Our mission is to:

- Provide an intellectual home for pharmacoepidemiology at Penn
- Promote the conduct of applied and methodologic pharmacoepidemiology research
- Foster training of the next generation of pharmacoepidemiologists
- Expand number of Penn faculty members performing pharmacoepidemiology research

Selected Accomplishments Academic Year 2015-2016

Nudged FDA to required labeling changes for metformin

- On April 8, 2016 the FDA announced that it is requiring labeling changes for metformin-containing medicines to expand metformin’s use in patients with mild-moderate renal insufficiency. These changes were implemented in response to two Citizens’ Petitions submitted to FDA, one of which was written by James Flory, MD, MSCE, Assistant Professor of Healthcare Policy and Research at Will Cornell Medical College and CPeRT Adjunct Scholar, Sean Hennessy, PharmD, PhD, and colleagues. The new label will permit use of metformin in patients with mild-moderate renal insufficiency, and now defines renal insufficiency based on estimated glomerular filtration rate (eGFR) rather than serum creatinine. Further, it restricts the need to temporarily discontinue metformin in patients receiving iodinated contrast media to those whose eGFR is ≤60 mL/min/1.73m². These changes have the potential to improve the care of more than one million individuals with type-2 diabetes who are currently not receiving metformin because of mild-moderate renal insufficiency (Flory JH, Hennessy S. Metformin use reduction in mild to moderate renal impairment: possible inappropriate curbing of use based on Food and Drug Administration contraindications. JAMA internal medicine. 2015 Mar 1;175(3):458-9.).

Members’ Awards

- CPeRT Investigator Charles E. Leonard PharmD, MSCE and colleagues received the Drug Therapy Research Award from the American Society of Healthsystem Pharmacists Foundation for their study entitled “Empiric Potassium Supplementation and Increased Survival in Users of Loop Diuretics”
- CPeRT Investigator Vincent Lo Re, MD, MSCE was elected to a 3-year term on the Board of Directors of the International Society for Pharmacoepidemiology
- CPeRT Adjunct Investigator Brain L. Strom, MD, MPH for received the Oscar B. Hunter Career Award in Therapeutics from the American Society for Clinical Pharmacology and Therapeutics (ASCPT)
• CPeRT Director Sean Hennessy, PharmD, PhD was elected to the National Academy of Medicine. He is one of 70 regular members and 10 international members elected at NAM's annual meeting.

Pharmacoepidemiology Publications in journals with an Impact Factor >10
*listed in order of impact factor

• Lewis JD, Chen EZ, Baldassano RN, Otley AR, Griffiths AM, Lee D, Bittinger K, Bailey A, Friedman ES, Hoffmann C, Albenberg L, Sinha R, Compher C, Gilroy E, Nessel L, Grant A, Chehoud C, Li H, Wu GD, Bushman FD. Inflammation, Antibiotics, and Diet as Environmental Stressors of the Gut Microbiome in


