CURRICULUM VITAE

Andrea Jean Cook Updated: December 31, 2024

1. BIOGRAPHICAL INFORMATION:

Andrea J. Cook, Ph.D. Senior Biostatistics Investigator and Manager Division of Biostatistics Kaiser Permanente Washington Health Research Institute Kaiser Foundation Health Plan of Washington^{*} 1730 Minor Avenue, Suite 1300 Seattle, WA 98101-1448 Phone: (206)240-6333 Fax: (206)287-4710 Email: Andrea.J.Cook@kp.org Affiliate Professor

Dept. of Biostatistics, University of Washington

2. EDUCATION:

University of Washington, Seattle, WA B.S. in Applied Computational Mathematical Sciences · Minor: Mathematics · Cum Laude	Graduation: June 2001
Harvard University, Boston, MA	
M.S. in Biostatistics	Graduation: June 2003
Ph.D. in Biostatistics	Graduation: June 2005
· Dissertation Topic:	
Spatial Cluster Detection for discrete, survival, and longitudina	l outcomes
· Advisor: Dr. Yi Li	
3. LICENSURE:	

Not applicable

4. PROFESSIONAL POSITIONS:

Exchange Research Assistant Karolinska Institute, Stockholm, Sweden	Jun 2003 to Aug 2003
Research Assistant Dept of Biostatistics, Harvard School of Public Health, Boston, MA	Sep 2003 to Jun 2005
Research Scientist III Department of Biostatistics, University of Washington, Seattle, WA	Jul 2005 to May 2006
Assistant Investigator Division of Biostatistics, Kaiser Permanente Washington Health Research Instit	May 2006 to Apr 2012 ute,* Seattle, WA
Affiliate Assistant Professor Department of Biostatistics, University of Washington, Seattle, WA	Jan 2007 to Jun 2013
Associate Investigator Division of Biostatistics, Kaiser Permanente Washington Health Research Instit	May 2012 to Sep 2016 ute,* Seattle, WA
Affiliate Associate Professor Department of Biostatistics, University of Washington, Seattle, WA	Jul 2013 to Jul 2018
Senior Biostatistics Investigator Division of Biostatistics, Kaiser Permanente Washington Health Research Instit	Oct 2016 to Present ute,* Seattle, WA
Affiliate Professor Department of Biostatistics, University of Washington, Seattle, WA	Jul 2018 to Present
Manager Biostatistics Investigator Division of Biostatistics, Kaiser Permanente Washington Health Research Instit	Jul 2022 to Present ute,* Seattle, WA

Kaiser Permanente acquired Group Health in February 2017, at which point Group Health Research Institute became Kaiser Permanente Washington Health Research Institute.

5. HONORS, AWARDS, and SCHOLARSHIPS:

Deans List, Every quarter attended at Univ. of Wash., 1998-2001 Annual Deans List, Every year attended at Univ. of Wash., 1999-2001 VIGRE Grant Recipient, Univ. of Wash., 2000 Golden Key National Honor Society, 2000 and 2001 Cum Laude, Univ. of Wash., 2001 NIH Traineeship in Environmental Health, Harvard Univ., 2001-2003 Distinction in Teaching Award, Harvard Univ., 2002 and 2003 ENAR Student Paper Award 2005 JSM Environmental Student Paper Award runner-up 2005 NIH Travel Award, ENAR Young Investigators Meeting, Washington DC, 2007 Faculty Mentoring Award, GHRI 2013

6. OTHER PROFESSIONAL ACTIVITIES

National Committee Member:

- Member, Protocol Review Committee, Resuscitation Outcomes Consortium, 2006-2008
- Representative at Large, WNAR, 2010-2012
- Conference Co-Organizer, First Seattle Symposium on Health Care Data Analytics, 2014
- Conference Co-Organizer, Second Seattle Symposium on Health Care Data Analytics, 2016
- Member/Grader, WNAR Student Paper Competition, 2016
- Conference Co-Organizer, Third Seattle Symposium on Health Care Data Analytics, 2018
- Member, Educational Advisory Committee, ENAR, 2020
- Member/Grader, ASA Biometrics Section Early Career Paper Award, 2023
- Publications Officer, ASA Biometrics Section, 2025-2027
- Vice-Chair, ASA Council of Sections Governing Board (COSGB), 2025-2027

Advisory and Data Safety Monitoring Boards:

- Member, Data Safety Monitoring Board, Clinical Trial, Improving sleep for teens taking antidepressant medications through counseling (SleepWell), PI: Clarke (Kaiser Permanente Center for Health Research in Portland), 2015-2018.
- Member, Data Safety Monitoring Board, Clinical Trial, The Hospice Advance Dementia Symptom Management and Quality of Life Trial (HAS-QOL) PI: Brody (New York University), 2019 to 2023.
- Member, Data Safety Monitoring Board, Pragmatic Clinical Trial Network, VA-DOD-NIH Pain Management Collaboratory, 2019 to present.
- Member, Data Safety Monitoring Board, Clinical Trial, Effectiveness of an mHealth psychosocial intervention to prevent transition from acute to chronic postsurgical pain in adolescents (SurgeryPal) PIs: Rabbitts and Palermo (Seattle Children's Research Institute), 2020 to present.
- Member, Data Safety Monitoring Board, Clinical Trial, Effectiveness of Wellness Intervention for Smokers with HIV (WISH) PIs: Catz, McClure, and Crothers (UC Davis), 2020 to present.

NIH Grant Review Panels

- REsearching COVID to Enhance Recovery (RECOVER) Initiative Coordinating Center, NIH, 2021 Referee for:

- Biometrics, Biostatistics, Communication in Statistics, Statistics in Medicine, Critical Care, International Journal of Health Geographics, Preventing Chronic Disease, Prevention Science, Journal of the National Cancer Institute (JNCI), and Vaccine
- Memberships:
 - American Statistical Association (ASA)
 - International Biometric Society WNAR
- Conference Organizer:

- Seattle Symposium Health Care Data Analytics 2014, 2016, 2018

Conference Session Organizer:

- WNAR 2010: Statistical Methods for Vaccine Safety
- MSPW 2010: Postmarketing drug surveillance

- Seattle Symposium Health Care Data Analytics 2014, 2016, 2018 Conference Session Chairs:

- ENAR 2009 and 2010

- ENAR 2009 and 20 WNAD /IDC 2015
- WNAR/IBC 2015
- Seattle Symposium Health Care Data Analytics 2014, 2016, 2018

