors, 2020
- 2018 Best Reviewer, Pharmacoepidemiology and Drug Safety, 2019

RICHARD SEGAL, R.PH., PH.D., M.S.
Associate Dean, Professor, and Graduate Program Director

- APhA-APPM Presentation Merit Award Finalist, American Pharmacists Association, 2020

HUI SHAO, M.D., PH.D.
Assistant Professor

- Health Economics Research Group Kaafee Billah Award, Centers for Disease Control and Prevention, 2019-2020

SCOTT MARTIN VOURI, PHARM.D., PH.D., BCGP
Clinical Assistant Professor and Assistant Director of Pharmacy Services-UF Health Physicians

- Junior Investigator Intensive, US Deprescribing Research Network (USDeN), 2020
- Junior Review Program, Journal of the American Geriatrics Society, 2019

YU-JUNG “JENNY” WEI, PH.D.
Assistant Professor

- The American Society of Clinical Pharmacology and Therapeutics (ASCP) William B. Abrams Award in Geriatric Clinical Pharmacology, 2020



ALMUT WINTERSTEIN, R.PH., PH.D., FISPE
Dr. Robert and Barbara Crisafi Chair and Professor

- President, International Society of Pharmacoepidemiology, 2019-20
- Chair, ISPE scientific program committee for 2020 midyear meeting
- Member, scientific programming committee for 2020 Pharmaceutical Sciences World Congress, 2019-20
- Director, Consortium for Medical Marijuana Clinical Outcomes Research
- Director, Center for Drug Evaluations and Safety (CoDES)
- FDA Outstanding Service Award — for dedicated service to public health and exceptional leadership in the field of drug safety, Food and Drug Administration (FDA), 2019
- UF Term Professorship, University of Florida, 2018-2020

TRANSLATING BIG DATA INTO EVEN **BIGGER, HEALTHIER AND SAFER OUTCOMES**



UF RESEARCHERS DETERMINE THE RISK OF PREGNANCY LOSS ASSOCIATED WITH A COMMONLY USED IMMUNOSUPPRESSANT DRUG, EFFECTIVE RISK MANAGEMENT STRATEGIES ARE WARRANTED

Researchers in the University of Florida College of Pharmacy have determined that mycophenolate, a common drug used to weaken the immune system, is approximately two times more likely to cause miscarriage among women exposed to the drug during their pregnancy. They compared the risk to azathioprine, which is considered a safe alternative for women of child-bearing age depending on their medical condition.


Mycophenolate was approved by the U.S. Food and Drug Administration in 1995 and became the mainstay of the post-transplantation regimen. Currently, it is prescribed for several other indications that are caused by over activation of the immune system, including systemic lupus (an inflammatory disease of skin and internal organs), psoriasis (an inflammatory condition of skin and joints) and autoimmune hepatitis (an inflammatory disease of liver).

The risk of miscarriage and birth defects was discovered in the early 2000s by several medical case reports, and the FDA took action in 2008 to update the label with a strong warning against maternal exposure. To date, no studies had quantified the amount of increased risk of miscarriage compared to a safer treatment option. The lead authors, Thuy Thai and Amir Sarayani, conducted the study under supervision of Almut Winterstein, Ph.D., R.Ph.

1.

Alipour Haris G*, Sarayani A, Winterstein AG. Letter Regarding Article, "Marijuana use among young adults (18-44 years of age) and risk of stroke: A behavioral risk factor surveillance system survey analysis". *Stroke*. 2020 May;51(5):e91. PMID: 32252600.

2.

 Alrwisan AA*, Wei YJ, Brumback BA, Antonelli PJ, Winterstein AG. Concomitant use of quinolones and stimulants and the risk of adverse cardiovascular symptoms: A retrospective cohort study. *Pharmacotherapy*. 2019 Dec;39(12):1167-1178. PMID: 31674031.

3.

Baltussen R, Marsh K, Thokala P, Diaby V, Castro H, Cleemput I, Garau M, Iskrov G, Olyaeemanesh A, Mirelman A, Mobinizadeh M, Morton A, Tringali M, van Til J, Valentim J, Wagner M, Youngkong S, Zah V, Toll A, Jansen M, Bijlmakers L, Oortwijn W, and Broekhuizen H. Multicriteria decision analysis to support health technology assessment agencies: Benefits, limitations, and the way forward. *Value Health*. 2019;22(11):1283-1288. PMID: 31708065.

4.

Bhattacharjee S, Lee JK, Vadieli N, Patanwala AE, Malone DC, Knapp SM, Lo-Ciganic W, Burke, WJ. Extent and factors associated with adherence to antidepressant treatment during acute and continuation phase depression treatment among older adults with dementia and major depressive disorder. *Neuropsychiatr Dis Treat*. 2020;16:1433-1450. PMID: 32606697.

5.

Boemmel-Wegmann*, Lo Re V, Park H. Early treatment uptake and cost burden of hepatitis C therapies among newly diagnosed hepatitis C patients with a particular focus on HIV coinfection. [published online ahead of print, 2020 Jan 14]. *Dig Dis Sci*. 2020;10.1007/s10620-019-06037-z. PMID: 31938995.

6.

Brokenshire S, Lemon SJ, Staley B, Voils A, Hincapie-Castillo JM. Impact of injectable opioid restrictions during a critical drug shortage period: Interrupted time series for institutional opioid utilization. *Pain Medicine*. PMID: N/A.

7.

Brown JD, Costales B, van Boemmel-Wegmann S, Goodin A, Segal S, Winterstein AG. Characteristics of older adults who were early adopters of medical cannabis in the Florida medical marijuana use registry. *JCM* 2020; Apr 18;9(4). pii: E1166. PMID: 32325769.


8.

Brown JD, Delcher PC, Bae J, Roussos-Ross D, Goodin AJ. OB/GYN perceptions of prescription drug monitoring programs as a primary prevention tool for neonatal abstinence syndrome. *Res Social Adm Pharm*. 2020 Mar 31;S1551-7411(19)31166-0. PMID: 32265114. [Epub ahead of print].

9.

Brown JD, Wang CY, Pahor M, Manini T. Three-year post-intervention follow-up comparison of healthcare resource utilization and costs in the Lifestyle Interventions and Independence for Elders (LIFE) Study. *Journals of Gerontology: Medical Sciences*. 2020 Apr 9. PMID:32270182.

10.

 Brown JD, Winterstein AG. Potential adverse drug events and drug-drug interactions with medical and consumer cannabidiol (CBD) use. *J Clin Med*. 2019, 8(7), 989; PMID:31288397.

11.

Brown JD. Antihypertensives and COVID-19. *Lancet Respir Med*. 2020 May 1;8(5):E28. PMID: 32222168.


12.

Brown JD. Cannabidiol as prophylaxis for SARS-CoV-2 and COVID-19? Unfounded claims versus potential risks of medications during the pandemic. *Res Social Adm Pharm*. 2020 Mar 31;S1551-7411(20)30300-4. PMID: 32273254. [Epub ahead of print].

13.