**Education and Training**

- Welcomed Darcy Ellis, MPH as a new epidemiology PhD student focusing on pharmacoepidemiology. Darcy joins Meijia Zhou, MHS and Todd Miano, PharmD, MSCE as pharmacoepidemiology-focused epidemiology PhD students.
- Welcomed Megan Noe, MD as a new pharmacoepidemiology fellow and Master of Science in Clinical Epidemiology (MSCE) trainee supported by Penn’s Clinical Pharmacoepidemiology Training Program (T32GM075766).
- Said farewell to Matthew Bassagia, DO, Rana Hamdy, MD, MPH, and Nathan Parker, MD as pharmacoepidemiology fellows and MSCE trainees supported by Penn’s Clinical Pharmacoepidemiology Training Program (T32GM075766).
- Recognized the following current or former CPeRT Investigators-in-Training for graduating from the MSCE program: Katrina Abuabara, MD, Dana Byrne, MD, Zelma Chiesa-Fuxench, MD, Jordana Cohen, MD, Jori Fleisher, MD, Todd Miano, PharmD, Junko Takeshita, MD, PhD, Alysha Taxter, MD, Brian VanderBeek, MD, and Jennifer Wilkes, MD.
- Continued to support Ashkan Ertefaie, PhD as a CPeRT-supported postdoctoral fellow in Causal Inference in Pharmacoepidemiology.
- Responded to Solicitation FDA-16-223-SOL-00010 entitled Instructor Led Training on Pharmacoepidemiology.
- Submitted application for a predoctoral T32 grant entitled Training in the Health Effects of Medications in the Elderly (THEME).
- Continued to lead the Pharmacoepidemiology Concentration of Master of Science in Clinical Epidemiology (MSCE) program, the most highly-subscribed of the CCEB’s MSCE concentrations.
- Hosted annual meeting of the External Advisory Committee of the Clinical Pharmacoepidemiology Training Program, which is supported by T32GM075766.
- Continued to receive institutional support for pharmacoepidemiology training programs from Pfizer Inc and Sanofi US.
New and ongoing individual fellowship and career development awards by CPeRT members (not an exhaustive list of Penn pharmacoepidemiology awards)

- K23EY025729 Patient Centered Care for Diabetic Macular Edema Sep 2015-Aug 2016 (VanderBeek) (new award).
- F32HL124914 Comparative Effectiveness of Enoxaparin vs. Dalteparin for Thromboprophylaxis Sep 2014-Sep 2016 (Miano).
- K08DK095951 Microvascular Disease, Statins, Ace-Inhibitors and Post-Operative SBO Sep 2012-Jul 2017 (Scott).
- K08DK098272 A Population-Based Cohort to Study Outcomes in End-Stage Liver Disease Patients Sep 2013-Jul 2018 (Goldberg).
- 5K23AR063764-03 Identification of Early Psoriatic Arthritis (Ogdie)
- 5IK2CX000955-03 Body composition, bone structure, and joint damage in rheumatoid arthritis (Baker)
- 2016 Innovative Research Grant, Rheumatology Research Foundation, Optimizing Clinical Trial Design in Psoriatic Arthritis (Ogdie) (New Award)

New and Ongoing Extramural Awards Leveraging CPeRT Pilot Grants

- R01 CA206465-01 HIV and Aging Mechanisms for Hepatocellular Cancer (Justice, Lo Re). Enabled in part by CPeRT Pilot Study: Evaluation the risk of liver decompensation associated with current and cumulative use of mitochondrial toxic nucleoside analogues (Lo Re) (new award).
- 5P50CA174523 SPORE in Skin Cancer (Herlyn). Enabled in part by CPeRT Pilot Study: Association of Inherited Variation with Immune Mediated Adverse Events and Response to Ipilimumab (Kanetsky & Nathanson).
- ‘The risk of keratinocyte cancer in user of antihypertensive medications’ Dermatology Foundation-July 1, 2015 to June 30, 2016 (Chiesa-Fuxench) (new award), enabled in part by CPeRT pilot study entitled “Validation of cutaneous squamous cell carcinoma in The Health Improvement Network”.

Support of research infrastructure

- Continued to provide access to and basic support for use of The Health
Improvement Network (THIN) by Penn investigators.

- In collaboration with the Leonard Davis Institute of Health Economics, continued to provide access to and basic support for use of Clinformatics™ Data Mart Database by Penn researchers.

**Seminars**

**CPeRT-sponsored Center for Clinical Epidemiology and Biostatistics (CCEB) Thursday-morning seminars**

- December 1, 2016- TBA (Tannenbaum, UMontreal).
- October 13, 2016- TBA (Gagne, Harvard).
- June 9, 2016, “Results of a National Education Intervention on Extended-Release Opioids” (Coplan, Purdue Pharma/Penn)
- April 28, 2016, “Medication Therapy Weak Spots and the Risk of Falling in the Nursing Home Setting” (Boyce, Pitt).
- January 14, 2016- “Using big data to emulate a target trial when a randomized trial is not available” (Hernan, Harvard).
- September 17, 2015- “Using Biomedical Informatics Approaches to Identify Drug-Drug Interactions with Insulin Secretagogues” (Han, Penn).