a) Peer-reviewed research articles

- 1. Cook AJ, Gold DR, and Li Y (2007) Spatial Cluster Detection for Censored Outcome Data *Biometrics* 63(2): 540-549
- Brasel KJ, Bulger E, Cook AJ, Morrison LJ, Newgard CD, Tisherman SA, Kerby JD, Coimbra R, Hata JS, Hoyt DB and the ROC Investigators (2008) Hypertonic resuscitation: Design and implementation of a prehospital intervention trial J Am Coll Surg 206(2): 220-232
- 3. Rea TD, **Cook AJ**, and Hallstrom A (2008) CPR during ischemia and reperfusion: a model for survival benefits *Resuscitation* 77(1): 6-9
- 4. Green BB, Ralston JD, Fishman PA, Catz SL, Cook A, Carlson J, Tyll L, Carrell D, and Thompson RS (2008) Electronic Communications and Home Blood Pressure Monitoring (e-BP) study: Design, delivery, and evaluation framework *Contemp Clin Trials* 29(3): 376-395
- 5. Green BB, **Cook AJ**, Ralston JD, Fishman PA, Catz SL, Carlson J, Tyll L, Carrell D, Larson EB, and Thompson RS (2008) Effectiveness of home blood pressure monitoring, Web communication, and pharmacist care on hypertension control: a randomized controlled trial *JAMA* 299(24): 2857-2867
- 6. Stiell IG, Callaway C, Davis D, Terndrup T, Powell J, Cook A, Kudenchuk PJ, Daya M, Kerber R, Idris A, Morrison LJ, Aufderheide T, and the ROC investigators (2008) Resuscitation Outcomes Consortium (ROC) PRIMED Cardiac Arrest Trial Methods Part 2: Rationale and Methodology for "Analyze Later vs Analyze Early" protocol *Resuscitation* 28(2): 186-195
- 7. Bulger EM, Schmidt TA, Cook AJ, Brasel KJ, Griffiths DE, Kudenchuk P, Davis D, Bardarson B, Idris AH, Aufderheide TP, and the ROC Investigators (2009) The Random Digit Dialing Survey as a Tool for Community Consultation for Research involving the Emergency Medicine Exception from Informed Consent Ann Emerg Med 53(3): 341-350
- Carney PA, Kettler M, Cook AJ, Geller BM, Karliner L, Miglioretti DL, Aiello Bowles E, Buist DS, Gallagher T, and Elmore JG (2009) An assessment of the likelihood, frequency, and content of communication between radiologists and women receiving screening and diagnostic mammography *Acad Radiol* 16(9):1056-1063
- Cook AJ, Gold DR, and Li Yi (2009) Spatial Cluster Detection for Repeatedly Measured Outcomes while Accounting for Residential History *Biom J* 51(5):801-818
- 10. Cherkin DC, Sherman KJ, Kahn J, Erro JH, Deyo RA, Haneuse SJ, and **Cook AJ** (2009) Effectiveness of focused structural massage and relaxation massage for chronic low back pain: Protocol for a randomized clinical trial *Trials* 10(1):96
- Gallagher TH, Cook AJ, Brenner J, Carney PA, Miglioretti DL, Geller B, Kerlikowske K, Onega T, Rosenburg RD, Yankaskas B, Lehman CD, and Elmore JG (2009) Disclosing harmful mammography errors to patients *Radiology* 253(2):443-452
- Rea TD, Cook AJ, Stiell IG, Powell J, Bigham B, Callaway CW, Aufderheide TP, Morrison L, Terndrup TE, Beaudoin T, Wittwer L, Davis D, Idris A, Nichol G and Resuscitation Outcomes Consortium Investigators (2010) Predicting Survival following Out-of-hospital Cardiac Arrest: Role of the Utstein Data Elements Ann Emerg Med 55(3): 249–257
- Sherman KJ, Cherkin DC, Cook AJ, Hawkes RJ, Deyo RA, Wellman R, and Khalsa PS (2010) Comparison of yoga versus stretching for chronic low back pain: protocol for the Yoga Exercise Selfcare (YES) trial *Trials* 11(1): 36
- 14. Cook AJ, Elmore JG, Miglioretti DL, Sickles EA, Aiello Bowles EJ, Cutter GR, and Carney PA (2010) Decreased accuracy in interpretation of community-based screeing mammography for women with multiple clinical risk factors *J Clin Epidemiol* 63(4): 441-451
- Sherman KJ, Ludman EJ, Cook AJ, Hawkes RJ, Roy-Byrne PP, Bentley S, Brooks MZ and Cherkin DC (2010) Effectiveness of therapeutic massage for generalized anxiety disorder: a randomized controlled trial *Depress Anxiety* 27(5)441-450
- 16. Grow HM, **Cook AJ**, Arterburn DE, Saelens BE, Drewnowski A, and Lozano P (2010) Child Obesity associated with social disadvantage of children's neighborhoods *Soc Sci Med* 71(3):584–591

- Kerlikowske K, Cook AJ, Buist DS, Cummings SR, Vachon C, Vacek P, and Miglioretti DL (2010) Breast Cancer Risk by Breast Density, Menopause, and Postmenopausal Hormone Therapy Use J Clin Oncol 28(24):3830–3837
- 18. Cook AJ, Li Yi, Arterburn D, and Tiwari RC (2010) Spatial cluster detection for weighted outcomes using cumulative geographic residuals *Biometrics* 66(3):783–792
- 19. Green BB, Anderson ML, Ralston JD, Catz S, Fishman PA, and **Cook AJ** (2011) Patient Ability and Willingness to Participate in a Web-Based Intervention to Improve Hypertension Control *J Med Internet Res* 13(1):e1
- 20. Carney PA, Geller BM, Sickles EA, Miglioretti DL, Aiello Bowles EJ, Abraham L, Feig SA, Brown D, Cook AJ, Yankaskas BC, and Elmore JG (2011) Feasibility and Satisfaction Associated with Using a Tailored Web-based Intervention for Recalibrating Radiologists Thresholds for Conducting Additional Work-up Acad Radiol 18(3):369-376
- 21. Carney PA, Aiello Bowles EJ, Sickles EA, Miglioretti DL, Geller BM, Feig SA, Jackson S, Brown D, Cook A, Yankaskas BC, Miglioretti DL, and Elmore JG (2011) Using a Tailored Web-based Intervention to Set Goals to Reduce Unnecessary Recall Acad Radiol 18(4):495-503
- 22. Li L, Kulldorff M, Nelson JC, and **Cook AJ** (2011) A propensity score-enhanced sequential analytic method for comparative drug safety surveillance *Stat Biosci* 3:45
- 23. Moudon AV, Cook AJ, Ulmer J, Hurvitz PM, Drewnowski A (2011) A neighborhood wealth metric for use in health studies Am J Prev Med 41(1):88-97
- 24. Cherkin DC, Sherman KJ, Kahn J, Wellman R, Cook AJ, Johnson E, Erro J, Delaney K, and Deyo RA (2011) A Comparison of the Effects of Two Types of Massage and Usual Care on Chronic Back Pain: A Randomized, Controlled Trial Ann Intern Med 155(1):1-9
- Onega T, Cook A, Kirlin B, Shi X, Alford-Teaster J, Tuzzio L, and Buist DS (2011) The Influence of Travel Time on Breast Cancer Characteristics, Receipt of Primary Therapy, and Surveillance Mammography Breast Cancer Res Treat 129(1):269-275
- 26. Aggarwal A, Monsivais P, **Cook AJ**, and Drewnowski A (2011) Does Diet Cost Mediate the Relation Between Socioeconomic Position and Diet Quality? *Eur J of Clin Nutr* 65:1059-1066
- 27. Fishman PA, Anderson M, Cook AJ, Larson EB, Ralston JD, Catz SL, Carlson J, and Green BB (2011) Accuracy of blood pressure measurements reported in an electronic medical record during routine primary care visits J Clin Hypertens 13(11):821-828
- 28. Sherman KJ, Cherkin DC, Wellman RD, Cook AJ, Hawkes RJ, Delaney K, and Deyo RA (2011) A Randomized Trial Comparing Yoga, Stretching, and a Self-care Book for Chronic Low Back Pain Arch Intern Med 171(22):2019-2026
- 29. Cook AJ, Wellman RD, Tiwari RC, Li L, Heckbert S, Marsh T, Heagerty P, and Nelson JC (2012) Statistical approaches to group sequential monitoring of postmarket safety surveillance data: Current state of the art for use in the mini-sentinel pilot *Pharmacoepidemiol Drug Saf* 21 Suppl:72-81
- 30. Nelson JC, Cook AJ, Yu O, Dominguez C, Zhao S, Greene SK, Fireman BH, Jacobsen SJ, Weintraub ES, and Jackson LA (2012) Challenges in the design and analysis of sequentially monitored postmarket safety surveillance evaluations using electronic observational health care data *Pharmacoepidemiol Drug Saf* 21 Suppl: 62-71
- 31. Zhao S^{*}, **Cook A**, Jackson L, and Nelson J (2012) Statistical performance of group sequential methods for post-licensure medical product safety surveillance: a simulation study *Stat Interface* 5:381-390
- 32. Carney PA, Cook AJ, Miglioretti DL Feig SA, Bowles EA, Geller BM, Kerlikowske K, Kettler M, Onega T, and Elmore JG (2012) Use of Clinical History in the Interpretation of Screening Mammography in Community-Based Settings, J Clin Epidemiol 65(2):219-230
- 33. Jackson SL, **Cook AJ**, Miglioretti DL, Carney PA, Geller BM, Onega T, Rosenberg RD, Brenner RJ, and Elmore JG (2012) Are radiologists' goals for mammography accuracy consistent with published recommendations? *Acad Radiol* 19(3):289-295
- 34. Green BB, Anderson ML, **Cook AJ**, Catz S, Fishman PA, McClure JB, and Reid R (2012) Using body mass index data in the electronic health record to calculate cardiovascular risk *Am J Prev Med* 42(4):342-347