Brown JD. Potential adverse drug events with tetrahydrocannabinol (THC) due to drug–drug interactions. *J Clin Med*. 2020 Mar 27;9(4):919. PMID: 32230864.

14.

 Brown P, RELISH Consortium [Brown JD, Goodin AJ], Zhou Y. Large expert-curated database for benchmarking document similarity detection in biomedical literature search. *Database*. 2019, baz085, 1-67. PMID: 32681638.


15.

Chalasani R, Lo-Ciganic W, Huang JL, Guo J, Weiss JC, Kuza CC, Gellad WF. Occupational patterns of opioid-related overdose deaths among Arizona Medicaid enrollees, 2008-2017. *J Gen Intern Med*. 2020 Feb 10. PMID: 32043261. [Epub ahead of print].

16.

Chang C-Y*, Park H, Malone DC, Wang C-Y, Wilson DL, Yeh Y-M, Boemmel-Wegmann SV, Lo-Ciganic W. Immune checkpoint inhibitors and risk of immune-related adverse events among patients with advanced melanoma: a systematic review and network meta-analysis. *JAMA Netw Open*. 2020; 3(3):e201611. PMID: 32211869.

17.

 Cheng Y*, Goodin AJ, Pahor M, Manini T, Brown JD. Healthcare utilization and physical functioning in older adults in the United States. *J Am Geriatr Soc*. 2020 Feb;68(2):266-271. Epub 2019 Nov 22. PMID: 31755551.

18.

Chien HS, Kao Yang YH, Kwok CK, Chalasani P, Wilson D, Lo-Ciganic W. Aromatase inhibitors and risk of arthritis and carpal tunnel syndrome among Taiwanese women with breast cancer: a nationwide claims data analysis. *J Clin Med*. 2020; 9(2):pii:E566. PMID: 32092973.

19.

Choi Y*, Park H, Hampp C, Brumback B, Meissner HC, Li Y, Roussos-Ross D, Zhu Y, Henriksen C, Winterstein AG. Usability of encounter data for Medicaid comprehensive managed care vs traditional Medicaid fee-for-service claims among pregnant women. *Pharmacoepidemiol Drug Saf*. 2019 Jan;29(1):30-38. PMID: 31737976.

20.

Dave C*, Goodin A, Zhu Y, Winterstein A, Wang X, Alrwisan A, Hartzema A. Prevalence of maternal risk factors related to neonatal abstinence syndrome in a commercial claims database: 2011-2015. *Pharmacotherapy*. 2019 Oct;39(10):1005-1011. PMID: 31361913.

21.

Dawwas GK*, Dietrich E, Davis K, Park H. Comparative effectiveness and safety of direct acting oral anticoagulants and warfarin in patients with venous thromboembolism and active cancer. *Clin Ther*. 2019 [in press]. PMID: 32768247.

22.

Dawwas GK*, Leonard C, Garg M, Vouri S, Smith S, Park H. Twelve-years trends in Pharmacologic treatment of type 2 diabetes among patients with heart failure in the United States. *Diabetes Obes Metab*. 2020:1-6. PMID: 31903713.

23.

Dawwas GK*, Dietrich E, Winchester D, Winterstein AG, Segal R, Park H. Comparative effectiveness and safety of ticagrelor versus prasugrel in patients with acute coronary syndrome: A retrospective cohort analysis. *Pharmacotherapy*. 2019 Sep;39(9):912-920. PMID: 31332815.

24.

Dawwas GK*, Smith S, Dietrich E, Lo-Ciganic W, Park H. Comparative effectiveness and safety of apixaban compared to warfarin in patients with venous thromboembolism. *Am J Health Syst Pharm*. 2020; 77(3):188-195. PMID: 31974557.

25.

Desai R*, Dietrich E, Park H, Smith S. Out-of-pocket payment for ambulatory blood pressure monitoring among commercially-insured in the United States. *Am J Hypertens*. 2020 [in press]. PMID: N/A.

26.

Desai R*, Park H, Dietrich E, Smith S. Trends in ambulatory blood pressure monitoring use for confirmation or monitoring of hypertension and resistant hypertension among the commercially-insured in the U.S., 2008-2017. *International Journal of Cardiology Hypertension* 2020; 6; 100033. PMID: N/A.

22 | UF DEPARTMENT OF PHARMACEUTICAL OUTCOMES & POLICY

UF STUDY FINDS FDA STRATEGY CUTS FETAL EXPOSURE TO HARMFUL IMMUNOSUPPRESSIVE DRUG, **BUT RISKS REMAIN**

University of Florida researchers determined an FDA-approved program deters pregnant women from starting a potentially harmful immunosuppressive drug. But for women taking the drug, the program was not effective at reducing conception.



Mycophenolate helps prevent organ rejection after transplantation and is increasingly used for a variety of autoimmune disorders such as lupus or psoriasis. However, mycophenolate also can increase the risk of miscarriage and birth defects. The FDA implemented a Risk Evaluation and Mitigation Strategy, or REMS, program in 2012 because of fetal safety concerns involving

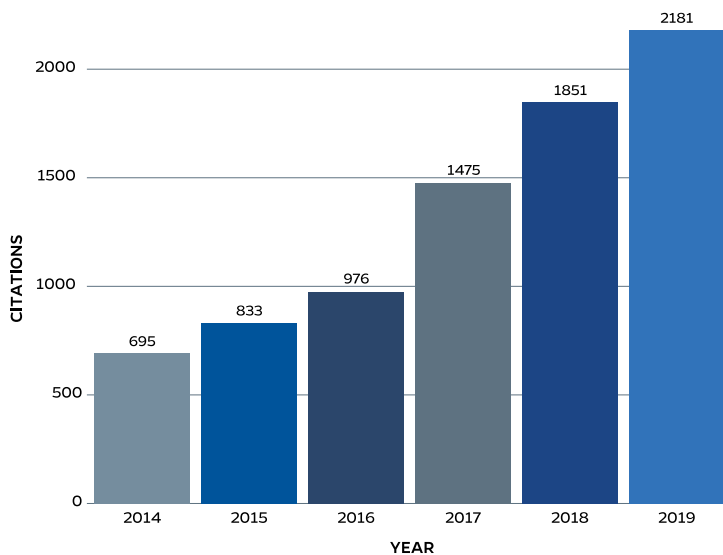
mycophenolate. The REMS requires certain precautions, including mandatory prescriber trainings, a patient acknowledgment form and other measures to ensure the drug is used safely.

“As chair of the drug safety and risk management advisory committee for the FDA, I was oftentimes faced with the need to make REMS program recommendations for drugs with certain safety concerns,” said Almut Winterstein, R.Ph., Ph.D., FISPE, a professor and the Dr. Robert and Barbara Crisafi Chair. “Unfortunately, there is little evidence of the effectiveness of REMS programs to mitigate risk, and we were left questioning whether provider trainings and consent forms were really moving the needle in terms of safety. Our study shows there is value in continuing REMS programs to improve drug safety, but more needs to be done to tailor them to a specific clinical scenario to ensure they are effective.”

