

CURRICULUM VITAE

Michele Jonsson Funk, PhD

21 May 2024

PERSONAL

Office Department of Epidemiology
Gillings School of Global Public Health
University of North Carolina at Chapel Hill
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EDUCATION

2003 **Doctor of Philosophy:**
Epidemiology
University of North Carolina, Chapel Hill, NC
Dissertation: Impact of deferred highly active antiretroviral therapy on HIV disease progression and survival
Advisor: James C. Thomas, PhD

2000 **Master of Science in Public Health:**
Epidemiology
University of North Carolina, Chapel Hill, NC
Thesis: Epidemiology of chlamydial and gonococcal infection at a U.S. Army installation
Advisor: William Miller, MD, PhD, MPH

1994 **Bachelor of Arts:**
Psychology
Reed College, Portland, OR
Thesis: Addiction to stress: Opioid mediation of “learned industriousness” as assessed by a titration schedule
Advisor: Dell Rhodes, PhD

PROFESSIONAL EXPERIENCE

Associate Professor with Tenure

2020 – Present Department of Epidemiology
Gillings School of Global Public Health
University of North Carolina at Chapel Hill

Associate Director

2020 – Present Advanced Clinical Study Methods Core
NC Diabetes Research Center
A research center founded by: Duke University (Duke), The University of

North Carolina at Chapel Hill (UNC), Wake Forest School of Medicine (WF),
and North Carolina A&T State University (NC A&T)

Director, Center for Pharmacoepidemiology

Head, Pharmacoepidemiology Program

2018 – Present
Department of Epidemiology
Gillings School of Global Public Health
University of North Carolina at Chapel Hill

Deputy Director

2018 – Present
Epidemiology and Research Design Service
(FKA Comparative Effectiveness Research [CER] Strategic Initiative)
North Carolina Translational and Clinical Sciences (NC TraCS) Institute
Collaborative Partnership between UNC, RTI, and NC A&T State University

Research Associate Professor

2015 – 2021
Department of Epidemiology
Gillings School of Global Public Health
University of North Carolina at Chapel Hill

Research Assistant Professor

2006 – 2015
Department of Epidemiology
Gillings School of Global Public Health
University of North Carolina at Chapel Hill

Director, Methods Core

2004 – 2018
Center for Women’s Health Research
School of Medicine
University of North Carolina at Chapel Hill

Research Instructor

2004 – 2006
Department of Epidemiology
School of Public Health
University of North Carolina at Chapel Hill

Graduate Research Assistant

1999 – 2003
Worldwide Epidemiology
GlaxoSmithKline
Research Triangle Park, NC

Graduate Research Assistant

1998 – 1999
Department of Epidemiology
School of Public Health
University of North Carolina at Chapel Hill

Usability Specialist

1995 – 1998
Rhotech (Microsoft Corporation)
Redmond, WA

HONORS AND MEMBERSHIPS

2023 – Present	Non-FACA Special Government Employee, Center for Drug Evaluation and Research (CDER), Food and Drug Administration
2022	Temporary Member, Oncology Drugs Advisory Committee (ODAC), Food and Drug Administration
2021 – Present	Member, Clinical Advisory Committee, NIH-funded Medical Imaging and Data Resource Center (MIDRC)
2021 – Present	Methods Council, Center for Observational Research (CfOR), Amgen
2021	Nominee, Faculty Award for Excellence in Doctoral Mentoring, The Graduate School, University of North Carolina at Chapel Hill
2020 – 2023	Member, Fellowships and Awards Committee, International Society of Pharmacoepidemiology
2020 – 2022	Invited Member, Steering Committee, Real World Data Working Group, COVID R&D Alliance (cross-industry effort to address the COVID pandemic with 23 participating biopharmaceutical and life science companies)
2020 – Present	Invited Member, Working Group XIII – Real-World Data and Real-World Evidence in Regulatory Decision Making, Council for International Organizations of Medical Sciences (CIOMS)
2018, 2019	Nominee, University Award for the Advancement of Women, University of North Carolina at Chapel Hill
2018 – Present	Director, Center for Pharmacoepidemiology (formerly known as: UNC-GSK Center of Excellence in Pharmacoepidemiology and Public Health), Department of Epidemiology, UNC Gillings School of Global Public Health.
2018 – Present	Fellow, International Society of Pharmacoepidemiology (FISPE)
2018	Article of the Year, “Resolving an apparent paradox in doubly-robust estimators”, American Journal of Epidemiology
2018	Nominee, Harriet Hylton Barr Distinguished Alumni Award, University of North Carolina at Chapel Hill
2017 – Present	Invited Member, Epidemiology & Clinical Advisory Board (ECAB), Observational Pharmaco-Epidemiology Research & Analysis (OPERA), Epididian
2017 – 2020	Elected Member, Board of Directors, Representing Academia Americas, International Society for Pharmacoepidemiology
2016 – Present	Invited Member, Interdisciplinary Advisory Committee (IIAC), Building Interdisciplinary Research Careers in Women’s Health (BIRCWH) Program, University of North Carolina at Chapel Hill
2016 – 2017	Past-Chair, Comparative Effectiveness Research SIG, International Society for Pharmacoepidemiology

2016	Nominee, John E Larsh Jr. Award for Mentorship, Gillings School of Global Public Health, University of North Carolina at Chapel Hill
2015 – 2021	Leader, Pharmacoepidemiology Resource Laboratory, Building Interdisciplinary Research Careers in Women’s Health (BIRCWH) Program, University of North Carolina at Chapel Hill
2015 – 2016	Elected Chair, Comparative Effectiveness Research SIG, International Society for Pharmacoepidemiology
2014, 2015	Best Peer Reviews, Pharmacoepidemiology & Drug Safety
2014 – Present	Member, Education Committee, International Society for Pharmacoepidemiology
2014 – 2015	Chair-Elect, Comparative Effectiveness Research SIG, International Society for Pharmacoepidemiology
2012 – Present	Member, Comparative Effectiveness Research SIG, International Society for Pharmacoepidemiology
2010 – Present	Member, Scientific Program Committee, International Society for Pharmacoepidemiology
2008 – Present	Member, Academic Council, International Society for Pharmacoepidemiology
2005 – Present	Elected Fellow, Cecil G. Sheps Center for Health Services Research, University of North Carolina at Chapel Hill
2004 – Present	Invited Member, Delta Omega, Honorary Public Health Society, Theta Chapter, University of North Carolina at Chapel Hill
2004 – Present	Member, International Society for Pharmacoepidemiology (ISPE)
2004 – 2015, 2020	Member, Society for Epidemiologic Research (SER)
2004 – 2008	Alumni Trustee, Reed College, Portland, Oregon
2004 – 2008	Member, International AIDS Society (IAS)
2002 – 2010	Honorary Research Fellow, HIV division, Medical Research Council Clinical Trials Unit, London, United Kingdom
2000 – 2002	Pre-doctoral fellowship in pharmacoepidemiology, jointly sponsored by GlaxoSmithKline and the Department of Epidemiology, University of North Carolina at Chapel Hill
2000	Young Investigator Award, American Gastroenterological Association
1998 – 1999	Graduate Merit Assistantship, Department of Epidemiology, University of North Carolina at Chapel Hill
1993, 1994	Commendation for Excellence in Scholarship, Reed College
1992, 1993	Amatai M. Brodie Memorial Scholarship, Reed College
1990 – 1994	Plano & Flora S. McCourtney Foundation Scholarship, Reed College

BIBIOGRAPHY AND PRODUCTS OF SCHOLARSHIP

Books & Chapters

2021

Raman S, Lund JL, Landi SN, **Jonsson Funk M**. Chapter 11: Approaches to mitigate bias in the design and analysis of pRCTs. In: Girman CJ and Ritchey ME (eds.), *Pragmatic Randomized Clinical Trials Using Primary Data Collection and Electronic Health Records*. Elsevier (Apr 21, 2021, 19 pages).
<https://doi.org/10.1016/B978-0-12-817663-4.00021-0>

2010

Jonsson Funk M, Westreich D, Wiesen C, Davidian M. Doubly robust estimation of treatment effects. In: Faries D, Leon AC, Haro JM, and Obenchain RL (eds.), *Analysis of Observational Health Care Data Using SAS*. SAS Press, 2010. p.85-104. ISBN-10: 1607642271 | ISBN-13: 978-1607642275.

2008

Dasgupta N§, **Jonsson Funk M**, Brownstein JS. Comparing unintentional opioid poisoning mortality in metropolitan and non-metropolitan counties, United States, 1999-2003. In: Thomas YF, Richardson D, and Cheung I (eds.), *Geography and Drug Addiction*. Springer Science+Business Media B.V. 2008. p.175-192. ISBN-10: 1402085087 | ISBN-13: 978-1402085086.

Refereed Papers / Articles (§ Indicates a Jonsson Funk mentee/student)

Google Scholar Citation Report (8 May 2024): 9029 times cited, h-index: 39, i10-index: 87, i100-index: 19
For all publications see: <https://www.ncbi.nlm.nih.gov/myncbi/michele.jonsson.funk.1/bibliography/public/>

Online ahead of print, in press, and accepted (8)

134. Htoo P, Edwards JK, Gokhale M, Pate V, Buse JB, **Jonsson Funk M**, Stürmer T. Systematic Approach to the Evaluation of Instrumental Variable Assumptions: Applied Example of Glucose-lowering Medications and Risk for Hospitalized Heart Failure in Older Adults. *AJE*. (Accepted 5/7/2024)
133. Hoffman SR, Smith JS, **Jonsson Funk M**, Hudgens MG, Poole C, Nicholson WK, Baird DD, Harmon QE. Combined oral contraceptive utilization and uterine fibroid incidence: a prospective study in a cohort of African-American women. *PLoS ONE*. *In press* (accepted 5/8/2024)
132. Kahkoska AR, Busby-Whitehead J, **Jonsson Funk M**, Pratley RE, Weinstock RS, Young LA, Weinstein JM. Receipt of Diabetes Management Services Among Older Adults with Type 1 and Type 2 Diabetes in the United States Based on Medicare Fee-for-Service Data, 2015 – 2019. Accepted April 28, 2024. *Diabetes Care*.
131. §Latour CD, Delgado M, Su I, Wiener C, Acheampong CO, Poole C, Edwards JK, Quinto K, Stürmer T, Lund JL, Li J, Lopez N, Concato J, **Jonsson Funk M**. (in press). "Use of Sensitivity Analyses to Assess Uncontrolled Confounding from Unmeasured Variables in Observational, Active Comparator Pharmacoeconomic Studies: A Systematic Review." *American Journal of Epidemiology*. (accepted 12/3/2023)

130. ŞIsmail S, **Funk MJ**, Flythe JE. Ondansetron and the Risk of Sudden Cardiac Death among Individuals Receiving Maintenance Hemodialysis. *J Am Soc Nephrol*. 2024 Feb 27. doi: 10.1681/ASN.000000000000336. Epub ahead of print. PMID: 38409683.
129. Wang T, Keil AP, Kim S, Wyss R, Htoo PT, **Funk MJ**, Buse JB, Kosorok MR, Stürmer T. Iterative Causal Forest: A Novel Algorithm for Subgroup Identification. *Am J Epidemiol*. 2023 Nov 7:kwad219. doi: 10.1093/aje/kwad219. Epub ahead of print. PMID: 37943684.
128. Hsu CD, Henderson LM, Jackson BE, Baggett CD, **Jonsson Funk M**, Olshan AF, Gupta P, Barritt AS, Sanoff HK, Wheeler SB, Moon AM, Lund JL. Hepatocellular Carcinoma Surveillance Among Individuals with Cirrhosis: Trends by Payer, Etiology and Calendar Year, from a Statewide, Multi-Payer Dataset, 2010-2018. *Cancer Epidemiol Biomarkers Prev*. 2023 May 10:EPI-22-1358. doi: 10.1158/1055-9965.EPI-22-1358. Epub ahead of print. PMID: 37163379.
127. Yang JY, Lund JL, **Funk MJ**, Hudgens MG, Lewis JD, Kappelman MD. Utilization of Treat-to-Target Monitoring Colonoscopy after Treatment Initiation in the US-Based Study of a Prospective Adult Research Cohort with Inflammatory Bowel Disease (SPARC IBD). *Am J Gastroenterol*. 2023 Apr 13. doi: 10.14309/ajg.0000000000002294. Epub ahead of print. PMID: 37053548.