- 35. Carney PA, Abraham L, Cook A, Feig SA, Sickles EA, Miglioretti DL, Geller BM, Yankaskas BC, and Elmore JG (2012) Impact of an Educational Intervention Designed to Reduce Unnecessary Recall During Screening Mammography, Acad Radiol 19: 1114-1120
- 36. Cook AJ, Elmore JG, Zhu W, Jackson SL, Carney PA, Flowers C, Onega T, Geller B, Rosenberg RD, and Miglioretti DL (2012) Mammographic interpretation: Radiologists' ability to accurately estimate their performance and compare it with that of their peers Am J Roentgenol 199(3): 695-702
- 37. Sherman KJ, Cook AJ, Kahn JR, Hawkes RJ, Wellman RD, and Cherkin DC (2012) Dosing study of massage for chronic neck pain: protocol for the Dose Response Evaluation and Analysis of Massage [DREAM] trial BMC Complement Altern Med 12(1):158
- 38. Cook AJ, Gold DR, and Li Y (2013) Spatial Cluster Detection for Longitudinal Outcomes using Administrative Regions Commun Stat Theory Methods 42(12):2105-2117
- 39. Nelson JC, Yu O, Dominguez-Islas CP, Cook AJ, Peterson D, Greene SK, Yih WK, Daley MF, Jacobsen SJ, Klein NP, Weintraub ES, Broder KR, and Jackson LA (2013) Adapting group sequential methods to observational post-licensure safety surveillance: Results of a pentavalent combination DTaP-IPV-Hib vaccine safety study Am J Epidemiol 177(2):131-141
- 40. Sherman KJ, Wellman RD, **Cook AJ**, Cherkin DC, and Ceballos RM (2013) Mediators of yoga and stretching for chronic low back pain *Evid Based Complement Alternat Med* 2013:130818
- 41. Green BB, Anderson ML, Ralston JD, Catz SL, and **Cook AJ** (2013) Blood pressure 1 year after completion of web-based pharmacist care JAMA Internal Medicine 173(13):1250-1252
- Fishman PA, Cook AJ, Anderson ML, Ralston JD, Catz SL, Carrell D, Carlson J, and Green BB (2013) Improving BP control through electronic communications: an economic evaluation AJMC 19(9):709:716
- 43. Aggarwal A, Monsivais P, **Cook AJ**, and Drewnowski A (2014) Positive attitude towards healthy eating predicts higher diet quality at all cost levels of supermarkets *J Acad Nutr Diet* 114(2)266-272
- 44. Ralston JD, **Cook AJ**, Anderson ML, Catz SL, Fishman PA, Carlson J, Johnson R, and Green BB (2014) Home blood pressure monitoring, secure electronic messaging and medication intensification for improving hypertension control: A Mediation Analysis Applied Clinical Informatics 5(1):232-248
- 45. Sherman KJ, Cook AJ, Wellman RD, Hawkes RJ, Kahn JR, Deyo RA, and Cherkin DC (2014) Five-Week Outcomes from a Dosing Trial of Therapeutic Massage for Chronic Neck Pain Ann Fam Med 12(2):112-120
- 46. Green BB, Anderson ML, Cook AJ, Catz S, Fishman PA McClure JB and Reid RJ (2014) e-Care for Heart Wellness: A Feasibility Trial to Decrease Blood Pressure and Cardiovascular Risk AM J Prev Med 46(4):368-377
- 47. Aggarwal A, Cook AJ, Jiao J, Sequin RA, Vernez Moudon A, Hurvitz PM and Drewnowski A (2014) Access to supermarkets and fruit and vegetable consumption Am J Public Health 104(5):917-923
- 48. Cherkin DC, Sherman KJ, Balderson BH, Turner JA, **Cook AJ**, Stoelb B, Herman PM, Deyo RA, and Hawkes RJ (2014) Comparison of complementary and alternative medicine with conventional mind-body therapies for chronic back pain: protocol for the Mind-body Approaches to Pain (MAP) randomized controlled trial *Trials* 15:211
- Cook AJ, Wellman RD, Nelson JC, Jackson LA, and Tiwari RC (2015) Group sequential method for observational data using generalized estimating equations: Application Vaccine Safety Datalink (VSD) JRSS-C 64(2):319-338
- 50. Rosenberg D, Cook A, Gell N, Lozano P, Grothaus L, and Arterburn D (2015) Relationships between sitting time and health indicators, costs, and utilization in older adults *Prev Med Rep* 2: 247-249
- Stratton KG*, Cook AJ, Jackson LA, and Nelson JC (2015) Simulation study comparing exposure matching with regression adjustment in an observational safety setting with group sequential monitoring Stat Med 34(7): 1117-33
- 52. Nelson JC, **Cook AJ**, Yu O, Zhao S, Jackson LA, and Psaty BM (2015) Methods for observational post-licensure medical product safety surveillance *Stat Methods Med Res* 24(2): 177-193
- 53. Cook AJ, Wellman RD, Cherkin DC, Kahn JR, and Sherman KJ (2015) Randomized clinical trial assessing if additional massage treatments for chronic neck pain improve 12 and 26 week outcomes *Spine J* 15: 2206-2215

- 54. Huang R, Moudon AV, **Cook AJ**, and Drewnowski A (2015) The spatial clustering of obesity: does the built environment matter? *J Hum Nutr Diet* 28(6): 604-612
- 55. Drewnowski A, Aggarwal A, Cook A, Stewart O, and Moudon AV (2016) Geographic disparities in Healthy Eating Index scores (HEI-2005 and 2010) by residential property values: Findings from Seattle Obesity Study (SOS) Prev Med 83: 46-55
- 56. Cherkin DC, Sherman KJ, Balderson BH, Cook AJ, Anderson ML, Hawkes RJ, Hansen KE, and Turner JA (2016) Effect of Mindfulness-Based Stress Reduction vs Cognitive Behavioral Therapy or Usual Care on back pain and functional limitations in adults with chronic low back pain: A randomized clinical trial JAMA 315(12): 1240-1249
- 57. Xu S, Shetterly S, **Cook AJ**, Raebel MA, Goonesekera S, Shoaibi A, Roy J, and Fireman B (2016) Evaluation of propensity scores, disease risk scores, and regression in confounder adjustment for the safety of emerging treatment with group sequential monitoring *Pharmacoepidemiol Drug Saf* 25(4):453-461
- 58. Cherkin D, Balderson B, Brewer G, Cook A, Estlin KT, Foster NE, Hill JC, Hawkes R, Hsu C, Jensen M, LaPorte AM, Levine MD, Piekara D, Rock P, Sherman K, Sowden G, Wellman R, and Yeoman J (2016) Evaluation of a risk-stratification strategy to improve primary care for low back pain: the MATCH cluster randomized trial protocol BMC Musculoskelet Disord 17(1): 361
- 59. Nelson JC, Wellman R, Yu O, **Cook AJ**, Maro J, Oullet-Hellstrom R, Boudreau D, Floyd J, Heckbert S, Pinheiro S, Reichman M, and Shoaibi A (2016) A synthesis of current surveillance planning methods for the sequential monitoring of drug and vaccine adverse effects using electronic health care data *eGEMs* 4(1):1219
- 60. Cook AJ, Delong E, Murray DM, Vollmer W, and Heagerty PJ (2016) Statistical Lessons Learned for Designing Cluster Randomized Pragmatic Clinical Trials from the NIH Health Care Systems Collaboratory Biostatistics and Design Core *Clin Trials* 13(5): 504-512
- 61. Parchman ML, Fagnan LJ, Dorr DA, Evans P, **Cook AJ**, Penfold, RB, Hsu C, Cheadle A, Baldwin LM, and Tuzzio L (2016) Study protocol for "Healthy Hearts Northwest": a 2x2 randomized factorial trial to build quality improvement capacity in primary care *Implement Sci* 11(1):138.
- 62. Elmore JG, Cook AJ, Bogart A, Carney PA, Geller BM, Taplin SH, Buist DS, Onega T, Lee CI, and Miglioretti DL (2016) Radiologists' interpretive skills in screening vs diagnostic mammography: are they related? *Clin Imaging* 40(6): 1096-1103
- 63. Turner JA, Anderson ML, Balderson BH, Cook AJ, Sherman KJ, and Cherkin DC (2016) Mindfulnessbased stress reduction and cognitive-behavioral therapy for chronic low back pain: similar effects on mindfulness, catastrophizing, self-efficacy, and acceptance in a randomized controlled trial *PAIN* 157(11):2434-2444.
- 64. Cherkin DC, Anderson ML, Sherman KJ, Balderson BH, Cook AJ, Hanson KE, and Turner JA (2017) Two-Year Follow-up of a Randomized Clinical Trial of Mindfulness-Based Stress Reduction vs Cognitive Behavioral Therapy or Usual Care for Chronic Low Back Pain JAMA 317(6):642-644.
- 65. McClure JB, Blasi PR, **Cook A**, Bush T, Fishman P, Nelson J, Anderson ML, and Catz SL (2017) Oral health 4 life: Design and methods of a semi-pragmatic randomized trial to promote oral health care and smoking abstinence among tobacco quitline callers. *Contemp Clin Trials* 57: 90-97.
- 66. Green BB, Anderson ML, **Cook AJ**, Chubak J, Fuller S, Meenan RT, and Vernon SW (2017) A centralized mailed program with stepped increases of support increases time in compliance with colorectal cancer screening guidelines over 5 years: A randomized trial. *Cancer* 123(22): 4472-4480.
- 67. Toh S, Rasmussen-Torvik LJ, Harmata EE, Pardee R, Saizan R, Malanga E, Sturtevant JL, Horgan CE, Anau J, Janning CD, Wellman RD, Coley RY, Cook AJ, Courcoulas AP, Coleman KJ, Williams NA, McTigue KM, Arterburn D, McClay J; PCORnet Bariatric Surgery Collaborative (2017) The National Patient-Centered Clinical Research Network (PCORnet) Bariatric Study Cohort. JMIR Res Protoc 6(12): e222.
- Drewnowski A, Buszkiewicz J, Aggarwal A, Cook A, and Moudon AV (2017) A new method to visualize obesity prevalence in Seattle-King County at the census block level. Obes Sci Pract 4(1):14-19.
- 69. Cherkin D, Balderson B, Wellman R, Hsu C, Sherman KJ, Evers SC, Hawkes R, Cook A, Levine MD, Piekara D, Rock P, Estlin KT, Brewer G, Jensen M, LaPorte AM, Yeoman J, Sowden G, Hill JC, and Foster NE (2018) Effect of low back pain risk-stratification strategy on patient outcomes and care

processes: The MATCH randomized trial in Primary Care. J Gen Intern Med 33(8): 1324-1336.