Researchers in the UF College of Pharmacy used a large national private insurance claims database to evaluate the rate of fetal mycophenolate exposure during REMS (2012-14) compared with prior years (2007-12) when only written information about fetal concerns was provided via the drug label and a medication guide. The study determined women treated during the REMS period were 58% less likely to be pregnant on the first day of treatment compared to when only written information was used. Importantly, UF researchers also examined whether REMS helped deter women from becoming pregnant during mycophenolate treatment and found REMS was not effective in preventing conception.

“The FDA implemented several rules to ensure no fetal exposure, including a consent form which requires women to agree to use two forms of contraception if they are sexually active,” Winterstein said. “It appears the strategy has not worked to ensure patients successfully follow the strict contraception warnings.”

TOTAL CITATIONS FOR POP FACULTY PUBLICATIONS



27.

Diaby V, Alqhtani H, van Boemmel-Wegmann S, Wang CY, Ali AA, Balkrishnan R, Ko Y, Palacio S, and de Lima Lopes G.. 2020. A cost-effectiveness analysis of trastuzumab-containing treatment sequences for HER-2 positive metastatic breast cancer patients in Taiwan. *The Breast*. 49: 141-148. PMID:31805500.

28.

Diaby V, Wang CY, Alqhtani H, van Boemmel-Wegmann S, Ali AA, Balkrishnan R, Ko Y, Palacio S, and de Lima Lopes G. 2020. Dataset used in the economic evaluation trastuzumab-based regimens for HER-2 positive metastatic breast cancer patients in the Taiwanese healthcare setting. *Data Brief*. 29: 105194. PMID: 32071975.

29.

Diaby V, Ali AA, Montero AJ. 2019. Value assessment frameworks in the United States: A call for patient engagement. *Pharmacoeconomics-Open*. 1-3. PMID: 30182346.

30.

Dietrich E, Desai R, Garg M, Park H, Smith S. Reimbursement of ambulatory blood pressure monitoring in the U.S. commercial insurance market place. *J of Clin Hypertens* 2020;22(1):6-15. PMID: 31873973.

31.

Dobbins JM, Elliott S, Cordier T, Haugh G, Renda A, Happe LE, Turchin A. Primary care provider encounter cadence and HbA1c control in older patients with diabetes. *Am J Prev Med*. 2019;57(4):e95-101. PMID: 31542146.

32.

El Rouby N, Alrwisan A, Langaee T, Lipori G, Angiolillo DJ, Franchi F, Riva A, Elsey A, Johnson JA, Cavallari LH, Winterstein AG. Clinical utility of pharmacogene panel-based testing in patients undergoing percutaneous coronary intervention (PCI). *Clin Transl Sci*. 2020 May;13(3):473-481. PMID: 31758664.

33.

Gembarski J, Couto J, Wilson, M, and the Joint Research Committee of AMCP and the AMCP Foundation. Top evidentiary gaps in managed care pharmacy: A research agenda. *J Manag Care Spec Pharm*. 2020;26(4):375-381. PMID: 32130069.

34.

Goodin AJ, Talbert J, Freeman PR, Hahn EJ and A Fallin-Bennett. (2020). Appalachian disparities in tobacco cessation treatment utilization in medicaid. *Subst Abuse Treat Prev Policy*. 15(5). PMID: 31959212.

35.

Grundmann O, Segal R, Pullo J, Davis L, Felix-Irizarry Y, Da Silva L, and Holets T. The pharmacist as an LGBTQ+ ally. *Am J Pharm Educ*. 2020 Jul;84(7):ajpe7835. PMID: 32773835.

36.

Happe L, Brown JD, Gatwood J, Wang SV, Schneeweiss S. Application of a graphical depiction of longitudinal study designs to managed care pharmacy research. *J Manag Care Spec Pharm*. 2020 Mar;26(3):268-274. PMID: 32105168.

37.

35

Hayes CJ, Krebs E, Hudson T, Brown JD, Martin BC. Impact of opioid dose escalation on the development of substance use disorders, accidents, self-inflicted injuries, opioid overdoses, and alcohol and non-opioid drug-related overdoses: A retrospective cohort study. *Addiction*. 2020 Jun;115(6):1098-1112. Epub 2020 Jan 15. PMID: 31944486.

38.

163

Hayes CJ, Krebs E, Hudson T, Brown JD, Martin BC. Impact of opioid dose escalation on pain intensity: A retrospective cohort study. *Pain*. 2020 May;161(5):979-988. PMID: 31917775.

39.

Hincapie-Castillo JM*, Staley B, Henriksen C, Saidi A, Lipori GP, Winterstein AG. Development of a predictive model for drug-associated QT prolongation in the inpatient setting using electronic health record data. *Am J Health Syst Pharm* 2019 Jul 2;76(14):1059-1070. PMID: 31185072.

40.

88

Hincapie-Castillo JM, Goodin A, Possinger M, Usmani S, Vouri S. Changes in opioid use after Florida's restriction law for acute pain prescriptions. *JAMA Netw Open*. 2020;3(2):e200234. PMID: 32108887.

41.

Hong D, Shen Y, Monnette A, Liu S, Shao H, Nauman E, Shi L. Does the encounter type matter when defining diabetes complications in electronic health records? *Medical Care*, 2020; 58(1):53-59. PMID: 32011424.

42.

460

Hong Y, Hincapie-Castillo JM, Segal S, Mainous A. Socioeconomic and demographic characteristics of Americans who purchase prescription drugs outside the United States. *JAMA Netw Open*. 2020;3(6):e208968. PMID: 32579194.

43.

Kebodeaux CK, Woodyard JL, Kachlic MD, Allen SM, Schadler AD, Vouri SM. Student pharmacists' ability to organize complex medication regimens according to the universal medication schedule. *Am J Pharm Ed*. 2020. ajpe7531. PMID: N/A.

44.

Knox CA*, Hampp C, Palmsten K, Zhu Y, Setoguchi S, Brumback B, Segal R, Winterstein AG. Validation of mother-infant linkage using Medicaid Case ID variable within the Medicaid Analytic eXtract (MAX) database. *Pharmacoepidem Drug Saf* 2019 Sep;28(9):1222-1230. PMID: 31286606.

45.

Kristi A, Shao H, Shi L. Policy options for addressing the high cost of specialty pharmaceuticals. *Glob Health J*. 2019;3(4):79-83. PMID: N/A.

46.





Kristin M, Zhuo X, Bardenheier B, Shao H, Laxy M, Schulze M. Selecting the optimal risk threshold of diabetes risk scores to identify high-risk individuals for diabetes prevention: A cost-effectiveness analysis. *Acta Diabetologica*,2020;57:440-454. PMID: 31745647.

47.

Laxy M, Zhang P, Ng B, Shao H, Ali M, Albright A, and Gregg E. Implementing lifestyle change interventions to prevent Type 2 Diabetes in US Medicaid programs: Cost Effectiveness, and Cost, Health, and Health Equity Impact. *Appl Health Econ Health Policy*. 2020. PMID: 32607728. [Epub ahead of print].

48.