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126. ŞHer QL, Dejene SZ, Ismail S, Wang T, **Jonsson-Funk M**, Pate V, Min JY, Flory J. Validation of an international classification of disease, tenth revision, clinical modification (ICD-10-CM) algorithm in identifying severe hypoglycaemia events for real-world studies. *Diabetes Obes Metab*. 2024 Apr;26(4):1282-1290. doi: 10.1111/dom.15428. Epub 2024 Jan 11. PMID: 38204417.
125. Virkud AV, Chang PP, **Funk MJ**, Kshirsagar AV, Edwards JK, Pate V, Kosorok MR, Gower EW. Comparative Effect of Loop Diuretic Prescription on Mortality and Heart Failure Readmission. *Am J Cardiol*. 2024 Jan 1;210:208-216. doi: 10.1016/j.amjcard.2023.08.162. Epub 2023 Nov 14. PMID: 37972425.

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124. Dawwas GK, Weiss A, Constant BD, Parlett LE, Haynes K, Yang JY, Brensinger C, Wu Q, Pate V, **Jonsson Funk M**, Schaubel DE, Hurtado-Lorenzo A, David Kappelman M, Lewis JD. Development and Validation of Claims-Based Definitions to Identify Incident and Prevalent Inflammatory Bowel Disease in Administrative Healthcare Databases. *Inflamm Bowel Dis*. 2023 Dec 5;29(12):1993-1996. doi: 10.1093/ibd/izad053. PMID: 37043675; PMCID: PMC10697409.
123. Duchesneau ED, Shmuel S, Faurot KR, Park J, Musty A, Pate V, Kinlaw AC, Stürmer T, Yang YC, **Funk MJ**, Lund JL. Translation of a Claims-Based Frailty Index From the International Classification of Diseases, Ninth Revision, Clinical Modification to the Tenth Revision. *Am J Epidemiol*. 2023 Nov 10;192(12):2085-2093. doi: 10.1093/aje/kwad151. PMID: 37431778.
122. Zhang J, Latour CD, Olawore O, Pate V, Friedlander DF, Stürmer T, **Jonsson Funk M**, Jensen BC. Cardiovascular Outcomes of α -Blockers vs 5- α Reductase Inhibitors for Benign Prostatic Hyperplasia.

JAMA Netw Open. 2023 Nov 1;6(11):e2343299. doi: 10.1001/jamanetworkopen.2023.43299. PMID: 37962887; PMCID: PMC10646730.

121. Zimmerman KO, Westreich D, **Funk MJ**, Benjamin DK Jr, Turner D, Stürmer T. Comparative Effectiveness of Dual- Versus Mono-Sedative Therapy on Opioid Administration, Sedative Administration, and Sedation Level in Mechanically Ventilated, Critically Ill Children. *J Pediatr Pharmacol Ther.* 2023;28(5):409-416. doi: 10.5863/1551-6776-28.5.409. Epub 2023 Oct 3. PMID: 38130497; PMCID: PMC10731925.
120. Lewis JD, Parlett LE, **Jonsson Funk ML**, Brensinger C, Pate V, Wu Q, Dawwas GK, Weiss A, Constant BD, McCauley M, Haynes K, Yang JY, Schaubel DE, Hurtado-Lorenzo A, Kappelman MD. Incidence, Prevalence, and Racial and Ethnic Distribution of Inflammatory Bowel Disease in the United States. *Gastroenterology.* 2023 Nov;165(5):1197-1205.e2. doi: 10.1053/j.gastro.2023.07.003. Epub 2023 Jul 20. PMID: 37481117; PMCID: PMC10592313.
119. Brannock MD, Chew RF, Preiss AJ, Hadley EC, Redfield S, McMurry JA, Leese PJ, Girvin AT, Crosskey M, Zhou AG, Moffitt RA, **Funk MJ**, Pfaff ER, Haendel MA, Chute CG; N3C; RECOVER Consortia. Long COVID risk and pre-COVID vaccination in an EHR-based cohort study from the RECOVER program. *Nat Commun.* 2023 May 22;14(1):2914. doi: 10.1038/s41467-023-38388-7. PMID: 37217471; PMCID: PMC10201472.
118. D'Arcy ME, Stürmer T, Sandler RS, Baron JA, **Jonsson-Funk ML**, Troester MA, Lund JL. Healthcare system engagement and algorithm-identified cancer incidence following initiation of a new medication. *Pharmacoepidemiol Drug Saf.* 2023 Mar;32(3):321-329. doi: 10.1002/pds.5556. Epub 2022 Nov 30. PMID: 36394182; PMCID: PMC9931672.
117. Sidky H, Young JC, Girvin AT, Lee E, Shao YR, Hotaling N, Michael S, Wilkins KJ, Setoguchi S, **Funk MJ**; N3C Consortium. Data quality considerations for evaluating COVID-19 treatments using real world data: learnings from the National COVID Cohort Collaborative (N3C). *BMC Med Res Methodol.* 2023 Feb 17;23(1):46. doi: 10.1186/s12874-023-01839-2. PMID: 36800930; PMCID: PMC9936475.

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116. § Ross RK, Su IH, Webster-Clark M, **Jonsson Funk M**. Nondifferential Treatment Misclassification Biases Toward the Null? Not a Safe Bet for Active Comparator Studies. *Am J Epidemiol.* 2022 Oct 20;191(11):1917-1925. doi: 10.1093/aje/kwac131. PMID: 35882378.
115. § Young JC, Dasgupta N, Stürmer T, Pate V, **Jonsson Funk M**. Considerations for observational study design: Comparing the evidence of opioid use between electronic health records and insurance claims. *Pharmacoepidemiol Drug Saf.* 2022 Aug;31(8):913-920. doi: 10.1002/pds.5452. Epub 2022 May 23. PMID: 35560685; PMCID: PMC9271595. **Ronald D. Mann Best Paper Award, Honorable Mention 2022**
114. Stuebe AM, Tucker C, Ferrari RM, McClain E, **Jonsson-Funk M**, Pate V, Bryant K, Charles N, Verbiest S. Perinatal morbidity and health utilization among mothers of medically fragile infants. *J Perinatol.* 2021 Aug 10. doi: 10.1038/s41372-021-01171-x. Epub ahead of print. PMID: 34376790.

113. Chun DS, Hicks B, Hinton SP, **Funk MJ**, Gooden K, Keil AP, Tan HJ, Stürmer T, Lund JL. Comparison of Approaches for Measuring Adherence and Persistence to Oral Oncologic Therapies in Patients Diagnosed with Metastatic Renal Cell Carcinoma. *Cancer Epidemiol Biomarkers Prev.* 2022 Apr 1;31(4):893-899. doi: 10.1158/1055-9965.EPI-21-0341. PMID: 35064061.
112. Duchesneau ED, Kinlaw AC, **Jonsson Funk M**, Pate V, Lund JL. Trends in the use of disease-modifying therapies among reproductive-aged women with multiple sclerosis in the United States from 2010 to 2019. *Pharmacoepidemiol Drug Saf.* 2022 Apr;31(4):481-487. doi: 10.1002/pds.5411. Epub 2022 Feb 7. PMID: 35088492. **Top 10 most-cited papers for 2021-2022 in PDS**
111. § Dejene SZ, **Funk MJ**, Pate V, Wu JM. Long-Term Outcomes After Midurethral Mesh Sling Surgery for Stress Urinary Incontinence. *Female Pelvic Med Reconstr Surg.* 2022 Apr 1;28(4):188-193. doi: 10.1097/SPV.0000000000001094. Epub 2021 Sep 30. PMID: 34608036; PMCID: PMC9169553.
110. Page JH, Londhe AA, Brooks C, Zhang J, Sprafka JM, Bennett C, Braunlin M, Brown CA, Charuworn P, Cheng A, Gill K, He F, Ma J, Petersen J, Ayodele O, Bao Y, Carlson KB, Chang SC, Devercelli G, **Jonsson-Funk M**, Jiang J, Keenan HA, Ren K, Roehl KA, Sanders L, Wang L, Wei Z, Xia Q, Yu P, Zhou L, Zhu J, Gondek K, Critchlow CW, Bradbury BD. Trends in characteristics and outcomes among US adults hospitalised with COVID-19 throughout 2020: an observational cohort study. *BMJ Open.* 2022 Feb 28;12(2):e055137. doi: 10.1136/bmjopen-2021-055137. PMID: 35228287; PMCID: PMC8886119.
109. § Young JC, Dasgupta N, Chidgey BA, Stürmer T, Pate V, Hudgens M, **Jonsson Funk M**. Impacts of Initial Prescription Length and Prescribing Limits on Risk of Prolonged Postsurgical Opioid Use. *Med Care.* 2022 Jan 1;60(1):75-82. doi: 10.1097/MLR.0000000000001663. PMID: 34812786.

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108. Ayodele O, Ren K, Zhao J, Signorovitch J, **Jonsson Funk M**, Zhu J, Bao Y, Gondek K, Keenan H; R&D COVID Alliance. Real-world treatment patterns and clinical outcomes for inpatients with COVID-19 in the US from September 2020 to February 2021. *PLoS One.* 2021 Dec 28;16(12):e0261707. doi: 10.1371/journal.pone.0261707. PMID: 34962924; PMCID: PMC8714107.
107. § Young JC, Dasgupta N, Chidgey BA, Stürmer T, Pate V, Hudgens M, **Jonsson Funk M**. Day-of-Surgery Gabapentinoids and Prolonged Opioid Use: A Retrospective Cohort Study of Medicare Patients Using Electronic Health Records. *Anesth Analg.* 2021 Nov 1;133(5):1119-1128. doi: 10.1213/ANE.0000000000005656. PMID: 34260433; PMCID: PMC8542643.
106. Zhu J, Wei Z, Suryavanshi M, Chen X, Xia Q, Jiang J, Ayodele O, Bradbury BD, Brooks C, Brown CA, Cheng A, Critchlow CW, Devercelli G, Gandhi V, Gondek K, Londhe AA, Ma J, **Jonsson-Funk M**, Keenan HA, Manne S, Ren K, Sanders L, Yu P, Zhang J, Zhou L, Bao Y. Characteristics and outcomes of hospitalised adults with COVID-19 in a Global Health Research Network: a cohort study. *BMJ Open.* 2021 Aug 6;11(8):e051588. doi: 10.1136/bmjopen-2021-051588. PMID: 34362806; PMCID: PMC8350974.