- 70. Inge TH, Coley RY, Bazzano LA, Xanthakos SA, McTigue K, Arterburn D, Williams N, Wellman R, Coleman KJ, Courcoulas A, Desai NK, Anau J, Pardee R, Toh S, Janning C, Cook A, Sturtevant SM, Horgan C, Zebrick AJ, and Michalsky M, PCORnet Bariatric Study Collaborative (2018) Comparative Effectiveness of Bariatric Procedures among Adolescents: The PCORnet Bariatric Study. Surg Obes Relat Dis 14(9): 1374-1386.
- 71. Arterburn D, Wellman R, Emiliano A, Smith SR, Odegaard AO, Murali S, Williams N, Coleman KJ, Courcoulas A, Coley RY, Anau J, Pardee R, Toh S, Janning C, Cook A, Sturtevant J, Horgan C, and McTigue KM, for the PCORnet Bariatric Study Collaborative. (2018) Comparative Effectiveness of Bariatric Procedures 1 for Weight Loss among 46,510 PCORnet Patients: A Cohort Study. Ann Intern Med 169(11): 741-750.
- 72. Toh S, Wellman R, Coley RY, Horgan C, Sturtevant J, Moyneur E, Janning C, Pardee R, Coleman KJ, Arterburn D, McTigue K, Anau J, and Cook AJ (2018) Combining distributed regression and propensity scores: a doubly privacy-protecting analytic method for multicenter research. *Clin Epidemiol* 10: 1773-1786.
- 73. Drewnowski A, Arterburn D, Zane J, Aggarwal A, Gupta S, Hurvitz PM, Moudon AV, Bobb J, Cook A, Lozano P, and Rosenburg D. (2019) The Moving to Health (M2H) approach to natural experiment research: A paradigm shift to studies on built environment and health. SSM Popul Health 7:100345.
- 74. Green BB, Anderson ML, Campbell J, Cook AJ, Ehrlich K, Evers S, Hall YN, Hsu H, Joseph D, Klasnja P, Margolis KL, McClure JB, Munson SA, and Thompson MJ (2019) Blood Pressure Checks and Diagnosing Hypertension (BP-CHECK): Design and Methods of a Randomized Controlled Diagnostic Study Comparing Clinic, Home, Kiosk, and 24-Hour Ambulatory BP Monitoring. Contemp Clin Trials 79: 1-13.
- 75. Shortreed SM, Rutter CM, **Cook AJ**, and Simon G (2019) Improving pragmatic clinical trial design using real-world data. *Clin Trials* 16(3):273-282.
- 76. Shortreed SM, Cook AJ, Coley RY, Bobb JF, and Nelson JC (2019) Challenges and Opportunities for Using Big Health Care Data to Advance Medical Science and Public Health. Am J Epidemiol 188(5): 851-861.
- 77. Cook AJ, Wellman RD, Marsh T, Shoaibi A, Tiwari, R, Nguyen, M, Boudreau D, Weintraub ES, Jackson L, and Nelson JC (2019) Applying sequential surveillance methods that use regression adjustment or weighting to control confounding in a multisite, rare-event, distributed setting: Part 2 in-depth example of a re-analysis of the measles-mumps-rubella-varicella combination vaccine and seizure risk. J Clin Epidemiol 113:114-122.
- 78. Green BB, Anderson ML, Cook AJ, Chubak J, Fuller S, Kimbel KJ, Kullgren JT, Meenan RT, Vernon SW (2019) Financial Incentives to Increase Colorectal Cancer Screening Uptake and Decrease Disparities: A Randomized Clinical Trial. JAMA Netw Open 2(7):e196570.
- 79. Parchman ML, Anderson ML, Dorr DA, Fagnan LJ, O'Maera ES, Tuzzio L, Penfold RB, Cook AJ, Hummel J, Conway C, Cholan R, and Baldwin LM (2019) A Randomized Trial of External Practice Support to Improve Cardiovascular Risk Factors in Primary Care. Ann Fam Med 17(Suppl 1): S40-S49.
- 80. Shi X^{*}, Wellman R, Heagerty PJ, Nelson JC, and **Cook AJ** (2020) Safety Surveillance and the Estimation of Risk in Select Populations: Flexible Methods to Control for Confounding while Targeting Marginal Comparisons via Standardization *Stat Med* 39(4): 369-386.
- 81. Courcoulas A, Coley RY, Clark JM, McBride CL, Cirelli E, McTigue K, Arterburn D, Coleman KJ, Wellman R, Anau J, Toh S, Janning CD, Cook AJ, Williams N, Sturtevant JL, Horgan C, Tavakkoli A; PCORnet Bariatric Study Collaborative. (2020) Interventions and Operations 5 Years After Bariatric Surgery in a Cohort From the US National Patient-Centered Clinical Research Network Bariatric Study. JAMA Surg 155(3):194-204.
- 82. McTigue KM, Wellman R, Nauman E, Anau J, Coley RY, Odor A, Tice J, Coleman KJ, Courcoulas A, Pardee RE, Toh S, Janning CD, Williams N, Cook A, Sturtevant JL, Horgan C, Arterburn D; PCORnet Bariatric Study Collaborative (2020) Comparing the 5-Year Diabetes Outcomes of Sleeve Gastrectomy and Gastric Bypass: The National Patient-Centered Clinical Research Network (PCOR-Net) Bariatric Study. JAMA Surg 155(5):e200087.