Li Y*, Delcher C, Brown JD, Wei Y-J, Reisfield GM, Winterstein AG. Impact of Schedule IV controlled substance classification on carisoprodol utilization in the United States: an interrupted time series analysis. *Drug Alcohol Dependence* 2019(Jul);202:172-177. PMID: 31352307.

49. Li Y*, Delcher C, Wei YJ, Reisfield GM, Brown JD, Tighe PJ, Winterstein AG. Risk of opioid overdose associated with concomitant use of opioids and skeletal muscle relaxants: a population-based cohort study. *Clin Pharmacol Ther.* 2020 Jul;108(1):81-89. PMID: 32022906.
50.  Limdi NA, Cavallari LH, Lee CR, Hillegass WB, Holmes AM, Skaar TC, Pisu M, Dillon C, Beitelshes AL, Empey PE, Duarte JD, Diaby V, Gong Y, Johnson JA, Graves J, Garbett S, Zhou Z, Peterson JF. 2020. Cost-effectiveness of CYP2C19-guided antiplatelet therapy in patients with acute coronary syndrome and percutaneous coronary intervention informed by real-world data. *Pharmacogenomics J.* PMID: 32042096. [Epub ahead of print].
51. Marcum ZA, Chang C-Y, Barthold D, Holmes HM, Lo-Ciganic W. Association between pharmaceutical industry payments and prescribing of branded memantine and donepezil combination. *Neurology Clinical Practice.* 2020; (in press). PMID: N/A.
52. Metes ID, Xue L, Chang CH, Huskamp HA, Gellad WF, Zhang R, Lo-Ciganic W, Choudhry NK, Richards-Shubik S, Guclu H, Donohue JM. Association between physician adoption of a new oral antidiabetic medication and Medicare and Medicaid drug spending. *BMC Health Serv Res.* 2019; 19(1):703. PMID: 31619229.
53. Muñoz MA*, Dal Pan GJ, Wei YJ, Delcher C, Xiao H, Kortepeter CM, Winterstein AG. Towards automating adverse event review: A prediction model for case report utility. *Drug Saf.* 2020 Apr;43(4):329-338. PMID: 31912439.
54. Muñoz MA*, Delcher C, Dal Pan GJ, Kortepeter CM, Wu E, Jenny Wei YJ, Xiao H, Winterstein AG. Impact of a new consumer form on the quantity and quality of adverse event reports submitted to the United States Food and Drug Administration. *Pharmacotherapy.* 2019 Nov;39(11):1042-1052. PMID: 31479525.
55. Nguyen T, Liu X, Abuhashem W, Bussing R, Winterstein AG. Quality of evidence supporting major psychotropic drug-drug interaction warnings: A systematic literature review. *Pharmacotherapy.* 2020 May;40(5):455-468. PMID: 32107798.
56. Olasupo O*, Segal R, and Brown J. 2019. Missed opportunities for pneumococcal vaccinations in high risk and older adults in the United States. *J Infect Public Health.* 2020 Jan;13(1):101-103 PMID: 31279802.
57. Osborne V*, Striley CW, Nixon SJ, Winterstein AG, Cottler LB. Sex differences in peer and parental risk factors for non-medical use of prescription opioids in youth. *Am J Drug Alcohol Abuse.* 2019 Oct 11:1-13. PMID: 31603348.
58. Padilla M, Roussos-Ross D and AJ Goodin. (2020). Assessing the utility of the Healthy Start Screen to predict an elevated Edinburgh Postnatal Depression Scale Score. *J Perinat Med.* 2020 Jun 25;48(5):483-487. PMID: 32286250.
59. Patel K, Brown JD. Disparities in the use of cardiac rehabilitations after a myocardial infarction in the United States. *Journal of Clinical Medicine.* 2019 Jul 10;8(7):1006. PMID: 31295853.
60.  Pham PN*, Lesko L, Schmidt S, Lip GYH, Brown JD. Association of oral anticoagulants and verapamil or diltiazem with adverse bleeding events in patients with non-valvular atrial fibrillation and normal renal function. *JAMA Netw Open* 2020 Apr 1;3(4):e203593. PMID: 32329770.
61. Pottgård A, Klungel O, Winterstein A, Huybrechts K, Hallas J, Schneeweiss S, Evans S, Bate A, Pont L, Trifirò G, Smith M, Bourke A. The International Society for Pharmacoeconomics's comments on the core recommendations in the summary of the Heads of Medicines Agencies (HMA) - EMA Joint Big Data Task Force. *Pharmacoeconom Drug Saf.* 2019 Dec;28(12):1640-1641. PMID: 31642154.
62. Qin W, Xu L, Shao H. An exploratory spatial analysis of overweight and obesity among children and adolescents in Shandong, China. *BMJ Open.* 2019 Aug 22;9(8):e028152. PMID: 31444183.
63. Qin W, Xu L, Sun L, Jiajia Li, and Shao H. Association between frailty and life satisfaction among older people in Shandong, China: The differences in age and general self-efficacy. *Psychogeriatrics,* 2020;20(2):172-179. PMID: 31680393.
64. Rhew K, Brown JD, Oh JM. Atopic disease and anemia in Korean patients: cross-sectional study with propensity score analysis. *Int J Environ Res Public Health.* 2020 Mar 18;17(6):1978. PMID: 32197291.
65. Rhew K, Han N, Goodin AJ and JM Oh. Domperidone prescribing patterns in pediatric patients before and after safety warning in South Korea. *International Journal of Clinical Pharmacology and Therapeutics.* Accepted: March 10, 2020. Forthcoming. PMID: N/A.
66. Riaz M*, Brown JD. Association of adverse drug events with hospitalization outcomes and costs in older adults in the United States: Analysis using Nationwide Readmissions Database. *Pharmaceut Med.* 2019 Aug;33(4):321-329. PMID: 31933184.
67. Rogers H, Beveridge M, Puente J, Wixson S, Loy B, Happe LE. Incidence of non-melanoma skin cancer in the US population aged 65 years and older. 2014. *J Am Acad Dermatol.* 2019; pii: S0190-9622(19)32687-8. PMID: 31499148. [Epub ahead of print].
68. Sarayani A*, Albogami Y, Elkhider M, Hincapie-Castillo JM, Brumback BA, Winterstein AG. Comparative effectiveness of risk mitigation strategies to prevent fetal exposure to mycophenolate. *BMJ Qual Saf.* 2019 Oct 24. PMID: 31649165. [Epub ahead of print].
69.  Sarayani A*, Cicali B, Henriksen CH, Brown JD. Safety signals for QT prolongation or Torsades de Pointes associated with azithromycin with or without chloroquine or hydroxychloroquine. *Res Social Adm Pharm.* 2020 Apr 19. PMID:32327397. [Epub ahead of print].
70. Segal R, Angaran DM, Odedina FT, Zeigler ML, and Wallace JL. 2020. Opportunities and responsibilities for pharmacists to improve their effectiveness in addressing medication adherence through culturally sensitive collaborations with community health workers. *J Am Pharm Assoc.* Jul-Aug 2020;60(4):e25-e30. PMID: 32217086.
71. Shah C, Brown JD. Reliability and validity of the short form 12 item version 2 (SF-12v2) health-related quality of life survey and disutilities associated with relevant conditions in the U.S. older adult population. *J Clin Med.* 020 Feb 29;9(3):661. PMID: 32121371.
72. Shao H, Lin J, Zhuo X, Rolka D, Greg E, Zhang P. Influence of diabetes complications on HbA1c treatment goals among older US adults: A cost-effectiveness analysis. *Diabetes Care,* 2019; 42(11): 2136-2142. PMID: 31530661.
73. Shao H, Shi L, Fonseca V. Using the BRAVO Risk Engine to predict cardiovascular outcomes in clinical trials With sodium-glucose transporter 2 inhibitors. *Diabetes Care,* 2020. 2020 Jul;43(7):1530-1536. PMID: 32345650. [Epub ahead of print].
74. Shao H, Yang S, Fonseca V, Stoecker C, Shi L. Addressing regional differences in diabetes progression: global calibration for diabetes simulation model. *Value Health,* 2019;22(12):1402-1409. PMID: 31806197.
75.  Shao, Y, Shao, H, Shi, L. Serum uric acid as a risk factor of all-cause mortality and cardiovascular events among type 2 diabetes population: Meta-analysis of correlational evidence. *J Diabetes Complications.* 2019;21. PMID: 31439471.
76. Shen Y*, Lo-Ciganic W, Segal R, Goodin AJ. Prevalence of substance use disorder and psychiatric comorbidity burden among pregnant women with opioid use disorder in a large administrative database, 2009-2014. *J Psychosom Obstet Gynaecol.* 2020; 18:1-7. PMID: 32067526. [Epub ahead of print].