105. Ross RK, Kinlaw AC, Herzog MM, **Jonsson Funk M**, Gerber JS. Fluoroquinolone Antibiotics and Tendon Injury in Adolescents. *Pediatrics*. 2021 Jun;147(6):e2020033316. doi: 10.1542/peds.2020-033316. Epub 2021 May 14. PMID: 33990459; PMCID: PMC8168605.
104. § Conover MM, Rothman KJ, Stürmer T, Ellis AR, Poole C, **Jonsson Funk M**. Propensity score trimming mitigates bias due to covariate measurement error in inverse probability of treatment weighted analyses: A plasmode simulation. *Stat Med*. 2021 Apr;40(9):2101-2112. doi: 10.1002/sim.8887. Epub 2021 Feb 23. PMID: 33622016.
103. § Young JC, Dasgupta N, Chidgey BA, **Jonsson Funk M**. Postsurgical Opioid Prescriptions and Risk of Long-term Use: An Observational Cohort Study Across the United States. *Ann Surg*. 2021 Apr 1;273(4):743-750. doi: 10.1097/SLA.0000000000003549. PMID: 31404007; PMCID: PMC7440649.
102. § Suarez EA, Boggess K, Engel SM, Stürmer T, Lund JL, **Funk MJ**. Ondansetron use in early pregnancy and the risk of late pregnancy outcomes. *Pharmacoepidemiol Drug Saf*. 2021 Feb;30(2):114-125. doi: 10.1002/pds.5151. Epub 2020 Nov 9. PMID: 33067868.
101. § Suarez EA, Boggess K, Engel SM, Stürmer T, Lund JL, **Jonsson Funk M**. Ondansetron use in early pregnancy and the risk of miscarriage. *Pharmacoepidemiol Drug Saf*. 2021 Feb;30(2):103-113. doi: 10.1002/pds.5143. Epub 2020 Oct 12. PMID: 33000871.

2020 (11)

100. Ross RK, Kuo TM, Webster-Clark M, Lewis CL, Kistler CE, **Jonsson Funk M**, Lund JL. Validation of a 5-year mortality prediction model among US Medicare beneficiaries. *J Am Geriatr Soc*. 2020 Dec;68(12):2898-2902. doi: 10.1111/jgs.16816. Epub 2020 Sep 5. PMID: 32889756
99. Willis-Gray MG, Young JC, Pate V, **Jonsson Funk M**, Wu JM. Perioperative opioid prescriptions associated with stress incontinence and pelvic organ prolapse surgery. *Am J Obstet Gynecol*. 2020 Dec;223(6):894.e1-894.e9. doi: 10.1016/j.ajog.2020.07.004. Epub 2020 Jul 9. PMID: 32653459
98. Webster-Clark M, **Jonsson Funk M**, Stürmer T. Single-Arm Trials with External Comparators and Confounder Misclassification: How Adjustment Can Fail. *Med Care*. 2020 Dec;58(12):1116-1121. doi: 10.1097/MLR.0000000000001400. PMID: 32925456.
97. Venkatesh KK, Pate V, Boggess KA, Jones HE, **Funk MJ**, Smid MC. Trends in Opioid and Psychotropic Prescription in Pregnancy in the United States From 2001 to 2015 in a Privately Insured Population : A Cross-sectional Study. *Ann Intern Med*. 2020 Dec 1;173(11_Supplement):S19-S28. doi: 10.7326/M19-3249. PMID: 33253018.
96. Hoffman SR, Nicholson WK, Smith JS, **Jonsson Funk M**, Hudgens MG, Poole C, Baird DD, Harmon QE. Reasons for Hormonal Contraceptive Use in a Cohort of African-American Women Living in the Detroit Area. *Contraception*. 2020 Nov;102(5):346-348. doi: 10.1016/j.contraception.2020.07.093. Epub 2020 Aug 6. PMID: 32768397
95. Webster-Clark M, Baron JA, **Jonsson Funk M**, Westreich D. How Subgroup Analyses Can Miss the Trees for the Forest Plots: A Simulation Study. *J Clin Epidemiol*. 2020 Oct;126:65-70. doi: 10.1016/j.jclinepi.2020.06.020. Epub 2020 Jun 19. PMID: 32565216

94. Kinsey TL, Stürmer T, **Funk MJ**, Poole C, Simpson RJ, Glynn RJ. Incidence of venous thromboembolism following initiation of non-steroidal anti-inflammatory drugs in U.S. women. *Rheumatology (Oxford)*. 2020 Sep 1;59(9):2502-2511. doi: 10.1093/rheumatology/kez653. PMID: 31990357
93. § Young JC, **Jonsson Funk M**, Dasgupta N. Medical Use of Long-term Extended-release Opioid Analgesics in Commercially Insured Adults in the United States. *Pain Med*. 2020 Apr 1;21(4):724-735. doi: 10.1093/pm/pnz155. PMID: 31340004
92. Rivera DR, Gokhale MN, Reynolds MW, Andrews EB, Chun D, Haynes K, **Jonsson-Funk ML**, Lynch KE, Lund JL, Strongman H, Bhullar H, Raman SR. Linking Electronic Health Data in Pharmacoepidemiology: Appropriateness and Feasibility. *Pharmacoepidemiol Drug Saf*. 2020 Jan;29(1):18-29. doi: 10.1002/pds.4918. PMID: 31950565
91. § Young JC, Wu JM, Willis-Gray M, Pate V, **Jonsson Funk M**. Persistent opioid use after hysterectomy in the United States, 2005-2015. *Obstet Gynecol*. 2020 Jan;135(1):123-132. doi: 10.1097/AOG.0000000000003612. PMID: 31809429
90. Stürmer T, Wang T, Golightly YM, Keil A, Lund JL, **Jonsson Funk M**. Methodological Considerations When Analyzing and Interpreting Real-World Data. *Rheumatology (Oxford)*. 2020 Jan 1;59(1):14-25. doi: 10.1093/rheumatology/kez320. PMID: 31834408

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89. § Landi SN, Radke S, Boggess K, Engel SM, Stürmer T, Howe AS, **Jonsson Funk M**. Comparative effectiveness of metformin versus insulin for gestational diabetes in New Zealand. *Pharmacoepidemiology and Drug Safety*, 2019 Dec;28(12):1609-1619. doi: 10.1002/pds.4907. . Epub 2019 Nov 6. PMID: 31693269
88. Htoo PT, Simpson RJ, Stürmer T, **Jonsson Funk M**, Pate V, Lund JL. Renin-Angiotensin-Aldosterone System-Based Antihypertensive Agents and the Risk of Colorectal Cancer Among Medicare Beneficiaries. *Epidemiology* 2019 Nov;30(6):867-875. doi: 10.1097/EDE.0000000000001065. PMID: 31348009
87. Mayer SE, Tan HJ, Peacock Hinton S, Sanoff HK, Stürmer T, Hester LL, Faurot KR, **Jonsson Funk M**, Lund JL. Comparison of Medicare claims-based proxy measures of poor function and associations with treatment receipt and mortality in older colon cancer patients. *Med Care*. 2019 Apr;57(4):286-294. doi: 10.1097/MLR.0000000000001073. PMID: 30789540
86. § Landi SN, Radke S, Engel SM, Boggess K, Stürmer T, Howe AS, **Funk MJ**. Association of Long-term Child Growth and Developmental Outcomes With Metformin vs Insulin Treatment for Gestational Diabetes. *JAMA Pediatr*. 2019 Feb 1;173(2):160-168. doi: 10.1001/jamapediatrics.2018.4214. PMID: 30508164
85. Hong JL, Webster-Clark M, **Jonsson Funk M**, Stürmer T, Dempster SE, Cole SR, Herr I, LoCasale R. Comparison of Methods to Generalize Randomized Clinical Trial Results without Individual-Level Data for the Target Population. *Am J Epidemiol*. 2019 Feb 1;188(2):426-437. doi: 10.1093/aje/kwy233. PMID: 30312378

84. § Young JC, Lund JL, Dasgupta N, **Jonsson Funk M**. Opioid Tolerance and Clinically Recognized Opioid Poisoning among Patients Prescribed Extended-Release Long-Acting Opioids. *Pharmacoepidemiol Drug Saf*. 2019 Jan;28(1):39-47. doi: 10.1002/pds.4572. Epub 2018 Jun 11. PMID: 29888409

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27. Webster-Clark M, **Jonsson Funk M**, Lund JL, Glynn R, Stürmer T, Kinlaw A. Evaluating when effect estimates change after propensity score trimming because of differing effect measure modifier distributions. *Pharmacoepidemiology Drug Safety*. 2021; **30**(S1):71. [https://doi.org/ 10.1002/pds.5305](https://doi.org/10.1002/pds.5305) [Abstract]
 26. Shmuel S, Pate V, Naumann RB, Hanson LC, **Jonsson Funk M**, Lund JL. Longitudinal patterns of anticholinergic and sedative drug load among older adults. *Pharmacoepidemiology Drug Safety*. 2021; **30**(S1):266. [https://doi.org/ 10.1002/pds.5305](https://doi.org/10.1002/pds.5305) [Abstract]
 25. Park J, Dejene S, Mayer SE, Kinlaw A, Nichols HB, **Jonsson-Funk M**, Pate V, Park EM, Reeder-Hayes KE, Lund JL. Antidepressant dispensing among women with breast cancer, United States, 2001-2018. *Pharmacoepidemiology Drug Safety*. 2020; **29**(S3):29. <https://doi.org/10.1002/pds.5114> [Abstract]
 24. Chun D, Hicks B, Peacock-Hinton S, Tan HJ, **Jonsson-Funk M**, Keil A, Stürmer T, Lund J. Methodologic considerations for evaluating adherence to oral oncologic therapy in a high mortality population. *Pharmacoepidemiology Drug Safety*. 2020; **29**(S3):32. <https://doi.org/10.1002/pds.5114> [Abstract]
 23. § Young JC, Dasgupta N, Pate B, Stürmer T, Chidgey BA, **Jonsson Funk M**. Estimating the impact of prescribing limits on prolonged opioid use following surgery. *Pharmacoepidemiology Drug Safety*. 2020; **29**(S3):155. <https://doi.org/10.1002/pds.5114> [Abstract]
 22. Duchesneau EM, **Jonsson Funk M**, Kinlaw AC, Lund JL. Trends in the use of disease-modifying therapies among reproductive-aged women with multiple sclerosis in the United States 2001-2017. *Pharmacoepidemiology Drug Safety*. 2020; **29**(S3):237. <https://doi.org/10.1002/pds.5114> [Abstract]
 21. Dejene S, Park J, Mayer SE, Kinlaw A, Nichols HB, **Jonsson-Funk M**, Pate V, Park EM, Reeder-Hayes KE, Lund JL. Antidepressant use and adherence among breast cancer patients using tamoxifen. *Pharmacoepidemiology Drug Safety*. 2020; **29**(S3):268. <https://doi.org/10.1002/pds.5114> [Abstract]
 20. Wang T, Keil AP, Pate V, **Jonsson Funk M**, Kosorok MR, Buse JB. Using machine learning to identify heterogeneous treatment effects: DPP-4i versus sulfonylurea on cardiovascular outcomes in US Medicare. *Pharmacoepidemiology Drug Safety*. 2020; **29**(S3):332. <https://doi.org/10.1002/pds.5114> [Abstract]
 19. Delgado M, Dard S, **Jonsson Funk M**, Carey T. Explaining the inexplicable: Irregularities in electronic health record derived data. *Pharmacoepidemiology Drug Safety*. 2020; **29**(S3):335. <https://doi.org/10.1002/pds.5114> [Abstract]
 18. Stürmer T, **Jonsson Funk M**, Klungel O, Bollaerts K. Use of external data in pharmacoepidemiology. *Pharmacoepidemiology Drug Safety*. 2020; **29**(S3):366. <https://doi.org/10.1002/pds.5114> [Abstract]
 17. Rao S, Kshirsager AV, Brookhart MA, Keil A, Loehr L, **Jonsson Funk M**, Poole C. Development and validation of a prediction model for 1-year risk of thromboembolism in hemodialysis patients with atrial fibrillation. *Pharmacoepidemiology Drug Safety*. 2020; **29**(S3):370. <https://doi.org/10.1002/pds.5114> [Abstract]