- 83. Mooney SJ, Bobb JF, Hurvitz PM, Anau J, Theis MK, Drewnowski A, Aggarwal A, Gupta S, Rosenberg DE, **Cook AJ**, Shi X, Lozano P, Moudon AV, and Arterburn D. (2020) Impact of Built Environments on Body Weight (the Moving to Health Study): Protocol for a Retrospective Longitudinal Observational Study. *JMIR Res Protoc* 219;9(5):e16787.
- 84. Chubak J, Anderson ML, **Cook AJ**, Murphy CC, Jackson ML, and Green BB (2020) Methodologic Considerations in Calculating and Analyzing Proportion of Time Covered as a Measure of Longitudinal Cancer Screening Adherence *Cancer Epidemiol Biomarkers Prev* 29(9): 1549-1556.
- 85. Lentz TA, Curtis LH, Rockhold FW, Martin D, Andersson TLG, Arias C, Berlin JA, Binns C, Cook A, Cziraky M, Dent R, Desai M, Emmett A, Esserman D, George J, Hantel S, Heagerty P, Hernandez AF, Hucko T, Khan N, Lee SF, LoCasale R, Mardekian J, McCall D, Monda K, Normand SL, Riesmeyer J, Roe M, Roessig L, Scott R, Siedentop H, Waldstreicher J, Wang L, Weerakkody G, Wolf M, and Ellenberg SS (2020) Designing, Conducting, Monitoring, and Analyzing Data from Pragmatic Randomized Clinical Trials: Proceedings from a Multi-stakeholder Think Tank Meeting *Ther Innov Regul Sci* 54(6): 1477-1488.
- 86. Rose CM, Gupta S, Buszkiewicz J, Ko LK, Mou J, Cook A, Moudon AV, Aggarwal A, Drewnowski A. (2020) Small increments in diet cost can improve compliance with the Dietary Guidelines for Americans Soc Sci Med 266:113359.
- 87. Gupta S, Rose CM, Buszkiewicz J, Ko LK, Mou J, **Cook A**, Aggarwal A, Drewnowski A (2020) Characterising percentage energy from ultra-processed foods by participant demographics, diet quality and diet cost: findings from the Seattle Obesity Study (SOS) III Br J of Nutr 126(5):773-781.
- 88. Buszkiewicz J, Rose C, Gupta S, Ko LK, Mou J, Moudon AV, Hurvitz PM, **Cook A**, Aggarwal A, Drewnowski A. (2020) A cross-sectional analysis of physical activity and weight misreporting in diverse populations: The Seattle Obesity Study III *Obes Sci Pract* 6(6):615-627.
- 89. Buszkiewicz JH, Bobb JF, Hurvitz PM, Arterburn D, Moudon AV, Cook A, Mooney SJ, Cruz M, Gupta S, Lozano P, Rosenberg DE, Theis MK, Anau J, and Drewnowski (2021) Does the built environment have independent obesogenic power? Urban form and trajectories of weight gain Int J Obes 45(9): 1914-1924.
- 90. Green BB, Anderson ML, Cook AJ, Chubak J, Fuller S, Meenan RT, Vernon SW (2021) Centralized Mailed Program with Stepped Support Increases Adherence to Colorectal Cancer Screening over 9 Years: A Randomized Trial J Gen Intern Med 28:1-8.
- 91. Wartko PD, Boudreau DM, Turner JA, Cook AJ, Wellman RD, Fujii MM, Garcia RC, Moser KA, and Sullivan MD (2021) STRategies to Improve Pain and Enjoy life (STRIPE): Protocol for a pragmatic randomized trial of pain coping skills training and opioid medication taper guidance for patients on long-term opioid therapy *Contemp Clin Trials* 110:106499.
- 92. Buszkiewicz JH, Bobb JF, Kapos F, Hurvitz PM, Arterburn D, Moudon AV, Cook A, Mooney SJ, Cruz M, Gupta S, Lozano P, Rosenberg DE, Theis MK, Anau J, and Drewnowski (2021) Differential associations of the built environment on weight gain by sex and race/ethnicity but not age *Int J Obes* 45(12):2648-2656.
- 93. Rosenberg DE, Greenwood-Hickman MA, Zhou J, Cook AJ, Mettert KD, Cooper J, Arterburn D, Green BB, Walsh-Bailey C, Kerr J, Owen N, Dunstan D, and McClure JB (2021) Protocol for a Randomized Controlled Trial of Sitting Reduction to Improve Cardiometabolic Health in Older Adults Contemp Clin Trials 111:106593.
- 94. Wang X, Turner EL, Li F, Wang R, Moyer J, Cook AJ, Murray DM, and Heagerty PJ (2022) Two Weights Make a Wrong: Cluster Randomized Trials with Variable Cluster Sizes and Heterogeneous Treatment Effects Contemp Clin Trials epub: doi: 10.1016/j.cct.2022.106702
- 95. Green BB, Anderson ML, Cook AJ, Ehrlich K, Hall YN, Hsu C, Joseph D, Klasnja P, Margolis KL, McClure JB, Munson SA, and Thompson M. (2022) Clinic, Home, and Kiosk blood pressure measurements for diagnosing hyptertension: a Randomized Diagnostic Study. J Gen Intern Med 37(12):2948-2956.
- 96. Green BB, Anderson ML, Cook AJ, Ehrlich K, Hall YN, Margolis KL, and Thompson M. (2022) Automated Office Blood Pressure and the Impact of Attendance and Rest on Diagnostic Accuracy. Am J Hypertens 35(7):638-646.
- 97. Bobb JF, Cruz MF, Mooney SJ, Drewnowski A, Arterburn D, and **Cook AJ** (2022) Accounting for spatial confounding in epidemiological studies of individual-level exposures: an exposure penalized

spline approach JRSS-A 185(3):1271–1293.

- 98. Greenwood-Hickman MA, Zhou J, Cook A, Mettert KD, Green B, McClure J, Arterburn D, Florez-Acevedo S, and Rosenberg DE (2022) Exploring Differences in Older Adult Accelerometer-Measured Sedentary Behavior and Resting Blood Pressure Before and During the COVID-19 Pandemic Gerontol Geriatr Med 8:23337214221096007
- 99. Cruz M, Drewnowski A, Bobb JF, Hurvitz PM, Moudon AV, **Cook A**, Mooney SJ, Buszkiewicz JH, Kapos F, Theis MK, Anau J, and Arterburn D (2022) Differences in weight gain following residential relocation in the Moving to Health(M2H) Study *Epidemiology* 33(5):747-755.
- 100. Buszkiewicz JH, Rose CM, Ko LK, Mou J, Moudon AV, Hurvitz PM, Cook AJ, and Drewnowski A. (2022) Associations between neighborhood built environment, residential property values, and adult BMI change: The Seattle Obesity Study III SSM Popul Health 19:101158.
- 101. Coleman KJ, Wellman R, Fitzpatrick SL, Conroy MB, Hlavin C, Lewis KH, Coley RY, McTigue KM, Tobin JN, McBride CL, Desai JR, Clark JM, Toh S, Sturtevant JL, Horgan CE, Duke MC, Williams N, Anau J, Horberg MA, Michalsky MP, Cook AJ, Arterburn DE, Apovian CM; PCORnet Bariatric Study Collaborative (2022) Comparative Safety and Effectiveness of Roux-en-Y Gastric Bypass and Sleeve Gastrectomy for Weight Loss and Type 2 Diabetes Across Race and Ethnicity in the PCORnet Bariatric Study Cohort JAMA Surg 157(10): 897-906.
- 102. Coughlin JW, Nauman E, Wellman R, Coley RY, McTigue KM, Coleman KJ, Jones DB, Lewis K, Tobin JN, Wee CC, Fitzpatrick SL, Desai JR, Murali S, Morrow EH, Rogers AM, Wood GC, Schlundt DG, Apovian CM, Duke MC, McClay JC, Soans R, Nemr R, Williams N, Courcoulas A, Holmes JH, Anau J, Toh S, Sturtevant JL, Horgan CE, Cook AJ, Arterburn DE; PCORnet Bariatric Study Collaborative. (2023) Preoperative Depression Status and Five Year Metabolic and Bariatric Surgery Outcomes in the PCORnet Bariatric Study Cohort. Ann Surg 277(4):637-646.
- 103. Chen JA, Anderson ML, Cherkin DC, Balderson BH, Cook AJ, Sherman KJ, and Turner JA (2023) Moderators and nonspecific predictors of treatment benefits in a randomized trial of mindfulness-based stress reduction versus cognitive-behavioral therapy versus usual care for chronic low back pain J Pain 24(2): 282-303.
- 104. Nelson JC, Ulloa-Perez E, Yu O, Cook AJ, Jackson MJ, Belongia E, Daley MF, Harpaz R, Kharbanda EO, Klein NP, Naleway A, Tseng HF, Weintraub E, and Yih WK (2023) Active Post-Licensure Safety Surveillance for Recombinant Zoster Vaccine Using Electronic Health Record Data Am J Epidemiol 192(2): 205-216.
- 105. Gray SL, Fornaro R, Turner J, Boudreau DM, Wellman R, Tannenbaum C, Marcum ZA, Balderson B, Cook A, Jacobsen AL, and Phelan EA (2023) Provider knowledge, beliefs, and self-efficacy to deprescribe opioids and sedative-hypnotics J of Am Geriatrics Soc 71(5): 1580-1586.
- 106. Thompson MJ, Anderson ML, Cook AJ, Ehrlich K, Hall YN, Hsu C, Margolis KL, McClure JB, Munson SA, and Green BB (2023) Acceptability and Adherence to Home, Kiosk, and Clinic Blood Pressure Measurement Compared to 24-H Ambulatory Monitoring. J Gen Intern Med 38(8):1854-1861.
- 107. Mayhew M, Balderson BH, Cook AJ, Dickerson JF, Elder CR, Firemark AJ, Haller IV, Justice M, Keefe FJ, McMullen CK, O'Keeffe-Rosetti MC, Owen-Smith AA, Rini C, Schneider JL, Von Korff M, Wandner LD, and DeBar LL. (2023) Comparing the clinical and cost-effectiveness of remote (telehealth and online) cognitive behavioral therapy-based treatments for high-impact chronic pain relative to usual care: study protocol for the RESOLVE multisite randomized control trial *Trials* 24(1):196.
- 108. DeBar LL, Justice M, Avins AL, Cook A, Eng CM, Herman PM, Hsu C, Nielsen A, Pressman A, Stone KL, Teets RY, and Wellman RD (2023) Acupuncture for Chronic Low Back Pain in Older Adults: Design and Protocol for the BackInAction Pragmatic Clinical Trial Contemp Clin Trials 128:107166.
- 109. Balderson BH, Gray SL, Fujii MM, Nakata KG, Williamson BD, **Cook AJ**, Wellman R, Theis MK, Lewis CC, Key D, and Phelan EA (2023) A health-system-embedded deprescribing intervention targeting patients and providers to prevent falls in older adults (STOP-FALLS trial): study protocol for a pragmatic cluster-randomized controlled trial *Trials* 24(1):322.
- 110. Wartko PD, Krakauer C, Turner JA, **Cook AJ**, Boudreau DM, and Sullivan MD (2023) STRategies to Improve Pain and Enjoy life (STRIPE): results of a pragmatic randomized trial of pain coping skills training and opioid medication taper guidance for patients on long-term opioid therapy *PAIN* 164(12):2852-2864.