FAST FACTS FOR 2020

34
ACTIVE
EXTRAMURALLY
FUNDED
PROJECTS

\$2.5M
EXTRAMURAL
FUNDING TO
POP FACULTY

\$20M
INVOLVING
DEPARTMENT
FACULTY

77. Smith SM, Gurka MJ, Winterstein AG, Handberg E, Pepine CJ, Cooper-DeHoff RM. Redefining resistant hypertension: A comparison of cardiovascular risk associated with the 2018 Versus 2008 American Heart Association definitions for resistant hypertension. *Circ Cardiovasc Qual Outcomes*. 2020 Feb;13:e005979. PMID: 32008359.

78. Smith SM, Winterstein AG, Pepine CJ, Cooper-DeHoff RM. Thiazide exposure and cardiovascular risk in Type 2 Diabetes Mellitus: A point of clarification. *Hypertension*. 2020 Feb 3;75:e2-e5. PMID: 32008437.

79. Song H, Jiang X, Henry L, Nguyen M, Park H. The impact of proton pump inhibitor uses on liver cancer and mortality in patients with chronic liver diseases: a systematic review and meta-analysis. *European Journal of Clinical Pharmacology* 2020 Jun; 76(6):851-866. PMID:32172363.

80. Song H (p), Squires P (g), Wilson D, Lo-Ciganic W, Cook R, Park H. Trends in HIV pre-exposure prophylaxis prescribing in the United States, 2012-2018. *JAMA* 2020 Jul;324(4):395-397. PMID: 32720996.

81. Talevi A, Morales JF, Hather G, Podichetty JT, Kim S, Bloomingdale PC, Kim S, Burton J, Brown JD, Winterstein AG, Schmidt S, White JK, Conrado DJ. Machine learning in drug discovery and development part 1: A primer. *CPT Pharmacometrics Syst Pharmacol*. 2020 Mar;9(3):129-142. PMID: 31905263.

82.  Teshome BF, Vouri SM, Hampton N, Kollef MH, Micek ST. Evaluation of a ceiling effect on the association of new resistance development to antipseudomonal beta-lactam antibiotic exposure in the critically ill. *Infect Control Hosp Epidemiol*. 2020. 27(1-2). PMID: 31983358.

83. Thai TN*, Sarayani A, Wang X, Albogami Y, Rasmussen SA, Winterstein AG. Risk of pregnancy loss in patients exposed to mycophenolate compared to azathioprine: A retrospective cohort study. *Pharmacoepidemiol Drug Saf*. 2020 Jun;29(6):716-724. PMID: 32347619.

84. Tran AD, Fogarty G, Nowak AK, Diaby V, Hong A, Watts C, Morton RL. 2020. Cost-effectiveness of subsequent hippocampal-avoidant whole brain radiotherapy versus stereotactic radiosurgery or surgery alone, for treatment of melanoma brain metastases. *Appl Health Econ Health Policy*. 22 January 2020. (Accepted). PMID: N/A.

85. Tran PT*, Winterstein AG, Wang X, Rhew K, Antonelli PJ. Appropriateness of otic quinolone use among privately insured US patients. *Otolaryngol Head Neck Surg*. 2020 Jan;162(1):102-102. PMID: 31743076.

86.  Vouri SM, Thai TN, Winterstein AG. An evaluation of co-use of chloroquine or hydroxychloroquine plus azithromycin on cardiac outcomes: A pharmacoepidemiological study to inform use during the COVID19 pandemic. *Res Social Adm Pharm*. 2020 Apr 30:S1551-7411(20)30468-X. PMID: 32409150. [Epub ahead of print].

87.  Vouri SM, Jiang X, Manini TM, Solberg LM, Pepine C, Malone DC, Winterstein AG. Magnitude of and characteristics associated with the treatment of calcium channel blocker-induced lower-extremity edema with loop diuretics. *JAMA Netw Open*. 2019; Dec 2;2(12):e1918425. PMID: 31880802.

88. Vouri SM, Possinger MC†, Usmani S*, Solberg LM, Manini T. Evaluation of the potential acetylcholinesterase inhibitor-induced rhinorrhea prescribing cascade. *J Am Geriatr Soc*. 2020;68(2):440-441. PMID: 31625144.

89. Vouri SM. Letter to the Editor- Re: Rhinorrhea as a result of Alzheimer's disease treatment: a case report. *Sr Care Pharm*. 2020; 35(4):148-149. PMID: 32192562.

90. Wang CY*, Brown JD. Readmissions after pancreatic surgery in patients with pancreatic cancer: Does hospital variation exist for quality measurement? *Visceral Medicine*. 2019. PMID: N/A.