16. § Latour C, Poole C, Edwards J, Stürmer T, Martin D, Lund JL, Lopez N, **Jonsson Funk M**. Use of sensitivity analyses to assess uncontrolled confounding in observational, head-to-head pharmacoepidemiologic studies: A systematic review. *Pharmacoepidemiology Drug Safety*. 2020; **29**(S3):380. <https://doi.org/10.1002/pds.5114> [Abstract]
15. § Young JC, Dasgupta N, Pate V, Stürmer T, Chidgey BA, **Jonsson Funk M**. Electronic medical records vs insurance claims: Comparing the magnitude of opioid use prior, during, and following surgery. *Pharmacoepidemiology Drug Safety*. 2020; **29**(S3):393. <https://doi.org/10.1002/pds.5114> [Abstract]
14. Ross RK, Gerber JS, Herzog MM, **Jonsson-Funk M**, Kinlaw AC. Fluoroquinolone antibiotic exposure and risk of achilles tendon injury in adolescents in the United States 2000-2018. *Pharmacoepidemiology Drug Safety*. 2020; **29**(S3):447. <https://doi.org/10.1002/pds.5114> [Abstract]
13. § Dejene SZ, Stuebe A, Tucker C, Pate V, Bryant K, **Jonsson-Funk M**. Birth control utilization among mothers of infants with an extended stay in the NICU. *Pharmacoepidemiology Drug Safety*. 2020; **29**(S3):551. <https://doi.org/10.1002/pds.5114> [Abstract]
12. Hoffman SR, Smith JS, **Jonsson Funk M**, Hudgens MG, Poole C, Nicholson WK, Baird DD, Harmon QE. Combined oral contraceptive utilization and uterine fibroid incidence in a novel cohort. *Pharmacoepidemiology Drug Safety*. 2020; **29**(S3):597. <https://doi.org/10.1002/pds.5114> [Abstract]
11. § Conover MM, Pate V, **Jonsson Funk M**. Modeling Effect Heterogeneity in the Presence of Heterogeneous Confounding: A Plasmode Simulation. *Pharmacoepidemiology Drug Safety*. 2019; **28**(S2):16. DOI: 10.1002/pds.4864 [Abstract]
10. § Conover MM, Pate V, **Jonsson Funk M**. Residual Confounding and Treatment Effect Heterogeneity: An applied example. *Pharmacoepidemiology Drug Safety*. 2019; **28**(S2):18. DOI: 10.1002/pds.4864 [Abstract]
9. § Young JC, Chidgey BA, Stürmer T, **Jonsson Funk M**. The proportion of patients in the United States receiving postsurgical opioids exceeding recommended thresholds increased between 2006 and 2015. *Pharmacoepidemiology Drug Safety*. 2019; **28**(S2):212. DOI: 10.1002/pds.4864 [Abstract]
8. § Young JC, Pate V, Wu JM, **Jonsson Funk M**. Estimates of prolonged opioid use following surgery vary by orders of magnitude across various definitions. *Pharmacoepidemiology Drug Safety*. 2019; **28**(S2):231. DOI: 10.1002/pds.4864 [Abstract]
7. § Dejene S, Wu JM, Pate V, **Jonsson-Funk M**. Long-term outcomes following mid-urethral mesh sling surgery for stress urinary incontinence. *Pharmacoepidemiology Drug Safety*. 2019; **28**(S2):255. DOI: 10.1002/pds.4864 [Abstract]
6. **Jonsson Funk M**, Conover MM, Pate V. Real-world evidence of statin effectiveness in older adults. *Pharmacoepidemiology Drug Safety*. 2019; **28**(S2):285. DOI: 10.1002/pds.4864 [Abstract]
5. D’Arcy M, Stürmer T, **Jonsson Funk M**. Detection of Prevalent Cancer among New Users without Routine Care. *Pharmacoepidemiology Drug Safety*. 2019; **28**(S2):43. DOI: 10.1002/pds.4864 [Abstract]

4. Kinsey T, Stürmer T, **Jonsson Funk M**, Poole C, Simpson RJ Jr, Glynn RJ. Analytic and design approaches to unmeasured confounding by body mass index. *Pharmacoepidemiology Drug Safety*. 2019; **28**(S2):309. DOI: 10.1002/pds.4864 [Abstract]
3. Wang T, Assimon MM, Pate V, Gower EW, Lund JL, **Jonsson-Funk ML**, Buse JB, Stürmer T. Bias reduction with multiple imputation of lab results from a limited internal sample. *Pharmacoepidemiology Drug Safety*. 2019; **28**(S2):313. DOI: 10.1002/pds.4864 [Abstract]
2. Htoo PT, **Jonsson-Funk M**, Fang G, Pate V, Buse J, Edwards JK, Dasgupta N, Stürmer T. Comparative performance of trend-in-trend design and instrumental variable methods in an active comparator new user setting. *Pharmacoepidemiology Drug Safety*. 2019; **28**(S2):404. DOI: 10.1002/pds.4864 [Abstract]
1. Hsu CD, Peacock Hinton S, Stürmer T, **Jonsson Funk M**, Reeder-Hayes KE, Sanoff HK, Lund JL. Association between concomitant hydrochlorothiazide and cyclophosphamide use, and chemotherapy regimen discontinuation in breast cancer patients. *Pharmacoepidemiology Drug Safety*. 2019; **28**(S2):444. DOI: 10.1002/pds.4864 [Abstract]

Dissertation

1. **Jonsson Funk M**. Impact of deferred highly active antiretroviral therapy on HIV disease progression and survival. PhD Dissertation, Department of Epidemiology, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, USA.

Other Unrefereed Works

Invited Oral Presentations

National

- | | |
|------|---|
| 2023 | Missing, Misclassified, or Mismeasured? Beware bias . Real-World Accelerator to Improve the Standard of collection and curation of race and Ethnicity data in healthcare (RAISE) Workshop 7, Reagan-Udall Foundation for the FDA. April 20, 2023 |
| 2022 | DETECTE: Detailing and Evaluating Tools to Expose Confounded Treatment Effects , DIA Real-World Evidence Conference, November 10-22, San Diego, CA. |
| 2022 | Causal Inference and Real World Evidence , BIO-PhRMA Workshop on Advancing Analytical Methodologies for Unmeasured Confounders in Real World Evidence, October 24, 2022 (virtual). |
| 2022 | Design, Analysis and Evaluation of Confounding Bias Using RWD , DIA Biostatistics Industry and Regulator Forum, April 6-8, 2022 (virtual). |
| 2021 | Real World Evidence: How Big Data is Changing Scientific Standards , National Press Foundation, July 22, 2021. |

- 2021 **Methods Council Session on RCT DUPLICATE**, Invited Panelist, Center for Observational Research, Amgen, May 4, 2021.
- 2021 **Evaluating RWE from Observational Studies in Regulatory Decision-Making: Lessons Learned from Trial Replication Analyses**; Invited Panelist, Virtual public meeting hosted by the Duke-Margolis Center for Health Policy and the U.S. Food & Drug Administration, February 16-17, 2021.
- 2021 **Enhancing the rigor of real-world evidence**, Continuing Education Speaker Series, Global Medical Affairs, Sarepta Therapeutics, March 19, 2021
- 2019 **Tailoring the Strength of Evidence in RWE**, Real World Evidence (RWE) Engagement Meeting, UCB, Atlanta, Georgia, October 1, 2019.
- 2019 **Estimating treatment effects without randomization: Historical controls**, Takeda, Boston MA, January 15, 2019.
- 2019 **Comparison and contrasting common data models**, Real World Evidence (RWE) Practice Team, UCB, Research Triangle Park, NC, September 24, 2019.
- 2019 **Generalizability versus Transportability**, Real World Evidence (RWE) Practice Team, UCB, Research Triangle Park, NC, June 11, 2019.
- 2018 **Role of machine learning in generating Real World Evidence**, UCB, Research Triangle Park, NC, Dec 4, 2018.
- 2018 **Measurement Error and Misclassification in Electronic Medical Records: Methods to Mitigate Bias**. UCB, Research Triangle Park, NC, August 28, 2018
- 2018 **Linking Electronic Health Data in Pharmacoepidemiology: Appropriateness and Feasibility**, UCB, Research Triangle Park, NC, May 22, 2018
- 2017 **Randomized Clinical Trials vs Real World Evidence Studies**, Advanced Real World Evidence, UCB, Research Triangle Park, NC, November 3, 2017.
- 2017 **Sources of Data for Pharmacoepidemiology**, Advanced Real-World Evidence, UCB, Research Triangle Park, NC, November 3, 2017.
- 2017 **Choosing the Right Study Design**, Advanced Real-World Evidence, UCB, Research Triangle Park, NC, November 3, 2017.
- 2017 **Opportunities and Challenges of machine learning approaches**, Center for Pharmacoepidemiology, Methodology Workshop, Collegeville, PA, Oct 13, 2017.
- 2017 **Big(ger) Data: The promise and perils of data linkage**, UNC Chapel Hill Health Informatics Symposium: Using Big Data to Move the Learning Health Systems To Reality. William and Ida Friday Center for Continuing Education, Chapel Hill, NC. April 7, 2017.
- 2016 **Linking UNC's EMR Data with Commercial Claims**. UNC Center for Pharmacoepidemiology Methodology Workshop. Collegeville PA. November 4, 2016.
- 2016 **Evaluating treatment effect heterogeneity in relevant (not relative) effect measures**, Session on Precision Medicine and Causal Inference – Beyond the Average Treatment Effect, Epidemiology Congress of the Americas, Miami, Florida, June 21-24, 2016.
- 2015 **Best practices for incorporating uncertainty about cases: quantitative bias analysis**. International Society for Pharmacoepidemiology, Boston, MA, August 23-26, 2015.