- 111. Williamson BD, Coley RY, Hsu C, McCracken CE, and **Cook AJ** (2024) Considerations for Subgroup Analyses in Cluster-Randomized Trials Based on Aggregated Individual-Level Predictors *Prev Sci* 25(Suppl 3):421-432.
- 112. Qiu H, **Cook AJ**, and Bobb JF (2024) Evaluating tests for cluster-randomized trials with few clusters under generalized linear mixed models with covariate adjustment: a simulation study *Stat Med* 43(2):201-215.
- 113. Hsu C, Williamson BD, Becker M, Berry B, **Cook AJ**, Derus A, Estrada C, Gacuiri M, Kone A, McCracken C, McDonald B, Piccorelli AV, Senturia K, Volney J, Wilson KB, and Green BB (2024) Engaging staff to improve COVID-19 vaccination response at long-term care facilities (ENSPIRE): A cluster randomized trial of co-designed, tailored vaccine promotion materials *Contemp Clin Trials* 136:107403.
- 114. Rosenberg DE, Cruz MF, Mooney SJ, Bobb JF, Drewnowski A, Moudon AV, **Cook AJ**, Hurvitz PM, Lozano P, Anau J, Theis MK, and Arterburn DE (2024) Neighborhood built and food environment in relation to glycemic control in people with type 2 diabetes in the Moving to Health Study. *Health Place* 86:103216.
- 115. Rosenberg DE, Zhu W, Greenwood-Hickman MA, **Cook AJ**, Acevedo SF, McClure JB, Arterburn DE, Cooper J, Owen N, Dunstan D, Perry SR, Yarborough L, Mettert KD, and Green BB (2024) Effectiveness of an Intervention to Reduce Sitting Time and Improve Blood Pressure in Older Adults: A Randomized Clinical Trial JAMA Netw Open 7(3):e243234
- 116. Lozano PM, Bobb JF, Kapos FP, Cruz M, Mooney SJ, Hurvitz PM, Anau J, Theis K, **Cook AJ**, Moudon AV, Arterburn D, and Drewnowsky A. (2024) Residential density is associated with BMI trajectories in children and adolescents: Findings from the M2H Study *APJM Focus* 3(3):100225
- 117. Phelan EA, Williamson BD, Balderson BH, Cook AJ, Piccorelli AV, Fujii MM, Nakata KG, Graham VF, Theis MK, Turner JP, Tannenbaum C, and Gray SL (2024) Reducing Central Nervous System-Active Medications to Prevent Falls and Injuries Among Older Adults: A Cluster Randomized Clinical Trial. JAMA Netw Open 7(7):e2424234.
- 118. Moyer JC, **Cook AJ**, Heagerty PJ, Li F, Pals SL, Turner EL, Wang X, Yu Q, Zhou Y, Murray DM (2024) Evaluating analytic models for individually randomized group treatment trials with complex clustering in nested and crossed designs *Stat Med* 43 (25): 4796-4818.
- 119. Li K, Emerman I, Cook AJ, Fireman BH, Sundaram M, Tseng HX, Weintraub ES, Yu O, Nelson JL, Shi X (2024) Using Double Negative Controls to Adjust for Healthy User Bias in a Recombinant Zoster Vaccine Safety Study Am J Epidemiol epub: doi: 10.1093/aje/kwae439.
- 120. Bobb J, Mooney S, Cruz M, Vernez Moudon A, Drewnowski A, Arterburn D, and **Cook A** (2024) Distributed lag models for retrospective cohort data with application to a study of built environment and body weight *Biometrics* In Press

* indicates student supervised by Cook

b) Other Peer-reviewed Scholarly Publications:

- 1. Cook, A.J. and Li, Y. (2008) Rejoinder to: Spatial Cluster Detection for Censored Outcome Data, Biometrics 64(4): 1289-1292.
- Drewnowski, A., Aggarwal, A., Cook, A.J., Stewart, O., and Moudon, A.V. (2016) Rejoinder to: Geographic disparities in Healthy Eating Index scores (HEI-2005 and 2010) by residential property values: Findings from Seattle Obesity Study (SOS) Prev Med 85:117-118.

c) Books and book chapters:

Not applicable

d) Other Non-peer-reviewed scholarly publications:

1. Cook, A.J., Wellman, R.D., Tiwari, R.C., Li, L., Heckbert, S., Marsh, T., Heagerty, P., and Nelson, J.C. (2011) Mini-Sentinel Methods Development: Statistical approaches for group sequential monitoring of postmarketing safety surveillance data: Overview and simulation evaluation of methods applicable to the Mini-Sentinel surveillance project, *FDA's Sentinel Initiative: Project Report.*

- Cook, A.J., Wellman, R.D., Marsh, T., Tiwari, R.C., Nguyen, M.D., Russek-Cohen, E., Jiang, Z., and Nelson, J.C. (2012) Mini-Sentinel Methods Development: Statistical Methods for Estimating Causal Risk Differences in the Distributed Data Setting for Postmarket Safety Outcomes, *FDA's Sentinel Initiative: Project Report.*
- 3. Cook, A.J., Wellman, R.D., Shoaibi, A., Tiwari, R.C., Boudreau, D., Goonesekera, S., Marsh, T.L., and Nelson, J.C. (2013) Mini-Sentinel Methods Development: Feasibility of New Mini-Sentinel Group Sequential Monitoring Methods in a Distributed Setting Implementation in Practice, *FDA's Sentinel Initiative: Project Report.*
- DeLong, E., Cook, A., NIH Biostatistics/Design Core. (2014) Unequal Cluster Sizes in Cluster-Randomized Clinical Trials. NIH Collaboratory Living Textbook; Available from: https://www. nihcollaboratory.org/Products/Varying-cluster-sizes_V1.0.pdf.
- DeLong, E., Li, L., Cook, A., NIH Biostatistics/Design Core. (2014) Pair-Matching vs stratification in Cluster-Randomized Trials. NIH Collaboratory Living Textbook; Available from: https://www. nihcollaboratory.org/Products/Pairing-vs-stratification_V1.0.pdf.
- DeLong, E., Li, L., Cook, A., NIH Biostatistics/Design Core. (2014) Key Issues in Extracting Usable Data from Electronic Health Records for Pragmatic Clinical Trials. NIH Collaboratory Living Textbook; Available from: https://www.nihcollaboratory.org/Products/Extracting-EHR-data_ V1.0.pdf.
- Xu, S., Shetterly, S., Cook, A.J., Raebel, M.A., Goonesekera, S., Shoaibi, A., Frimpong, E. Roy, J., Fireman, B., and McEvoy, B. (2014) Mini-Sentinel Methods Development: Statistical Methods for Improving Confounder Adjustment for Emergent Treatment Comparison, *FDA's Sentinel Initiative: Project Report.*
- Cook, A., NIH Biostatistics/Design Core. (2015) Small-Sample Robust Variance Correction for Generalized Estimating Equations for Use in Cluster Randomized Clinical Trials. NIH Collaboratory Living Textbook; Available from: https://www.nihcollaboratory.org/Products/Variance-correction-for-GEE_ V1.R0.pdf.
- 9. Cook, A.J., Wellman, R.D., Shoaibi, A., Tiwari, R.C., Heckbert, S.R., Li, L., Izem, R., Zhang, R., and Nelson, J.C. (2015) Mini-Sentinel Methods Development: Safety Signaling Methods for Survival Outcomes to Control for Confounding in the MSDD, *FDA's Sentinel Initiative: Project Report*.
- 10. Cook, A.J., Wellman, R.D., Xu, S., Izem, R., Zhang, R., Nguyen, M., Tiwari, R.C., Heckbert, S.R., Gruber, S., and Nelson, J.C. (2016) Mini-Sentinel Methods Development: Comparing Different Cox PH confounder adjustment methods including direct adjustment, propensity score adjustment (directly or through splines), and propensity score stratification in the setting of multiple sites, FDA's Sentinel Initiative: Project Report.
- 11. Cook, A.J., Li, F., Murray, D.M., Delong, E.R. (2018) Alternative Cluster Randomized Designs. NIH Collaboratory Living Textbook; Available from: http://rethinkingclinicaltrials.org/chapters/ design/analysis-plan-top/alternative-cluster-randomized-designs/.
- Green BB, Anderson ML, Cook AJ, et al. (2021) Comparing the Effectiveness of Home, Clinic, and Kiosk Blood Pressure Checks for Diagnosing High Blood Pressure – The BP-CHECK Study [Internet]. Washington (DC): Patient-Centered Outcomes Research Institute (PCORI); 2021 Aug. Available from: https://www.ncbi.nlm.nih.gov/books/NBK605480/ doi: 10.25302/08.2021.CER.151132979

e) Submitted Manuscripts:

- 1. Cook AJ, Wellman RD, Marsh T, Tiwari RC, Nguyen MD, Russek-Cohen E, Peng Y, and Nelson JC Estimating risk differences using large healthcare data networks for medical product postmarket safety outcomes in a distributed data setting and allowing for active postmarket surveillance
- 2. Danyang L, Cruz MF, Mooney SJ, **Cook AJ**, and Bobb JF Comparison of Spatial Spline Models and Matching Methods to Adjust for Unmeasured Spatial Confounding for Binary Exposures
- 3. Hyun NE, Idu A, **Cook A**, and Bobb J Increased risk of type I errors for detecting heterogeneity of treatment effects in cluster-randomized trials using mixed-effect models

8. PATENTS AND OTHER INTELLECTUAL PROPERTY:

Not Applicable

a) Funded Projects

- 1. Resuscitation Outcomes Consortium (ROC) Data Coordinating Center (5U01HL077863-04), PI: Emerson, NHLBI, Co-I, 0.20 1.00 FTE, 07/01/2005-04/30/2009.
- Understanding Variability in Community Mammography (5R01CA107623-06), PI: Elmore, NCI, Co-I, 0.10 - 0.20 FTE, 05/01/2006-04/30/2010.
- Electronic Communications and Home B.P. Monitoring (5R01HL075263-04), PI: Green, NHLBI, Co-I, 0.20 FTE, 05/1/2006-05/31/2008.
- Effect of Massage on Chronic Low Back Pain (5R01AT001927-04), PI: Cherkin, NCCAM, Co-I, 0.10 -0.15 FTE, 09/30/2005-08/31/2010.
- A Partly Conditional Survival Approach for Modeling the Time-Varying Association Between Breast Density and Breast Cancer Risk (263-MQ-612311), PI: Miglioretti, NCI, Co-I, 0.20 FTE, 09/20/2006-09/19/2007.
- Therapeutic Massage for Generalized Anxiety Disorder (5R21AT002560-03), PI: Sherman, NCCAM, Co-I, 0.05 FTE, 09/30/2006-08/31/2009.
- Effect of Yoga Versus Stretching on Chronic Back Pain (5U01AT003208-03), PI: Sherman, NCCAM, Co-I, 0.05-0.20 FTE, 09/30/2006-08/31/2010.
- Food Environment, Diet Quality, and Disparities in Obesity (1R01DK076608-01A1), PI: Drewnowski, NIDDK, Co-I, 0.20 FTE, 03/01/2008-02/28/2010.
- Development of a Versatile Geospatial Database within the CRN CRN Pilot: Cancer Research Network Across Health Care Systems (5U19CA079689-10), PI: Wagner, NCI, Project PI, 0.10 FTE, 05/01/2008-04/30/2009.
- Review of Statistical Methods for Post-Marketing Medical Product Safety (HHSF223200S31324P), PI: Nelson, FDA, Co-I, 0.10 FTE, 09/19/2008-03/18/2009.
- 11. Training doctors to disclose unanticipated outcomes to patients: Randomized Trial (R01HS16506-01), PI: Gallagher, AHRQ, Co-I, 0.05-0.15 FTE, 09/30/2008-09/29/2013.
- Dosing Study of Massage for Neck Pain (1R01AT004411-01A2), PI: Sherman, NCCAM, Co-I, 0.10-0.30 FTE, 6/1/2009-2/28/2013.
- Prospective Drug Safety Surveillance using Sequential Analytic Methods: Two Approaches for Confounding Adjustment (LI09OMOP1), PI: Li, Foundation for NIH, Site PI, 0.20 FTE, 09/01/2009-08/31/2010.
- 14. e-COMPARE: Comparing Pharmacist and Health Educator Web-based Care for Metabolic Syndrome (1RC1HL100590-01), PI: Green, NHLBI, Co-I, 0.05 FTE, 09/30/2009-07/31/2011.
- 15. Long-Term Outcomes and Costs of Web-Based Hypertension Care (2R01HL075263-05), PI: Green, NHLBI, Co-I, 0.05 FTE, 12/01/2009-11/30/2013.
- 16. Efforts to Develop the Sentinel Initiative: Sequential Testing Methods Development (Mini-Sentinel Task Order), PI: Platt, FDA, Task Order PI, 0.30 FTE, 02/01/2010-02/28/2011.
- 17. Enhancing current sequential analytic techniques to improve causal inference (Mini-Sentinel Task Order), PI: Platt, FDA, Task Order PI, 0.30 FTE, 03/01/2011-01/31/2012.
- Food Environment, Diet Quality, and Disparities in Obesity II (R210086001), PI: Drewnowski, NIDDK, Co-I, 0.10-0.30 FTE, 04/15/2011-02/29/2016.
- 19. Comparison of CAM and Conventional Mind-Body Therapies for Chronic Back Pain (R01AT006226), PI: Cherkin, NCCAM, Co-I, 0.05-0.15 FTE, 08/01/2011-05/31/2015.
- New Sequential Methods in the Distributed Data Setting, PI: Platt, FDA (Mini-Sentinel Task Order), Task Order PI, 0.30 FTE, 06/01/2012-05/31/2013.
- FDA Sentinel Emergent Treatment Task Order (Mini-Sentinel Task Order), PI: Platt, FDA (Mini-Sentinel Task Order), Co-I, 0.10 FTE, 09/01/2012-12/31/2013.
- 22. Vaccine Safety Datalink(VSD) Project: VSD Project Infrastructure Activities (200-2012-53421), PI: Jackson, CDC, Co-I, 0.10-0.20 FTE, 09/28/2012-09/27/2017.
- 23. Health Care Systems Research Collaboratory Coordinating Center (U54 AT007748), PI: Hernandez, NCCAM, Co-I, 0.15 FTE, 09/30/2012-08/31/2017.

- 24. Evaluation of a Patient-Centered Risk Stratification Method for Improving Primary Care for Back Pain (PCORI Pragmatic Trial), PI: Cherkin, PCORI, Co-I, 0.05-0.10 FTE, 03/01/2013-11/30/2016.
- 25. Systems of Support (SOS) to Increase Colon Cancer Screening and Follow-up (R01 CA121125), PI Green, NCI, Co-I 0.05-0.10 FTE, 09/01/2013-06/30/2019.
- Safety Signaling Methods for Survival Outcomes to Control for Confounding (Mini-Sentinel Task Order), PI: Platt, FDA, Task Order PI, 0.30 FTE, 09/01/2013-01/31/2015.
- Oral Health 4 Life: Promoting Oral Health among Tobacco Quitline Callers (U01 DE024462), PI: McClure, NIDCR, Co-I, 0.05 FTE, 08/01/2014-06/30/2017.
- 28. Comparison of safety signaling methods for survival outcomes to control for confounding in the MSDD (Mini-Sentinel Task Order), PI: Platt, FDA, Task Order PI, 0.30 FTE, 05/01/2015-10/31/2016.
- 29. Food Environment, Diet Quality and Disparities in Obesity II (2RO1 DK076608-08A1), PI: Drewnowski, NIDDK, Co-I, 0.05-0.15 FTE, 12/1/2015-7/31/2020.
- Ensuring Pragmatic and Appropriate Learning within Health Care Delivery Systems: Design, Analysis, and Interpretation of Longitudinal Cluster Randomized Trials (ME-1507-31750), PI: Heagerty, PCORI, Co-I, 0.15 FTE, 08/01/2016-05/31/2019.
- Blood Pressure Checks for Diagnosing Hypertension (BP-CHECK) (CER-1511-32979), PI: Green, PCORI, Co-I, 0.05-0.10 FTE, 11/1/2016-11/1/2019.
- Moving to Health: How Changing Built Environments Impact Weight and Glycemic Control (R01 DF114196), PI: Arterburn, NIDDK, Co-I, 0.15 FTE, 09/15/2017-06/30/2022.
- NIH Health Care Systems Research Collaboratory Coordinating Center (U24 AT009676), PI: Hernandez, NCCIH, Co-I, 0.10 FTE, 09/15/2017-08/31/2022.
- Vaccine Safety Datalink (VSD) Project: Infrastructure Activities (200-2012-53421), PI: Jackson, CDC, Co-I, 0.10 FTE, 09/28/2017-09/27/2022.
- Randomized Trial on Pain Self-Management Training to Support Prescription Opioid Taper (R01 DA044970), PI: Sullivan, NIDA, Site PI, 0.05-0.15 FTE, 03/15/2018-12/31/2022.
- 36. Randomized Trial to Reduce Sitting Time and Improve Cardiometabolic Health in Obese Older Adults (R01 HL132880), PI: Rosenburg, NHLBI, Co-I, 0.05-0.10 FTE, 06/01/2018-12/31/2023.
- Reducing CNS-active Medications to Prevent Falls and Injuries in Older Adults (U01 CE002967), PI: Phelan, CDC, Co-I, 0.10-0.20 FTE, 09/30/2018-12/31/2023.
- NIH HEAL Coordinating Center (U24 AT009676), PI: Hernandez, NCCIH, Co-I, 0.10 FTE, 09/28/2019-08/31/2024.
- Pragmatic Trial of Acupuncture for Chronic Low Back Pain in Older Adults (UH3 AT010739), PIs: DeBar and Cook, NCCIH, MPI, 0.10-0.30 FTE, 9/28/2019-8/31/2025.
- 40. Tailored Non-Pharmacotherapy Services for Chronic Pain: Testing Scalable and Pragmatic Approaches (UH3 AG067493), PI: DeBar, NIA, Site PI, 0.10-0.30 FTE, 9/30/2019-8/31/2025.
- 41. Engaging Staff to Improve COVID-19 Vaccination Rates at Long Term Care Facilities (ENSPIRE), PIs: Hsu and McCracken, PCORI, Co-I, 0.10-0.15, 8/1/2021 1/31/2023.
- NIH Health Care Systems Research Collaboratory Coordinating Center (U24 AT009676), PI: Hernandez, NCCIH, Co-I, 0.10 FTE, 09/1/2022-08/31/2028.
- 43. Vaccine Safety Datalink (VSD) Project: Infrastructure Activities (200-2012-53421), PI: Jackson, CDC, Co-I, 0.10 FTE, 09/28/2022-09/27/2027.
- 44. De Pie y a Movernos Study: Promoting Physical Activity in Older Latinx Adults, PI: Rosenberg, NIA, Co-I, 0.05 FTE, 9/1/2023-8/31/2027.