**CPeRT Research in Progress Series**

- May 16, 2016, “Towards metformin repurposing: Bridging pharmacoepidemiology and molecular discovery” (Breitenstein, Mayo)
- April 18, 2016, “Trajectories of chemotherapy-related cardiac dysfunction in breast cancer patients” (Finkleman, Penn).
- February 22, 2016, “Propensity Score Methods for Analyzing Observational Data Like Randomized Experiments: Challenges and Solutions for Rare Outcomes and Exposures” (Ross, Penn).
- November 16th, 2015, “Visit adherence for diabetic macular edema patients” (Vanderbeek, Penn).
Pharmacoepidemiology Rounds

- TBA Fall 2016: “Perspectives of an academic pharmacoepidemiologist” (Lo Re, Penn Faculty)
- June 17, 2016- "Using Directed Acyclic Graphs to Understand Confounding and Selection Bias: Part II" (Miano, PhD Student)
- May 20, 2016- "Using Directed Acyclic Graphs to Understand Confounding and Selection Bias" (Miano, PhD Student)
- May 13, 2016- "Who is overriding severe DDI alerts: Understanding the provider profile" (Acton, Post-Bac Student)
- April 29, 2016- "Preoperative timing of biologic therapy and the risk of infection - a study using Medicare claims data” (George, MSCE Student)
- April 15, 2016- Peer-review of manuscript submitted for publication
- April 8, 2016- Peer-review of manuscript submitted for publication
- April 1, 2016- “Pilot Test of the Sentinel Modular Program for Propensity Score Matched Cohort Analyses: Application to Glyburide, Glipizide and Severe Hypoglycemia.”(Part 1) (Zhou, PhD Student)
- February 26, 2016- "Confounding and Missclassification: A case study” (Miano, PhD Student)
- February 19, 2016- "Early refills of inhaled medication and hospitalization for COPD exacerbation” (Parker, MSCE Student)
- January 15th, 2016- “Becoming an Independent Epidemiology Consultant: Legal and Logistic Considerations Before Hanging Your Shingle” (Ming, Adjunct Scholar CCEB and Michael J. Duffy, JD)
- January 8, 2016- "Selection Bias and Non-ignorable Missing Values in IV Analyses” (Ertefaie, Post-Doctoral Student)
- December 18, 2015- "Decoding the NDC: A Primer on the National Drug Code” (Leonard, Penn Faculty)
- December 11, 2016- "Using early refills of inhaled medication to predict COPD exacerbation: early results” (Parker, MSCE Student)
- December 4, 2016- "The Validity of Squamous Cell Carcinoma diagnosis codes for identifying cutaneous squamous cell carcinoma in The Health Improvement Network”(Fuxench, Penn Faculty)
- November 20, 2015- “Cost Comparison on a Phase 3 ALL Trial.” (DiNofia, Penn Faculty)
- November 13, 2015- "Effects of Fibrates on Blood Glucose and HbA1c in T2DM Patients – A study Protocol Using Optum Laboratory Results Data” (Han, Post-Doctoral Student)
- October 9, 2015- "Drug-drug Interactions between NSAIDs and Antiplatelet Agents”(Li, Eli Lilly)
- October 2, 2015- Peer-review of manuscript submitted for publication
- September 11, 2015- "Non-Collapsibility and Confounding” (Ertefaie, Post-Doctoral Student)
- September 18, 2015- “Matching on the disease risk score in comparative effectiveness research of new treatments “(Basiaga, MSCE Student)
- September 9, 2015- “Early refills of inhaled medication in COPD: preliminary data” (Parker, MSCE Student)

Philadelphia Clinical Pharmacology & Pharmacoepidemiology Seminar Group

CPeRT and the Jefferson/CHOP Clinical Pharmacology Training Program initiated a monthly joint fellows conference where current research is presented in an interdisciplinary environment. Fellows field questions from faculty and peers, and are able to hone their presentation skills in a collegial setting.