- 2015 **Assessing treatment effect heterogeneity in observational studies**, Advanced Topics in Pharmacoepidemiology, Pre-Conference Educational Session, 31st Annual meeting of the International Society for Pharmacoepidemiology & Public Health, Boston, MA, August 23-26, 2015.
- 2015 **Evaluating treatment effect heterogeneity in comparative effectiveness research**, Center for Health Services Research in Primary Care, Durham Veterans Administration Medical Center, Durham, NC, May 26, 2015.
- 2015 **Treatment effect heterogeneity: Where should we be looking and how?** Triangle Comparative Effectiveness Research Symposium, RTI International, Research Triangle Park, NC, May 14, 2015.
- 2013 **Treatment Effect Heterogeneity**, Training in Epidemiologic Methods • Division of Epidemiology, Center for Devices and Radiologic Health (CDRH), Food & Drug Administration, Bethesda, Maryland, January 24, 2013.
- 2013 **Systematic Reviews and Meta-Analysis**, Training in Epidemiologic Methods • Division of Epidemiology, Center for Devices and Radiologic Health (CDRH), Food & Drug Administration, Bethesda, Maryland, January 24, 2013.
- 2013 **Integrating Study Design and Analytic Strategy**, Training in Epidemiologic Methods • Division of Epidemiology, Center for Devices and Radiologic Health (CDRH), Food & Drug Administration, Bethesda, Maryland, January 25, 2013.
- 2013 **Propensity Score Estimation**, UNC Pharmacoepidemiology Methods Training Workshop • William and Ida Friday Center for Continuing Education, Chapel Hill, NC. May 21-24, 2013.
- 2013 **Data Sources**, UNC Pharmacoepidemiology Methods Training Workshop • William and Ida Friday Center for Continuing Education, Chapel Hill, NC. May 21-24, 2013.
- 2013 **Treatment Effect Heterogeneity**, Training in Epidemiologic Methods • Division of Epidemiology, Center for Devices and Radiologic Health (CDRH), Food & Drug Administration, Bethesda, Maryland. Jan 24-25, 2013.
- 2013 **Systematic Reviews and Meta-Analysis**, Training in Epidemiologic Methods • Division of Epidemiology, Center for Devices and Radiologic Health (CDRH), Food & Drug Administration, Bethesda, Maryland. Jan 24-25, 2013.
- 2013 **Integrating Study Design and Analytic Strategy**, Training in Epidemiologic Methods • Division of Epidemiology, Center for Devices and Radiologic Health (CDRH), Food & Drug Administration, Bethesda, Maryland. Jan 24-25, 2013.
- 2012 **Combining estimators in the pursuit of robustness**, Methodological Advancements Meeting: Innovative Directions in Estimating Impact, Administration for Families & Children (AFC) / Office of Planning, Research & Evaluation (OPRE), US DHHS, Sept 6-7, 2012, Washington, DC.
- 2012 **Doubly Robust Estimation** (Pre-conference workshop), 2012 Agency for Healthcare Research & Quality DEcIDE Methods Symposium: From Efficacy to Effectiveness, June 12, 2012, Rockville, Maryland.
- 2011 **Treatment Effect Heterogeneity**, UNC Pharmacoepidemiology Methods Workshop • The Carolina Club, Chapel Hill, NC. Dec 1-2, 2011.

- 2011 **Doubly Robust Estimation of Treatment Effects**, UNC Pharmacoepidemiology Methods Workshop • The Carolina Club, Chapel Hill, NC. Dec 1-2, 2011.
- 2009 **Doubly robust estimation of treatment effects: Twice as nice or double trouble?** University of Pennsylvania School of Medicine Center for Clinical Epidemiology and Biostatistics, Philadelphia, Pennsylvania, February 26, 2009.
- 2006 **Epidemiology: The Science of Public Health**, Psychology Colloquium, Reed College, Portland, Oregon, February 2, 2006.
- 2004 **Directed Acyclic Graphs: Identifying Sources of Bias with Causal Diagrams**, Oregon Health Sciences University, Portland, Oregon, October 6, 2004.

International

- 2024 **Intermediate Pharmacoepidemiology**. Course developer and Lead Faculty, Pre-Conference Educational Session, 40th Annual Meeting of the International Society for Pharmacoepidemiology & Public Health, Berlin, Germany, August 25, 2024.
- 2024 **Using generative AI to more efficiently conduct systematic reviews, solve coding problems, and communicate research findings: a student-led workshop (Symposium)**. 40th Annual Meeting of the International Society for Pharmacoepidemiology & Public Health, Berlin, Germany, August 26-28, 2024.
- 2024 **Estimating the Effects of Chronic Medications: Questions to Ask and Tools to Help Answer Them (Symposium)**. 40th Annual Meeting of the International Society for Pharmacoepidemiology & Public Health, Berlin, Germany, August 26-28, 2024.
- 2023 **Intermediate Pharmacoepidemiology**. Course developer and Lead Faculty, Pre-Conference Educational Session, 39th Annual Meeting of the International Society for Pharmacoepidemiology & Public Health, Halifax, Nova Scotia, Canada, August 23, 2023.
- 2023 **From Classic to Cutting Edge: Addressing Data Quality Challenges in Electronic Health Record Data (Symposium)**. 39th Annual Meeting of the International Society for Pharmacoepidemiology & Public Health, Halifax, Nova Scotia, Canada, August 26, 2023.
- 2022 **Intermediate Pharmacoepidemiology**. Course developer and Lead Faculty, Pre-Conference Educational Session, 38th Annual Meeting of the International Society for Pharmacoepidemiology & Public Health, Copenhagen Denmark, August 25, 2022.
- 2022 **COVID-19 vaccine effectiveness studies: Considerations of misclassification and confounding**. 38th Annual Meeting of the International Society for Pharmacoepidemiology & Public Health, Copenhagen Denmark, August 26-28, 2022.
- 2021 **Intermediate Pharmacoepidemiology**. Course developer and Lead Faculty, Pre-Conference Educational Session, 37th Annual meeting of the International Society for Pharmacoepidemiology & Public Health, All Access 2021.
- 2021 **Outcome Measurements for External Comparator Arms: New Opportunities for Epidemiology Methods Application and Development**. 37th Annual meeting of the International Society for Pharmacoepidemiology & Public Health, All Access, August 23-25, 2021.

- 2021 **Using Real World Evidence to Improve Public Health.** Canadian Network for Observational Drug Effect Studies (CNODES), June 16, 2021.
- 2020 **Intermediate Pharmacoepidemiology.** Course developer and Lead Faculty, Pre-Conference Educational Session, 36th Annual meeting of the International Society for Pharmacoepidemiology & Public Health, All Access, September 16-17, 2020
- 2020 **Validation studies and data linkages,** Use of External Data in Pharmacoepidemiology, International Society of Pharmacoepidemiology, All Access, September 16-17, 2020
- 2019 **Intermediate Pharmacoepidemiology.** Course developer and Lead Faculty, Pre-Conference Educational Session, 35th Annual meeting of the International Society for Pharmacoepidemiology & Public Health, Philadelphia, USA, August 2019.
- 2018 **Intermediate Pharmacoepidemiology.** Course developer and Lead Faculty, Pre-Conference Educational Session, 34th Annual meeting of the International Society for Pharmacoepidemiology & Public Health, Prague, Czech Republic, August 2018.
- 2017 **Intermediate Pharmacoepidemiology.** Course developer and Lead Faculty, Pre-Conference Educational Session, 33rd Annual meeting of the International Society for Pharmacoepidemiology & Public Health, Montreal, Canada, August 2017.
- 2016 **Perspectives from Causal Inference in the Era of Big (Healthcare) Data,** International Society for Pharmacoepidemiology, Dublin, Ireland, August 25-28, 2016.
- 2016 **Exploring innovative methods to conduct validation using United States Medicare administrative claims data,** International Society for Pharmacoepidemiology, Dublin, Ireland, August 25-28, 2016.
- 2014 **Bias Due to Misclassification in Comparative Effectiveness Research,** Pre-Conference Educational Session, 30th Annual meeting of the International Society for Pharmacoepidemiology & Public Health, Taipei, Taiwan, October 24-27, 2014.
- 2014 **Using propensity score methods to study newly marketed drugs/devices.** Pre-Conference Educational Session, 30th Annual meeting of the International Society for Pharmacoepidemiology & Public Health, Taipei, Taiwan, October 24-27, 2014.
- 2013 **Evaluating the Comparative Safety and Effectiveness of Mesh for Pelvic Organ Prolapse: Methodological Considerations,** Medical Device Epidemiology Pre-Conference Educational Session, 29th Annual meeting of the International Society for Pharmacoepidemiology & Public Health, August 24, 2013, Montreal, Canada.
- 2012 **Methodological Considerations: Evaluating the Comparative Safety and Effectiveness of Urogynecologic Surgical Mesh,** Medical Device Epidemiology Pre-Conference Educational Session, 28th Annual meeting of the International Society for Pharmacoepidemiology & Public Health, August 22, 2012, Barcelona, Spain.

TEACHING RECORD

- 2023- **Theory and Quantitative Methods in Epidemiology,** Epid 715, 4cr hrs (Lead faculty)
2024: Enrolled students: n=38
2023: Enrolled students: n=48

- 2023 **Pharmacovigilance**, Epid 799A, 1cr hr (co-lead)
Enrolled Students: n=9 (+1 auditor)
- 2022 **Epidemiologic Research Methods**, Epid 726 (Co-instructor)
Enrolled students: n=38
- 2021 **Pharmacovigilance**, Epid 799A (co-lead)
Enrolled Students: n=12
- 2020 **A Gentle Introduction to Simulation for Epidemiology**, EPID 799A (Lead faculty)
Enrolled Students: n=25, (+25 auditing)
- 2015 **Perspectives in Epidemiology and Public Health**, EPID 890 (Co-Lead)
Enrolled Students: n=6
- 2013-2021 **Methods and Issues in Pharmacoepidemiology**, EPID 765 (Co-Instructor)
Enrolled Students: 2013: n=21, 2015: n=22, 2017: n=24; 2019: n=17; 2021: n=33
- 2011- **Pharmacoepidemiology Seminar**, EPID 893 (Co-Lead)
Spring 2024 n=13
Spring 2023 n=7; Fall 2023 n=16
Spring 2022 n=14; Fall 2022 n=12
Spring 2021 n=19; Fall 2021 n=15
Spring 2020 n=14; Fall 2020 n=18
Spring 2019 n=12; Fall 2019 n=18
- 2006 **Clinical Research Skills**, EPID 206 (Co-Lead)
- 2005 **Clinical Epidemiology Research Methods**, EPID 205 (Co-Lead)
- 2005-2007 **Advanced Epidemiology Methods: Modeling Causal Effects**, EPID 730/369 (Lead instructor and course developer)
- 2005-2010 **Pharmacoepidemiology Journal Club** (Co-instructor)
- 2002 **Epidemiologic Research Methods**, EPID 201 (teaching assistant)
- 2001 **Advanced Methods in Epidemiologic Analysis**, EPID 269 (teaching assistant)

Guest Lectures in UNC Epidemiology Curriculum

- 2021 **Design of Clinical Research**, Epid 804, "Minimizing bias in design of non-interventional studies of devices and medications" Feb 23, 2021.
- 2021 **Epidemiologic Research Using Healthcare Databases**, Epid 766, "Medicare 101", April 15, 2021.
- 2020 **Design of Clinical Research**, Epid 804, "Minimizing bias in design of observational studies of devices and medications" Feb 11, 2020.
- 2019 **Design of Clinical Research**, Epid 804, "Minimizing bias in design of observational studies of devices and medications" March 5, 2019.
- 2019 **Epidemiologic Research Using Healthcare Databases**, Epid 766, "Medicare 101", March 26, 2019.