31


**PUBLICATIONS
FIRST AUTHORED
BY GRADUATE
STUDENTS**

160

TRAINEES

105

**PEER-REVIEWED
MANUSCRIPTS**

91. Wang CY*, Pham PN, Kim S, Lingeneni K, Schmidt S, Diaby V, Brown JD. Predicting cost-effectiveness of generic versus brand dabigatran using pharmacometric estimates among patients with atrial fibrillation in the United States. *Clinical and Translational Science*. 2020 Mar;13(2):352-361. Epub 2020 Feb 13. PMID: 32053288.
92. Wang Z*, Brumback B, Alrwisan A, Winterstein AG. Model-based standardization using outcome model with random effects. *Statistics in Medicine* 2019 Aug 15;38(18):3378-3394 PMID: 31150151.
93. Wei YJ, Solberg L, Chen C, Fillingim RB, Pahor M, DeKosky S, Winterstein AG. Agreement of Minimum Data Set 3.0 depression and behavioral symptoms with clinical diagnosis in a nursing home. *Aging Ment Health*. 2020 May 25:1-6.PMID: 32447973.
94. YJ, Solberg L, Chen C, Fillingim RB, Pahor M, DeKosky S, Winterstein AG. Pain assessments in MDS 3.0: Agreement with vital sign pain records of nursing home residents. *J Am Geriatr Soc* 2019 Nov;67(11):2421-2422. PMID: 31403708.
95.  Wei YJ, Chen C, Fillingim R, Schmidt SO, Winterstein AG. Trends in prescription opioid use and dose trajectories before opioid use disorder or overdose in US adults from 2006 to 2016: A cross-sectional study. *PLoS Med*. 2019 Nov 5;16(11):e1002941. PMID: 31689302.
96. Wei YJ, Chen C, Schmidt SO, LoCiganic WH, Winterstein AG. Trends in prior receipt of prescription opioid or adjuvant analgesics among patients with incident opioid use disorder or opioid-related overdose from 2006 to 2016. *Drug Alcohol Depend*. 2019 Sep 27;204:107600. PMID: 31586806.
97. Wei YJ, Solberg L, Chen C, Fillingim R, Pahor M, DeKosky S, Winterstein A. Agreement of Minimum Data Set 3.0 depression and behavioral symptoms with clinical diagnosis in a nursing home. *Aging Ment Health*. 2020 May 25;1-6. PMID:32447973.
98. Winterstein AG, Bussing R, Goodin A, Xu D, Keenan M, Turner K, Meyyur V, Duseja R, Campbell K. Development and validation of an administrative claims-based measure for all-cause 30-day risk-standardized readmissions after discharge from inpatient psychiatric facilities. *Med Care*. 2020 Mar;58(3):225-233. PMID: 32106165.
99. Winterstein AG, Girman CJ, Pottg rd A. Randomization versus real-world evidence. *N Engl J Med*. 2020 Jul 23;383(4):e21. PMID: 32706549.
100. Winterstein AG, Li Y, Gerhard T, Linden S, Shuster JJ. Medication use for ADHD and the risk of driving citations and crashes among teenage drivers: A population-based cohort study. *J Atten Disord*. 2020 Apr 26;1087054720915768. PMID: 32338114. [Epub ahead of print].
101. Xiao H, Jiang X, Chen C, Wang W, Wang CY, Ali AA, Berthe A, Moussa RK, and Diaby V. 2019. Using time series analysis to forecast the health-related quality of life of post-menopausal women with non-metastatic ER+ breast cancer: A tutorial and case study. *Res Social Adm Pharm*. 30650-3. PMID: 31753693.
102. Yoshida Yi, Cheng X, Shao H, Fonseca V, and Shi L. A systematic review of cost-effectiveness of sodium-glucose cotransporter inhibitors for Type 2 Diabetes. *Curr Diab Rep*. 2020 Mar 12;20(4):12. PMID: 32166504.
103. Zhou L, Bhattacharjee S, Kwok CK, Tighe PJ, Malone DC, Slack M, Wilson DL, Brown JD, Lo-Ciganic W. Trends, patient and prescriber characteristics in gabapentinoid use in a sample of United States ambulatory care visits from 2003 to 2016. *J Clin Med*. 2019; 9(1)pii: E83. PMID: 31905718.
104. Zhou L, Kwok CK, Ran D, Ashbeck EL, Lo-Ciganic W. Lack of evidence that beta blocker use reduces knee pain, areas of joint pain, or analgesic use among individuals with symptomatic knee osteoarthritis. *Osteoarthritis Cartil*. 2020; 28(1):53-61. PMID: 31526877.
105. Zou B, Yeo Y, Jeong D, Park H, Sheen E, Lee D, Linda H, Garcia G, Ingelsson E, Cheung R, Nguyen M. A nationwide study of inpatient admissions, mortality, and costs for patients with cirrhosis from 2005-2015 in the U.S. *Dig Dis Sci*. 2020 May;65(5):1520-1528. PMID: 31598919.

LETTER FROM THE GRADUATE DIRECTOR

As the department's graduate director, I am delighted to share information about the state of our graduate program. Our program is all about creating world-class researchers and policymakers in an interdisciplinary, collaborative environment. We have been laser-focused on preparing the next generation of independent, intellectual leaders in fields spanning academia, industry and regulatory science. Our graduate program offerings consist of M.S. degrees or a Ph.D. Our M.S. degree programs include a research-focused M.S., with a thesis program on campus, and an applied non-thesis M.S. degree that can be completed online. During the past academic year, 35 graduate students have been part of our residential graduate program, with almost all working on a doctoral degree. Our program continues to grow with ten new students beginning during the 2020-2021 academic year. Further, our students represent a mix in terms of their home country with 12 nations represented. Our students choose a specialization area, which includes pharmacoepidemiology and safety sciences, pharmacoconomics and outcomes research or pharmaceutical health services research.

During the past year, these students first-authored 31 papers in peer-reviewed journals, including papers published in high-impact journals such as Pharmacotherapy and JAMA Network Open. Our students have traveled extensively to speak about their research, giving more than 40 presentations at national or international research or professional meetings. The department also recognized two of its own graduate students who have been particularly meritorious in critical scientific skills including research, leadership and service. For 2019-20, Raj Desai received the "POP Graduate Student Publication Award," meant to recognize a graduate student who has displayed excellence in a single peer-reviewed article or a body of scientific work. Amir Sarayani, Pharm.D., M.S., was the recipient of the "Leadership Service Award," or the "POP Star" award, for a student who displays a passion for the department, for research, is a leader and an overall good citizen. Further, graduates during the prior academic year have found incredible positions upon finishing their degree program, such as director at Janssen Pharmaceuticals' Real-World Market Access Analytic and an associate professor at King Saud University.

The online M.S. program, and related graduate certificate programs, have offered state-of-the-art learning experiences to more than 100 students in the past year. The specialty tracks in applied pharmacoconomics, managed care pharmacy systems, patient safety in medication use and pharmaceutical regulation offer coursework tailored for working professionals. Students have raved about the value added from their participation in the program, and I encourage you to check out some of the student testimonials about how the program has impacted them professionally.



As you can tell, we are really proud of our students and graduates. They have accomplished a great deal during the past year, and most importantly, are making significant impacts on society through their research and their professional achievements.

RICHARD SEGAL, R.PH., PH.D., M.S.
Associate Dean, Professor and
Graduate Program Director

TRAINING THE NEXT GENERATION OF SCIENTISTS

2020 GRADUATES



YASSER ALBOGAMI, M.S., B.S. PHARM., PH.D.

Dissertation: Safety and Effectiveness of Pharmacological Treatments in Patients with Chronic Lower Respiratory Disease and Type II Diabetes

Advisor: Almut Winterstein

First position after graduation: Assistant Professor, King Saud University



SASCHA WEGMANN, M.S., B.S. PHARM., PH.D.