- May 31, 2016, “Decoding the Unknown: Bioanalysis of Ketamine and Norketamine / Identifying CML Patients in Medicaid using NDC” (Tran, Jefferson Fellow)
- April 26, 2016, “ODC1 Amplification and Polyamine Dependence in Neuroblastoma: Forming a Responder Hypothesis” (Flynn, CHOP Fellow)
- March 28, 2016,"Early Detection of COPD Exacerbations Using Early Refills of Inhaled Medication." (Parker, Penn MSCE Student)
- February 23, 2016, Pilot Test of the Sentinel Modular Program for Propensity Score Matched Cohort Analysis: Application to Glyburide, Glipizide and Severe Hypoglycemia (Zhou, Penn PhD Student)
- February 9, 2016, "Use of Pharmacokinetic Modeling in Clinical Research: Population Pharmacokinetic Modeling of Vancomycin In Extracorporeal Membrane Oxygenation (ECMO) Patients” (Moore, Jefferson Fellow)
- December 15, 2015, "Introduction to Physiologically Based Pharmacokinetic Modeling” (Zane, CHOP Fellow)
- October 27, 2015, “Anti-Tumor Activity and Sensitivity Evaluation of Novel BET Inhibitors in Neuroblastoma and The Pharmacokinetics of Ketamine in Extracorporeal Membrane Oxygenation (ECMO) Patients” (Healy, Jefferson Fellow)
- September 29, 2015, "Investigations of Factors That Effect Tacrolimus Pharmacokinetics After Bone Marrow Transplant" (Miano, Penn PhD Student)

Outreach and external publicity
• Implemented dynamic updates to CPeRT webpage (http://www.med.upenn.edu/cceb/cpert/), regularly adding links to Penn pharmacoepidemiology publications and news items.
• Initiated CPeRT twitter feed (https://twitter.com/PennCPeRT).
• Created LinkedIn group for “Alumni, fellows, faculty and friends’ of CPeRT, which adds CPeRT shield to the linked-in profiles of group members.
• Created google groups for Pharmacoepidemiology Rounds and Penn/Jefferson/CHOP Seminar group.

Plans for Academic Year 2016-17

Recruitment
• Recruit additional outstanding pharmacoepidemiology faculty and trainees.

Education and Training
• Continue to lead Penn pharmacoepidemiology education and training programs.
• Recruit for MSCE and PhD trainees at annual meetings of the International Society for Pharmacoepidemiology, the American Society for Clinical Pharmacology and Therapeutics, the American Society of Health-System Pharmacists, the American College of Clinical Pharmacy, as well as the 2016 Epidemiology Congress of the Americas.
• Implement Penn-FDA certificate program plans, if proposal is funded by FDA.
• Implement Training in the Health Effects of Medications (THEME) predoctoral training program, if proposal is funded by NIA.
• Consider new opportunities for non-degree training.

Support of pilot grants and student projects
• Continue to support pilot projects of meritorious applications.

Support of research infrastructure
• Continued to provide access to and basic support for use of THIN by Penn researchers.
• Together with LDI, continue to provide access to and basic support for Clinformatics™ Data Mart.

Seminars
• Continue CPeRT support of CCEB seminar speakers.
• Continue CPERT Research in Progress series.
• Continue Pharmacoepidemiology Rounds.
• Continue Penn-Jefferson-CHOP Clinical Pharmacology/Pharmacoepidemiology Seminars

Outreach / Social Media Presence
• Continue to develop CPeRT webpage (http://www.med.upenn.edu/cceb/cpert/).
• Continue to grow CPeRT twitter following (https://twitter.com/PennCPeRT).
• Continue to expand Linked-In group membership
• Continue google groups for Rounds class and Penn/Jefferson/CHOP Seminar group.
• Proceed from planning phase to installation of new CPeRT website in parallel with redesign of CCEB website.