- 2019 **Pharmacoepidemiology Seminar**, Epid 893, “Linking Electronic Health Records and Insurance Claims Data for Clinical Research: Opportunities and Challenges”, March 18, 2019.
- 2018 **Design of Clinical Research**, Epid 804, “Minimizing bias in design of observational studies of devices and medications”
- 2017 **Pharmacoepidemiology**, Epid 765, “Non-uniform treatment effects”
- 2016, 2017 **Epidemiologic Analysis of Time-to-Event Data**, Epid 722, “Doubly robust estimation”
- 2016 **Reproductive and Perinatal Epidemiology**, Epid 851, “Medications in Pregnancy”
- 2015 **Pharmacoepidemiology**, Epid 765, “Treatment effect heterogeneity”
- 2014 **Advanced Pharmacoepidemiologic Methods**, EPID 690, “Doubly Robust Estimation”
- 2011 **Readings in Epidemiologic Methods**, EPID 719, Guest consultant on epidemiologic research using administrative claims data
- 2011 **Epidemiologic Analysis of Time-to-Event Data**, EPID 722, “Comparing Groups in Time: Poisson Regression”
- 2011 **Epidemiologic Research with Healthcare Databases**, EPID 690, “Medicare 101: A crash course for epidemiologists”
- 2011 **Methods and Issues in Pharmacoepidemiology**, EPID 765, “Critical Reading of the Pharmacoepidemiologic Literature”
- 2010 **Readings in Epidemiologic Methods**, EPID 719, Guest consultant on doubly robust estimators
- 2009 **Methods and Issues in Pharmacoepidemiology**, EPID 765, “Doubly Robust Estimators: Twice as nice or double trouble?”
- 2007 **Readings in Epidemiologic Methods**, EPID 719, Guest consultant on propensity score methods
- 2006 **Fundamentals of Epidemiology**, EPID 710, Two guest lectures titled “Information bias” and “Selection bias”

GRADUATE STUDENT SUPERVISION

Name	Year Completed	Thesis / Dissertation Title
<i>Chair of Doctoral Committee (10)</i>		
Jacob Kahrs	2025 (anticipated)	Comparison of Antibiotic Safety and Effectiveness for the Treatment of Urinary Tract Infections During Pregnancy
Sara Dejene	2025 (anticipated)	Concomitant use of antidepressants and oral antidiabetic drugs and the risk of hypoglycemia
Jessica Young	2020	Opioids use for acute pain management associated with outpatient surgery: opportunities to reduce diversion and iatrogenic addiction
Elizabeth Suarez	2019	Safety of ondansetron exposure during pregnancy

Suzanne Landi	2018	Comparative safety and effectiveness of metformin versus insulin for the gestational diabetes
Mitchell Conover	2017	Methods for incorporating confounder data when duration of continuous enrollment varies
Joann Gruber	2017	Timing of rotavirus vaccination and incidence of severe rotavirus gastroenteritis among infants in low-and middle-income countries
Wendy Camelo Castillo, MD	2013	Pharmacological Treatment of Gestational Diabetes and Association with Adverse Maternal and Neonatal Outcomes
Kristen B Bibeau (Van Dole)	2011	Evaluation of the menopause-specific quality of life questionnaire and association of vasomotor and psychosocial symptoms among postmenopausal women in the United States
Mary Elizabeth Ritchey	2007	Central line-associated blood-stream infections and ventilator-associated pneumonias: changing infection rate across duration of hospitalization and with different definitions of time at risk

Chair of Master's Committee (7)

Sara Dejene	2021	Postpartum contraception utilization among commercially insured mothers of medically fragile infants
Jessica Young	2017	Tolerance prior to initiation of high dose opiates in the US
Mitchell Conover	2014	Hysteroscopic vs. laparoscopic sterilization: short term incidence of pain or bleeding, U.S. 2005-2011
Emily Ko, MD	2013	Metformin use and incidence of endometrial cancer in women with type II diabetes
Erica Berggren, MD	2011	Impact of changing diagnostic criteria for gestational diabetes on neonatal outcomes
Mary Elizabeth Ritchey	2007	Effect of antiretroviral class on hepatotoxicity in HIV-infected patients
Barbara Stegman, MD	2006	A Logistic Model for the Prediction of Endometriosis

Member of Doctoral Committee (23)

Chase Latour	2025 (anticipated)	Trial emulation for safety and effectiveness of prenatal antihypertensive exposure for chronic hypertension in pregnancy
Katie Mollan	2024 (anticipated)	Comparative Effectiveness of the Levonorgestrel (LNG) Implant and Depot Medroxyprogesterone Acetate

		(DMPA) Injectable for Pregnancy Prevention among Women Living with HIV on Efavirenz or Dolutegravir
Mekhala Dissanayake	2024 (anticipated)	Race and Racial Composition of County: Investigating Maternal Health Inequities and Healthcare Systems Factors in the Rural South
Jeff Yang	2023	Utilization and Effectiveness of Objective Treat-to-Target Assessment and Therapeutic Response among Inflammatory Bowel Disease Patients Treated in the United States
Sapna Rao	2022	Comparative effectiveness of anticoagulant therapy in hemodialysis patients with atrial fibrillation
Christine Hsu	2022	Hepatocellular Carcinoma Screening Trends in Individuals with Cirrhosis in North Carolina, 2006-2018
Tiansheng Wang	2022	Machine Learning Analysis of Heterogeneous Treatment Effects for Dipeptidyl Peptidase 4 Inhibitors' Cardiovascular Outcomes in Older Adults
Kanecia Zimmerman	2022	Safety and effectiveness of pediatric sedation and pain management during hospitalization
Arti Virkud	2022	Estimating the Comparative Effect of Loop Diuretics Using Claims and EHR Data and Precision Medicine Machine Learning Methods
Phyo Htoo	2020	Comparative performance of methods to estimate the effects of medications in the presence of a calendar time trend in prescribing
Sarah Hoffman	2019	Oral Contraceptives and Uterine Fibroid Development in Young, Black Women
Tracy Kinsey	2019	Initiation of non-steroidal anti-inflammatory drug use and risk for venous thromboembolism in U.S. women
Elizabeth Dehmer	2019	Pregnancy Complications and Maternal Chronic Kidney Disease
Mugdha Gokhale	2016	Cardiovascular effects of incretin-based antihyperglycemic drugs relative to treatment alternatives in older adults
Jonathan Todd	2015	Statin Use in the Women's Interagency HIV Study: Disparities in Use, Lipid Effects, and Unintended Effects
Jin-Liern Hong	2015	Breast Cancer Risk after Metformin initiation in Older Women – the Role of Study Design, Potential Confounding by Body Mass Index, and Differential Detection
Richard Wyss	2015	Disease Risk Scores for Confounding Control When Evaluating Evolving Drug Therapies

Nabarun Dasgupta	2013	Pharmacoepidemiology of the abuse of pharmaceutical controlled substances
Catherine Panozzo	2013	Patterns of rotavirus vaccine uptake, use, and effectiveness in privately-insured US children, 2006-2010
Stephanie Watkins	2012	Interventional Physical and Occupational Therapy Services and Motor Development among Low Birth Weight Infants
J Bradley Layton	2012	The Risk of Acute Kidney Injury in Statin Initiators
Reem Hasan	2009	Vaginal bleeding in early pregnancy: patterns, predictors, and association with miscarriage
Daniel Westreich	2008	Tuberculosis treatment and risk of stavudine substitution in first line antiretroviral therapy

Current Advisees

PhD Students (*prior to thesis proposal defense*): $n=7$

Megan Delgado (sixth year, PhD), Elyse Miller (third year, PhD), Madison (Maddy) Ponder (third year, PhD), Sherin Ismail Atta (third year, PhD), Amar Marthi (second year, PhD), Christine Ballard (second year, PhD), Zoey Song (second year, PhD)

FACULTY MENTORING

Name	Title, Department	Year(s)
Alan Kinlaw	Assistant Professor, Tenure Track, DPOP, School of Pharmacy	2024-
Anna Kahkoska	Assistant Professor, Tenure Track, Nutrition, SPH	2022-
Sara Levintow	Assistant Professor, Research Track, Epidemiology, SPH	2022 -
Mollie Wood	Assistant Professor, Tenure Track, Epidemiology, SPH	2021 -
Juan Hincapie-Castillo	Assistant Professor, Tenure Track, Epidemiology, SPH	2021 –
Sara Jones	Assistant Professor, Clinical Track, Epidemiology, SPH	2020 -
Radhika Dhingra	Assistant Professor, Research Track, Environmental Sciences, SPH	2020 - 2022

GRANTS & CONTRACTS

(Total costs, unless otherwise noted)

Current

F31HD115361 (Jonsson Funk / Kahrs)
NIH/NICHD

5/01/2024–4/31/2026
\$90,180

Comparison of Antimicrobial Safety and Effectiveness for the Treatment of Urinary Tract Infections During Pregnancy

This research will use electronic health records from a large integrated health system to evaluate the safety and effectiveness of specific antibiotics for asymptomatic and symptomatic UTI during pregnancy.

Role: Faculty Sponsor (No salary support)

1K01DE033698-01 (Hincapie-Castillo, PI)
NIH/NIDCR

02/05/2024 – 01/31/2029
\$619,794

Real-world Evidence Study with Patient Input to evaluate Treatment Effects in Trigeminal Neuralgia (RESPITE-TN)

This project aims to investigate the optimal pharmacological treatment approaches for TN among aging Americans by documenting patient-reported experiences of diagnosis and treatment, developing a validated algorithm to identify incident TN cases in Medicare data, and investigating the risk of drug-related injurious falls.