Dissertation: Treatment Patterns, Healthcare Resource Use, and Gastrointestinal Safety of Metastatic Melanoma Therapies with a Particular Emphasis on Immune-Checkpoint Inhibitors

Advisor: Haesuk Park

First position after graduation: Consultant for Real-World Evidence Projects and Market Access Strategies, Ingress-Health



BINGCAO WU, B.S., M.S., PH.D.

Dissertation: Real-World Evidence of Antidepressants Use in Breast Cancer Women with Post-Diagnosis Major Depressive Disorder: a Retrospective Cohort Study

Advisor: Hong Xiao

First position after graduation: Director, Real-World Market Access Analytics, Janssen Pharmaceuticals



ABDULRAHMAN ALSUHIBANI, M.S.

Thesis Title: Statins Use Following Bariatric Surgery: Factors Associated with the Discontinuation

Advisor: Scott Martin Vouri

First position after graduation: Ph.D. student, University of Cincinnati



MASHAEL ALASKAR, B.S. PHARM., M.S.

Thesis: Evaluation of the use of loop diuretics following fluid resuscitation in intensive care unit septic patients

Advisor: Scott Martin Vouri

First position after graduation: Quality and Safety Specialist, King Faisal Specialist Hospital and Research Center

TRAINING THE NEXT GENERATION OF SCIENTISTS

PH.D. STUDENTS



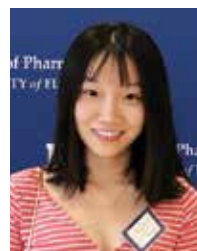
Hussain Alqhtani,
M.S., B.S. Pharm.



Aram Babcock,
Pharm.D., R.Ph., M.S.,
M.B.A.



Ching-Yuan "Peggy"
Chang, M.S., B.S.



Cheng "Alice" Chen,
B.S. Pharm.



Ziyen Chen, M.S.



Brianna Costales, B.S.



Raj Desai, M.S.



Mohannad Elkhider,
M.S., B.S. Pharm.



Ikenna Francis Unigwe,
Pharm.D., B.S.



Mahek Garg, M.S.,
B.S. Pharm.



Yushi Huang,
Pharm.D.



Xinyi "Rose" Jiang,
B.S.



Sebastian Jugl,
B.S. Pharm., R.Ph.



Motomori Lewis, B.S.



Earl Morris, Pharm.D.,
M.P.H.



Yun Sh Phuong
Pham, MSPH,
B.S. Pharm.



Munaza Riaz,
Pharm.D., M.Phil.



Amir Sarayani,
Pharm.D., M.P.H.



Yun Shen, M.P.H.



Nicole Smolinski,
Pharm.D.



Patrick Squires,
Pharm.D.



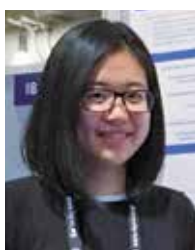
Thuy Thai, M.P.H.,
B.S. Pharm.



Phuong "Phoenix"
Tan Tran, M.P.H.,
B.S. Pharm.



Ching-Yu "Jessie"
Wang, B.S.



Xi Wang, M.P.H., B.M.



Seonkyeong Yang,
M.S., B.S. Pharm.

THESIS M.S. STUDENTS



Golnoosh Alipour
Haris, Pharm.D.



Shailina Keshwani,
B.S. Pharm., B.A.S.



Aimalohi Okpeku,
B.S. Pharm.



Yahan Zhang, M.S.
B.S. Pharm.

STUDENT AWARDS

GOLNOOSH ALIPOUR HARIS

- Read, Refute, Reward, International Society of Pharmacoepidemiology Student Chapter Award, 2020

CHING-YUAN “PEGGY” CHANG

- ACPE Spotlight poster presentation, 2019

CHENG “ALICE” CHEN

- Winner of Oral Competition at 33rd UF College of Pharmacy Annual Research Showcase, 2020

ZIYAN CHEN

- Read, Refute, Reward, International Society of Pharmacoepidemiology Student Chapter Award, 2020

BRIANNA COSTALES

- Travel grant, 35th International Conference on Pharmacoepidemiology and Therapeutic Risk Management, 2019
- Grinter Fellowship, 2019

RAJ DESAI

- POPStar Graduate Student Publishing Award, 2020

XINYI “ROSE” JIANG

- Travel grant, 35th International Conference on Pharmacoepidemiology and Therapeutic Risk Management, 2019

SEBASTIAN JUGL

- Grinter Fellowship, 2019

MOTOMORI LEWIS

- Student Scholarship, 36th International Conference on Pharmacoepidemiology and Therapeutic Risk Management, 2020
- McKnight Doctoral Fellowship, 2019
- Southern Regional Education Board Institute on Teaching and Mentoring Travel Award, 2019

EARL MORRIS

- Graduate School Preeminence Award, University of Florida Graduate School, 2020
- ICPE All Access Scholarship, 2020

PHUONG PHAM

- Grinter fellowship, 2019
- UF ORISE fellowship at FDA, 2019



Thuy Thai and Amir Sarayani receive the 2019 Annual ISPE Award for the second best abstract submitted by students

AMIR SARAYANI

- Travel grant, International Society of Pharmacoepidemiology, Midyear Conference, 2020
- Travel grant, 35th International Conference on Pharmacoepidemiology and Therapeutic Risk Management, 2019
- 2nd Best Student Abstract, 35th International Conference on Pharmacoepidemiology & Therapeutic Risk Management, 2019
- POPStar Leadership Service Award, 2020

PATRICK SQUIRES

- International Society for Pharmacoepidemiology (ISPE) Mid-Year Scholarship, 2020.

THUY THAI

- 2nd Best Student Abstract, 35th International Conference on Pharmacoepidemiology & Therapeutic Risk Management, 2019
- Travel grant, 35th International Conference on Pharmacoepidemiology and Therapeutic Risk Management, 2019

PHUONG “PHOENIX” TAN TRAN

- Read, Refute, Reward, International Society of Pharmacoepidemiology Student Chapter Award, 2020
- Grinter Fellowship, 2019

IKENNA UNIGWE

- McKnight Fellowship, 2020

SASCHA WEGMANN

- International Achievement Award, UF International Center, 2019

ONLINE GRADUATE PROGRAMS

The department of pharmaceutical outcomes and policy’s graduate programs include graduate certificates and training toward a non-thesis M.S. degree in four specialty tracks.

APPLIED PHARMACOECONOMICS

Applied pharmacoeconomics centers on the conversion of pharmacoeconomic principles, methods and theories into practice to assess the value of pharmaceutical products and services used in real-world settings. Pharmacoeconomic studies provide scientifically grounded data to inform the optimal allocation of health care resources.

TRACK DIRECTOR: Karam Diaby, Ph.D., M.SC.