Role: Primary Mentor (no salary support)

K01AG084971-01 (Kahkoska, PI)
NIH/NIA

1/31/2024-01/31/2028
\$520,968

Innovative medical technologies can improve health and increase longevity for older adults with chronic disease and multimorbidity, yet new data are needed to promote their adoption and effective use in real-world settings. For example, nearly a quarter of all adults ≥65 years old in the US have diabetes. Technology-based approaches to diabetes management, such as continuous glucose monitoring (CGM), can improve clinical outcomes and quality of life in this age group, in addition to preventing dangerous episodes of hypoglycemia. Despite the potential benefits, CGM remains underutilized among older adults compared to younger adults. The purpose of this project is to generate the scientific evidence needed to expand and improve the delivery of guidelines-aligned care for the expanding population of older adults with diabetes, and particularly with respect to rapidly emerging technology such as CGM. My proposal has exciting, high-impact training opportunities to address three fundamental gaps in the literature, including sparse research characterizing (1) patterns of CGM use among older adults and (2) the clinical effects of long-term use in such real-world settings, as well as a dearth of data on the (3) economic impacts of scaling CGM in this age group.

Role: Primary Mentor (no salary support)

7OT2OD036113-02 (Haendel, Chute, Pfaff, Moffitt, MPI)
NIH Office of the Director

9/2/2023-3/1/2025
\$19,381,451

All of Us Center for Linkage and Acquisition of Data (CLAD)

Through a subcontract with the University of Colorado Denver, UNC is supporting the identification, linkage, data quality, and documentation of insurance claims data for participants enrolled in the All of Us study. The initial contract is for a period of 18 months with additional years pending successful completion.

Role: Co-investigator (25%)

UM1TR004406 (Shaheen/Buse)
NIH/NCATS

4/28/2023–3/31/2030
\$69,005,276

North Carolina Translational and Clinical Sciences Institute (NC TraCS)

Support translational science to advance research on the benefits and/or harms of medical interventions including procedures, tests and treatments.

Role: Co-Investigator (20%)

Center for Pharmacoepidemiology (Jonsson Funk)
Members: GlaxoSmithKline (2013-), Merck Inc. (2014-2019),

1/1/2013- Present
\$3,750,000

**UCB BioSciences (2013-), Takeda (2017-), AbbVie (2019-),
Boehringer Ingelheim (2020-), Astellas (2022-), Sarepta (2022-)**

The Center provides unrestricted support for selected students, postdocs, staff and faculty affiliated with the pharmacoepidemiology program

Role: Director (2018-present); member (2013-2018)

**GlaxoSmithKline (Jonsson Funk)
N/A**

**2002-Present
\$3,335,000**

UNC-GSK Center of Excellence in Pharmacoepidemiology and Public Health

The Center provides unrestricted support for students, postdocs, and faculty affiliated with the pharmacoepidemiology program

Role: Director (2018-present); member (2004-2018)

**R36 AG075394 (Jonsson Funk / Dejene)
NIH/NIA**

**8/15/2022–5/31/2025(nce)
\$138,023**

Concomitant use of antidepressants and oral antidiabetic drugs and the risk of hypoglycemia

This research will use Medicare claims data to evaluate whether concurrent use of specific antidepressants in combination with oral antidiabetic drugs may interact to increase the risk of serious hypoglycemia.

Role: Faculty Sponsor (No salary support)

**1P30DK124723-01 (McClain/Buse)
NIH/NIDDK / Wake Forest**

**4/1/2020 – 3/31/2025
\$1,366,188 (UNC sub)**

NC Diabetes Research Center

Objectives of this project are to 1) enhance patient-centered outcomes research (PCOR) and comparative effectiveness research (CER) by directing investigators to appropriate resources and enhanced methods for trial design, cohort identification, data management and analysis; 2) implement advanced statistical and trial design methodologies as appropriate to diabetes studies to enhance efficiency; and 3) enhance the ability to approach clinical questions employing pragmatic trials.

Role: Associate Director, Advanced Clinical Study Methods Core (effort funded through TraCS)

**1U01DP006369-01 (Kappelman/Lewis)
CDC/Crohn's and Colitis Foundation of America (CCFA)**

**9/30/2018 – 9/29/2024
\$662,365**

Diversity Within the Incidence, Prevalence, Treatment and Outcomes of Patients with IBD

Aim are to 1) build a registry of patients with incident diagnosis of Crohn's Disease and Ulcerative Colitis by leveraging the existing research infrastructure of the Crohn's & Colitis Foundation and the ImproveCareNow Network; 2) estimate the prevalence and incidence of CD and UC at a national level using representative data that encompasses populations from all segments of the socioeconomic and geographic distribution of the United States; and 3) determine whether race and IBD practice volume are associated with patterns of care and key outcomes including use of biologics, steroids, narcotics, hospitalization and surgery at a national level and within high volume IBD centers.

Role: Co-I (10% effort in Year 1, 4% in Years 2-5)

**1R01AG056479 (Stürmer)
NIH/NIA**

**9/15/2017–5/31/2027
\$3,795,270**

Propensity scores and preventive drug use in the elderly (R01 AG023178)

Insights into and development of different novel analytic strategies to control for selection and confounding bias in non-experimental research based on propensity scores and validation data.

Role: Co-Investigator (15%)

Past

- 1U01DD001231-01 (Olshan/Desrosiers)** **9/1/2018 – 8/31/2023**
Centers for Disease Control and Prevention **\$4,999,266**
BD-STEPS II Core at North Carolina Center for Birth Defects Research and Prevention (NC BDSTEPS II Core)
Using a population-based, multi-center case-control study design, the new *Birth Defects Study To Evaluate Pregnancy exposures II* (BD-STEPS II) will conduct research with high potential to prevent birth defects by identifying modifiable maternal exposures in early pregnancy that may increase the risk of pregnancy affected by certain major, structural birth defects.
Role: Co-I (0% effort – transitioned to M Wood)
- 1 U54 TR002255 (Buse/Shahen)** **4/1/2018–4/27/2023**
NIH/NCATS **\$ 60,891,563**
Biostatistics, Epidemiology, and Research Design, NC TraCS
Support robust research to evaluate the benefits and/or harms of medical interventions including procedures, tests and treatments.
Role: Co-Investigator (20% effort)
- HHSF223201810183C (Marshall)** **9/1/2018 – 8/31/2022**
Food and Drug Administration (FDA) **\$7,991,522**
Methodological Advances in Evaluating Abuse Deterrent Opioid Analgesics
Despite efforts of established data providers, there is room for innovation in analytic methods for abuse deterrent formulations (ADFs). The outputs from each Aim will include computer code, guides and webinars disseminated for free via the Internet, coupled with gathering of feedback, allowing other researchers to advance the methodologic rigor of ADF epidemiology.
Role: Co-I (5% effort)
- 75F40119C10115 (Jonsson Funk)** **9/23/19–12/31/2021 (nce)**
Food and Drug Administration (FDA) **\$1,275,489**
Methodological Advances in the Assessment of Uncontrolled Confounding
This project will evaluate and inform the use of sensitivity analyses used to assess the risk of uncontrolled confounding in observational studies and provide training to FDA personnel.
Role: PI (40% effort)
- CER-2017C3-9230 (Flory / Jonsson Funk)** **1/1/19–10/31/2021 (nce)**
PCORI/Cornell University Weill Medical College **\$571,559**
Comparative Effectiveness of Metformin for Type 2 Diabetes with Chronic Kidney Disease
This proposed research tests the hypothesis that metformin is safer and more effective than commonly-used alternatives in improving patient-centered outcomes for patients with type 2 diabetes and chronic kidney disease.
Role: Site PI (20% effort in Year 1; 15% effort in Years 2-3)
- R36 DA045885 (Young)** **9/1/2018–8/31/2021 (nce)**
NIH/NIDA **\$147,655**

Identifying opportunities to reduce unnecessary opioid exposure and prevent iatrogenic addiction after surgery

Estimate the effect of initial post-operative opioid prescribing (Aim 1) and perioperative administration of gabapentinoids (Aim 2) on risk of long-term opioid use, adverse opioid-related outcomes, and mortality across a broad range of surgeries. Use linked Medicare claims and electronic medical record (EMR) data to evaluate agreement between data sources and quantify potential bias in studies limited to claims- or EMR-only data sources (Aim 3).

Role: Faculty Sponsor (No salary support)

6292-2019-R2TCB03 (Rosenthal / Klein & Jonsson Funk) 11/1/2020 – 8/14/2021

**Medical Device Innovation Consortium / Wake Forest University Health Sciences \$135,682 (UNC sub)
Cardiovascular ImPLantable Electrode CompARative Reliability (CLEAR)**

The primary goal of this study is to determine the feasibility of using electronic health record (EHR) to determine device reliability, using cardiac leads as a test case. The study will develop algorithms to determine cardiac lead failure using EHR data from three large integrated health systems. The study will then examine the agreement between device failure as captured by EHR data and by CMS claims data for Medicare beneficiaries and failure captured in the FDA's Maude database. An important objective of the study is to develop a framework for mobilizing device data from EHR and other hospital systems to the PCORnet Common Data Model that could be applied to data on cardiac leads and other medical devices.

Role: Co-PI (5%)

R40MC29455-01-00 (Stuebe) 4/1/2016 –3/31/2020 (nce)

HRSA

\$897,986

Care4Moms

Assess the unmet healthcare needs of mothers of medically fragile infants – those who spend 3 or more days in the NICU – compared to mothers of healthy infants.

Role: Co-Investigator (5% effort)

R01 HL118255 (Jonsson Funk) 5/1/2014–4/30/2020 (nce)

NIH/NHLBI

\$1,684,991

Methods for Estimating Sex Differences in Safety and Effectiveness of Drugs

The major goals of this project are to develop, test, implement, and disseminate reliable methods for evaluating sex differences in the comparative effectiveness and safety of pharmacotherapy.

Role: PI

2KR1001806 (Young) 1/1/2019-12/31/2019

NC TraCS Institute

\$2,000

Examining the role of perioperative gabapentinoid use in preventing long-term opioid therapy

Role: Faculty sponsor (No salary support)

2KR1001806 (Suarez) 4/1/2018-3/30/2019

NC TraCS Institute

\$2,000

Use of ondansetron for nausea and vomiting during pregnancy and adverse pregnancy outcomes

Role: Faculty sponsor (No salary support)

UL1 TR001111 (Buse/Carey) 9/26/2013–4/30/2018

NIH/NCATS

\$7,324,022

Comparative Effectiveness Research (CER) Strategic Initiative (SI), NC TraCS

Build infrastructure to support robust comparative effectiveness studies to provide definitive evidence of the benefits and/or harms of tests and treatments.

Role: Co-Investigator (25% effort)

(Stürmer)

10/1/2014 -9/31/2017

AstraZeneca

\$367,598

Estimating treatment effects in defined external populations based on data from RCTs

To develop a systematic approach in assessment of RCT generalizability to regional real-world populations which can be considered during both trial design and subsequent communications with regulators, payers and practitioners in both pre-launch and post launch stages

Role: Co-Investigator (15% effort)

R56 AG023178 (Stürmer)

4/1/2012 – 8/30/2016

NIH/NIA

\$1,174,552

Propensity scores and preventive drug use in the elderly (R01 AG023178)

Insights into and development of different novel analytic strategies to control for selection and confounding bias in non-experimental research based on propensity scores and validation data.

Role: Co-Investigator (5%)

RUF-IMEDS-FP_0004 (Jonsson Funk)

9/1/2015 – 8/31/2016

Reagan-Udall Foundation for the FDA – IMEDS

\$100,000

PROMPT Usability and Performance Evaluation

Evaluate the usability and bias of the PROMPT surveillance tool.