MANAGED CARE PHARMACY SYSTEMS

Managed care is a defined structure and process of designing and delivering covered health care benefits that balance clinical outcomes with access and costs. When applied to pharmacy, the result is optimized pharmaceutical treatments at a price that patients can afford. The curriculum in this program is an in-depth analysis of the structure, set-up, management and delivery of benefit coverage for medicines, as well as current innovations such as risk-sharing, drug pricing reform, and coverage of digital therapeutics.

TRACK DIRECTOR: Laura Happe, Pharm.D., M.P.H.

PATIENT SAFETY IN MEDICATION USE

This program focuses on the design and evaluation of quality improvement initiatives aimed at improving medication safety, as well as the systems used to advance medication use quality. Intended primarily for pharmacists and other clinicians familiar with the drug use system, the curriculum is designed to focus on competencies and skills needed by those acting as patient or medication safety officers or working in quality divisions in health systems or clinical operations.

TRACK DIRECTOR: Randy Hatton, Pharm.D.

PHARMACEUTICAL REGULATION

The curriculum in the pharmaceutical regulation track is designed to give students a firm grounding in the regulatory framework around the manufacturing, distribution, dispensing and use of pharmaceutical products, and to place pharmaceuticals in a large context of health care.

TRACK DIRECTOR: W. Thomas Smith, Pharm.D., J.D.

FAST FACTS FOR 2020



78

newly matriculated students



138

students taking courses



38

certificates awarded



28

faculty taught courses



40

M.S. graduates



INTRODUCING THE CENTER FOR DRUG EVALUATION AND SAFETY

Established in 2019, the University of Florida Center for Drug Evaluation and Safety, or CoDES, aims to improve public health by enhancing and disseminating evidence on the safety and value of medications in real-world populations. CoDES unites a multidisciplinary group of big data researchers in epidemiology, health economics, health services research and decision-sciences who evaluate and project drug outcomes to guide policy and clinical and personal decision-making. In addition to delivering new actionable evidence, CoDES fosters the development of new methods and analytic tools to enhance drug evaluation and regulatory science.

FOCUS

CoDES develops and integrates resources on the assessment and improvement of drug use locally, nationally and internationally through five distinct research programs:

- **PHASE IV STUDIES** evaluate drug safety and effectiveness in real-world populations to enhance pre-approval evidence.
- **PHARMACOECONOMIC STUDIES** assess the value of drugs and related programs to guide investment of personal, payer and societal resources.
- **MEDICATION USE QUALITY STUDIES** evaluate the quality and determinants of medication use to direct the allocation of programmatic resources and policy.
- **PHARMACEUTICAL PREDICTIVE ANALYTICS STUDIES** develop predictive tools for drug response and adverse events to support clinical care and related policy.
- **PHARMACEUTICAL POLICY STUDIES** evaluate policy surrounding medication use to enhance programmatic efforts aimed to improve access and quality of drug therapy.



CODES FEATURES

Activities at CoDES aim to build a foundation for real-world data research.

- **BIG DATA INFRASTRUCTURE** — CoDES has access to health care records for more than 300 million lives.
- **BIG DRUG DATA ANALYTICAL SUPPORT** — CoDES provides expertise in the measurement of drug exposure and outcomes/phenotypes, causal inference and predictive design and analysis.
- **RESEARCH EXCHANGE** — CoDES maintains an email listserv, website, Twitter account and seminar series.
- **POSTDOCTORAL FELLOWSHIP PROGRAM** — CoDES has introduced a postdoctoral fellowship program that capitalizes on the interdisciplinary nature of its researchers, with the goal of training the next generation of researchers.



FOLLOW CoDES ON TWITTER

@UFCODES



CoDES RESEARCH TEAM

PATRICK ANTONELLI, M.D.

Department of Otolaryngology,
College of Medicine

JOSHUA BROWN, PHARM.D., PH.D., M.S.

Department of Pharmaceutical Outcomes &
Policy, College of Pharmacy

BABETTE BRUMBACK, PH.D., M.A.

Department of Biostatistics, College of Public
Health and Health Professions

REGINA BUSSING, M.D., M.S.

Department of Psychiatry, College of Medicine

LARISA CAVALLARI, PHARM.D., BCPS, FCCP

Department of Pharmacotherapy and
Translational Research, College of Pharmacy

KARAM DIABY, PH.D., M.SC.

Department of Pharmaceutical Outcomes &
Policy, College of Pharmacy

ROGER FILLINGIM, PH.D.

Department of Community Dentistry,
College of Dentistry

AMIE J. GOODIN, PH.D., M.P.P.

Department of Pharmaceutical Outcomes &
Policy, College of Pharmacy

JUAN HINCAPIE-CASTILLO,

PHARM.D., M.S., PH.D.

Department of Pharmaceutical Outcomes &
Policy, College of Pharmacy

JENNY LO-CIGANIC, PH.D., M.S.,

M.S. PHARM.

Department of Pharmaceutical Outcomes &
Policy, College of Pharmacy

TODD MANINI, PH.D.

Department of Aging & Geriatric Research,
College of Medicine

HAESUK PARK, PH.D.

Department of Pharmaceutical Outcomes &
Policy, College of Pharmacy

SONJA RASMUSSEN, M.D., M.S.

Department of Pediatrics & Epidemiology,
College of Medicine and College of Public Health
and Health Professions

STEPHAN SCHMIDT, PH.D., F.C.P.

Department of Pharmaceutics,
College of Pharmacy

RICHARD SEGAL, R.PH., PH.D., M.S.

Department of Pharmaceutical Outcomes &
Policy, College of Pharmacy

HUI SHAO, PH.D., M.H.A., MBBS

Department of Pharmaceutical Outcomes &
Policy, College of Pharmacy

STEVE SMITH, PHARM.D., M.P.H.

Department of Pharmacotherapy and
Translational Research, College of Pharmacy

PATRICK TIGHE, M.D., M.S.

Department of Anesthesiology,
College of Medicine

SCOTT MARTIN VOURI, PHARM.D.,

PH.D., BCGP

Department of Pharmaceutical Outcomes &
Policy, College of Pharmacy

JENNY WEI, PH.D., M.S.

Department of Pharmaceutical Outcomes &
Policy, College of Pharmacy






POP'S NEW HOME

With groundbreaking planned for December 2020, here are some first images of the New Data Science and Informatics Institute, which will become the new home for POP and CoDES.





WE TRANSLATE BIG DATA INTO EVEN BIGGER, HEALTHIER and SAFER OUTCOMES

It's no secret drugs can do amazing, positive things for your health. But real-life medical miracles can turn into health threats. Many drugs have raised serious safety concerns after FDA approval, often because they were tested on only small samples or patients different than you.

At the University of Florida College of Pharmacy, we are working hard to gather and translate literally millions of real-life results into effective knowledge that can catch harmful side effects before they hurt you or your family. For us, this isn't just a numbers game. It's an opportunity to combine comprehensive data and proven expertise into a whole new way for pharmacists to improve and save patients' lives.

To learn more about how you can invest in our efforts to make drugs safer for you and your loved ones, please contact Elizabeth Zipper at 352.273.6605 or ezipper@cop.ufl.edu



Department of Pharmaceutical
Outcomes & Policy
UNIVERSITY of FLORIDA