Role: PI (15% effort)

1IP2PI000075-01 (Stürmer)

10/1/2012 – 12/31/2014

PCORI – Pilot Projects Program

\$690,502

Methods to Increase Validity of Comparative Effectiveness Research in the Elderly

The major goals of this project are to develop and refine methods to handle confounding by indication, selection bias due to treatment changes, evaluate treatment effect heterogeneity when the background risk varies across subgroups, and address concerns about competing risks.

Role: Co-Investigator (20% effort)

HHSF223201111878P (Stürmer)

9/26/2011 – 9/25/2013

FDA/CDRH

\$45,763

Advancing the Specialized Methodological Expertise for Medical Device Epidemiologists

The purpose of this service contract was to assess the current expertise within the Division of Epidemiology in the Office of Surveillance and Biometrics, Center for Devices and Radiological Health at FDA and to present proposed solutions for increasing specialized methodological expertise in targeted areas within the discipline of medical device epidemiology.

Role: Co-Investigator (No salary support)

(Jonsson Funk / Camelo Castillo)

1/1/2011-12/31/2012

NC Tracs

\$10,000

Developing Methods to Improve Estimation of Gestational Age at Delivery Using CDW-H

Identify items from billing data that could be used to improve estimation of gestational age for studies of drug effects on pregnancy outcomes.

Role: Co-PI (No salary support)

GIL200811.0010 (Stürmer) **8/1/2009 – 7/31/2012**
UNC Gillings Innovation Lab **\$250,000**

PharmacoEpidemiology Gillings Innovation Lab (PEGIL) for the Population-Based Evaluation of Drug Benefits and Harms in Older US Adults

Establish critical data infrastructure for conducting pharmacoepidemiology research on the safety and effectiveness of medications commonly used in older adults.

Role: Co-Investigator (No salary support)

K02 HS017950 (Jonsson Funk) **2/1/09-4/30/14**
DHHS/AHRQ **\$653,200**

Doubly robust estimation: Best practices for comparative effectiveness research

The major goals of this project were to systematically evaluate key aspects of doubly robust (DR) estimators including bias, efficiency, covariate selection, and non-uniform treatment effects using large scale simulations and applied analyses in comparative effectiveness research.

Role: PI (90% effort)

R01 HD049675 (Hartmann/Olshan) **5/01/06-2/28/11**
NIH/NICHD **\$2,497,836**

Non-steroidal Anti-Inflammatory Use and Miscarriage

This study was designed to address whether: 1) NSAID use is independently associated with increased risk of spontaneous abortion; 2) whether any effect depends on cumulative dose, regular vs. episodic use, or timing of exposure in critical developmental windows.

Role: Co-Investigator (30% effort)

U18 HS010397 (Guess/Stiles) **9/29/05 – 9/28/07**
DHHS/ARHQ **\$97,755**

Rational Therapeutics for the Pediatric Population: Supplement **(project directs)**

This study developed and disseminated SAS-based tools for conducting studies of comparative effectiveness using doubly-robust estimation.

Role: Co-Investigator, Project PI (20% effort)

(Jonsson Funk) **2005-2006**
UNC-GSK Center for Excellence in Pharmacoepidemiology & Public Health **\$12,850**

Prospective assessment of prescription and over-the-counter medication in the first trimester: Pilot of a web-based diary

Develop and pilot a web-based diary for collecting prospective data on exposure to over-the-counter pain medications during early pregnancy.

Role: PI (No salary support)

Contract No. 290-02-0016 (Lohr/Carey) **2005-2006**
AHRQ/OMAR **\$250,000**
Cesarean Delivery on Request **(direct cost)**

To systematically review the evidence on maternal and infant outcomes of cesarean delivery on maternal request (CDMR) compared with planned vaginal delivery (PVD).

Role: Epidemiologist (5% effort)

R01 AI066920 (Jonsson Funk)
NIH/NIAID

6/15/05-8/31/09
\$399,339

Effect of earlier HAART on HIV disease progression and survival

The primary aims of this study were to 1) obtain precise estimates of the effect of initiating HAART compared to deferring HAART on first AIDS diagnosis or death among asymptomatic seroconverters at each of three stages of HIV infection: 200-349, 350-499, and 500-1000 cells/mm³ and 2) determine the extent to which the observed effect of HAART is altered by adjusting for differences in the distribution of important predictors of disease progression and treatment initiation.

Role: PI (30% effort)

R34 HD048641 (Visco)
NIH/NICHD

1/1/2005-12/31/2006
\$146,000

Cesarean After Sphincter Tear (CAST) RCT Planning Grant

To plan and conduct essential pilot work for a future multicenter randomized clinical trial to quantify the effect of planned Cesarean section compared to a trial of vaginal delivery on the risk of developing anal incontinence among women that sustained a 3rd or 4th degree laceration of the anal sphincter during their first deliveries.

Role: Biostatistician (2% effort)

(Jonsson Funk)
UNC CFAR

6/21/2004-6/20/2006
\$20,000

Improving control of confounding in observational studies of HIV treatment effects and adverse events using artificial neural networks

To investigate the use of machine learning (including neural networks) to improve fit of propensity score models for control of confounding.

Role: PI (No salary support)

Pending

(Jonsson Funk & Lund, MPI)
FDA

9/1/2024-8/31/2026
\$804,923

The overarching goal of this project is to develop robust evidence to inform the design, analysis, critical review and interpretation of external control arm studies. We propose to evaluate strategies for the selection of index dates for individuals in the comparator arm of externally controlled trials of oncology therapeutics and how those strategies influence results in a variety of oncology settings. Aim 1. Using plasmode simulation where the true treatment effect is under investigator control, we will evaluate the bias and efficiency of strategies for selecting the index date for an external comparator group when multiple eligible times are available. Aim 2. Quantify and compare the cumulative risk of selected outcomes in external comparator case examples using real world and historical trial data and various index date selection approaches.

Role: CoPI (15%)

(Jonsson Funk)
FDA

9/1/2024-8/31/2026
\$467,287

Principled comparator selection: A tool to support and evaluate critical design decisions for externally controlled trials of effectiveness

The overarching goal of this project is to improve the selection of appropriate comparators for effectiveness studies using real-world data. The specific objectives are to: 1) describe patient selection into index and

comparator arms in existing RWE submitted to FDA using publicly available information; and 2) develop a flowchart with illustrative case studies to guide selection of comparators from RWD to support assessment of effectiveness.

Role: PI (11%)

(Kappelman)

4/1/2025-3/31/2031

Patient Centered Outcomes Research Institute (PCORI)

\$ 14,383,678

Comparative effectiveness of emerging medications in children with inflammatory bowel disease

In children with Crohn's disease or ulcerative colitis who are refractory to anti-TNF therapy, this study will compare the effectiveness of current and emerging therapies; describe the frequency of adverse events among initiators of specific treatments; and explore heterogeneity of treatment effects by age group, race/ethnicity, and disease phenotype.

Co-investigator (5%)

SERVICE

Epidemiology Department

- 2021- Member, Epidemiology Inclusive Excellence Committee
- 2021-2022 Member, Graduate Studies Committee
- 2018 - Director, Center for Pharmacoepidemiology
- 2018 - Head, pharmacoepidemiology program area
- 2014 Member, Search Committee, Research-Track Position in Pharmacoepidemiology, Department of Epidemiology
- 2013 Member, Selection Committee for the Kark Distinguished Teaching Assistant Award
- 2011 Member, Selection Committee for the Corroni-Huntley Scholarship and the Tyroler Scholarship, Department of Epidemiology
- 2008-2009 Member, Search Committee, Tenure-Track Position in Pharmacoepidemiology, Department of Epidemiology
- 2004 - Member, Pharmacoepidemiology / Healthcare Epi Qualifying Exam Committee, Department of Epidemiology

Gillings School of Global Public Health

2020 Invited reviewer, COVID-19 Gillings Innovation Laboratory (GIL)

University of North Carolina at Chapel Hill

2017 Invited reviewer, UNC Office of Research Development

2004 - 2013 Faculty mentor, TECT T32 training in epidemiology and clinical trials fellowship program

Professional and Public Service

2023 – Center for Innovative Statistics (CIS) Advisory Board, Astellas

2023 NIH/NCCIH, Training and Education Review Panel (ZAT1 AM(04))

2021 Invited speaker, Real World Evidence: How Big Data is Changing Scientific Standards, National Press Foundation, July 22, 2021.

2021 Invited Panelist, Methods Council Session on RCT DUPLICATE, Center for Observational Research, Amgen, May 4, 2021.

2021 Invited panelist, Evaluating RWE from Observational Studies in Regulatory Decision-Making: Lessons Learned from Trial Replication Analyses; Virtual public meeting hosted by the Duke-Margolis Center for Health Policy and the U.S. Food & Drug Administration, February 16-17, 2021.

2019 Invited Panelist and representative of the International Society for Pharmacoepidemiology and Public Health (ISPE), Public Stakeholder Meeting regarding International Conference on Harmonization (ICH) E8(R1) – General Considerations for Clinical Studies, Food and Drug Administration, October 31, 2019.

2018 - 2019 Member, Medicare Linkage Workgroup, PCORnet Coordinating Center

2018 Invited expert, Real World Evidence Collaborative Synthesis Workshop, Duke-Margolis RWE Collaborative, June 19, 2018.

2018 Invited expert, Real World Evidence and Real-World Data Workshop, Duke-Margolis RWE Collaborative, April 27, 2018.

2017 Report reviewer, Patient Centered Outcomes Research Institute

2016 - UNC representative, Data Request Review Committee (DRRC) for the Carolinas Collaborative

2015 Invited reviewer, Sir Henry Wellcome Postdoctoral Fellowship, Wellcome Trust

2014 - 2015 Ad-hoc reviewer, Pure Methods Study Section, Patient Centered Outcomes Research Institute

2012 Ad-hoc reviewer, Applications for MDEpiNet Master Contract, Center for Devices and Radiologic Health (CDRH), Food and Drug Administration (FDA)

2010 DEClDE report reviewer, Agency for Healthcare Research and Quality, Effective Health Care Program

Invited manuscript reviews

- 2019 - Statistics in Medicine
- 2017 - Pediatric Infectious Diseases Journal
- 2016 - Drug Safety
- 2016 - British Journal of Obstetrics and Gynecology
- 2016 - Circulation: Cardiovascular Quality & Outcomes
- 2014 - PLoS ONE
- 2012 - BMC Medical Research Methodology
- 2012 - Expert Opinion on Drug Safety
- 2011 - Pharmacoepidemiology & Drug Safety
- 2011 - Epidemiology
- 2008 - American Journal of Epidemiology
- 2008 - Antiviral Therapy
- 2007 - HIV Clinical Trials
- 2005 - Journal of Clinical Epidemiology
- 2004 - International Journal of Epidemiology

Invited Abstract Reviews

- 2011 Annual Scientific Meeting of the Society for Epidemiologic Research
- 2010 - Annual Scientific Meeting of the International Society for Pharmacoepidemiology
- 2004 – 2009 Annual Women’s Health Research Conference, University of North Carolina at Chapel Hill