b) Pending Applications

10. CONFERENCES and SYMPOSIUMS:

- 1. "Detecting Spatial Clustering in Matched Case-Control Studies", Harvard Environmental Statistics Symposium, Sheffield, MA (Nov 2004)
- 2. * "Detecting Spatial Clustering for Binary and Failure Time Outcomes", Group Health Research Institute Seminar, Seattle, WA (Feb 2005)
- 3. * "Detecting Spatial Clustering for Binary and Failure Time Outcomes", University of Washington, Department of Biostatistics Seminar, Seattle, WA (Feb 2005)

- 4. * "Detecting Spatial Clustering for Binary and Failure Time Outcomes", Oregon State University, Department of Public Health Seminar, Corvallis, OR (Mar 2005)
- 5. "Detecting Spatial Clustering in Matched Case-Control Studies", ENAR Student Awards Session, Austin, TX (Mar 2005)
- 6. "Detecting Spatial Clustering for Matched Case-Control Studies", JSM Environmental Student Awards Session, Minneapolis, MN (Aug 2005)
- 7. * "Spatial Cluster Detection for Repeated Measures Outcomes", University of Washington, Department of Biostatistics Seminar, Seattle, WA (Nov 2006)
- 8. "Spatial Cluster Detection for Repeated Measures Outcomes", JSM, Salt Lake City, UT (Aug 2007)
- 9. "Spatial Cluster Detection for Repeated Measures Outcomes", ENAR, Crystal City, VA (Mar 2008)
- 10. "Spatial Cluster Detection for Weighted Outcomes using Cumulative Geographic Residuals", ENAR, San Antonio, TX (Mar 2009)
- 11. *"Spatial Cluster detection for Censored Outcomes", International Conference on Financial Statistics and Financial Econometrics - Nonparametric Modeling and Its Application, Session: Censored Data Analysis with High Dimensional Covariates, Chengdu, China (Jul 2009)
- 12. "Methods for Post-marketing vaccine safety surveillance: The Vaccine Datalink experience", Group Health Research Institute Seminar, Seattle, WA (Oct 2008)
- 13. * "Incorporating confounder adjustment into methods for monitoring post-licensure vaccine safety", Pediatric Academic Society Meeting, Session: Statistical Advances for the Evaluation of Childhood Vaccines, Baltimore, MD (May 2009)
- 14. "Group Sequential Methods for Observational data Incorporating Confounding through Estimating Equations with application in Post-Marketing Vaccine/Drug Surveillance", University of Washington, Department of Biostatistics Seminar, Seattle, WA (Mar 2010)
- "Group Sequential Methods for Observational data Incorporating Confounding through Estimating Equations with application in Post-Marketing Vaccine/Drug Surveillance", ENAR, New Orleans, LA (Mar 2010)
- 16. *"Group Sequential Methods for Observational data Incorporating Confounding through Estimating Equations with application in Post-Marketing Vaccine/Drug Surveillance", MSPW, Session: Postmarketing drug safety, Ball State University, Muncie, IN (May 2010)
- 17. *"Group Sequential Methods for Observational data Incorporating Confounding through Estimating Equations with application in Post-Marketing Vaccine/Drug Surveillance", WNAR, Session: Statistical Methods for Vaccine Safety, Seattle, WA (Jun 2010)
- 18. *"Sequential Monitoring Task Order: Group Sequential Methods for Observational data Incorporating Confounding through Estimating Equations", FDA Mini-sentinel webinar (Jun 2010)
- 19. "Comparison of statistical approaches for Group Sequential Monitoring: simulation results and recommendations", VSD Annual Meeting, Portland, OR (Apr 2011)
- 20. *"Comparison of statistical approaches for Group Sequential Monitoring: simulation results and recommendations", FDA Mini-Sentinel Webinar (May 2011)
- 21. "Challenges in Conducting Sequentially Monitored Medical Product Safety Studies Using Electronic Health Care Utilization Data", ISPE, Chicago, IL (Aug 2011)
- 22. *"Group Sequential Methods for Observational data Incorporating Confounding through Estimating Equations with application in Post-Marketing Vaccine/Drug Surveillance", ISCB, Ottawa, ON, Canada (Aug 2011)
- 23. "Group Sequential Methods: Phase II", VSD Annual Meeting, Denver, CO (Mar 2012)
- 24. *"Summary of Mini-Sentinel PRISM task order for Estimating Risk Differences in the Distributed Data Setting for Postmarket Safety Outcomes", FDA Mini-Sentinel Webinar (May 2012)
- 25. *"Method for Estimating Risk Differences in the Distributed Data Setting for Postmarket Safety Outcomes", FDA Mini-Sentinel Annual Meeting (Feb 2013)
- 26. *"Methodological Challenges for Sequential Medical Product Safety Surveillance using Observational Healthcare Data", ENAR, Baltimore, MD (Mar 2014)

- 27. *"New Sequential Methods in a Distributed Data Setting applied to Mini-Sentinel Data", FDA Mini-Sentinel Webinar (Apr 2014)
- 28. *"Adapting Sequential Methods for Active Medical Product Safety Surveillance in a Distributed Health Care Database Setting", Seattle Symposium on Health Care Data Analytics, Seattle, WA (Sep 2014)
- 29. *"Methods for using EHR data to conduct Active Safety Surveillance Studies of New Medical Products", Duke Clinical Research Institute Seminar Series, Durham, NC (Oct 2014)
- 30. "Comparison of Different Sequential Methods Using the MMRV Example", VSD Annual Meeting, Atlanta, GA (Nov 2014)
- *"Safety Signaling Methods for Survival Outcomes to Control for Confounding", FDA Mini-Sentinel Webinar (Feb 2015)
- 32. "Risk Difference versus Odds Ratio for Surveillance: Application MMRV", VSD Annual Meeting (Nov 2015)
- 33. *"Survival Methods for Postmarketing Medical Product Surveillance in a Distributed Network", ENAR, Austin, TX (Mar 2016)
- 34. *"Group Sequential Monitoring for Drug and Vaccine Safety using Inverse Probability of Treatment Weighting", WNAR/IBC, Victoria, BC Canada (Jul 2016)
- 35. *"Comparing Propensity Score Stratification and Adjustment for the Cox PH Regression in the Setting of Multiple Sites", FDA Sentinel Webinar (Aug 2017)
- 36. *"Methods for using EHR data to Conduct Active Safety Surveillance Studies of New Medical Products", Emory University, Dept. of Biostatistics and Bioinformatics (Sep 2018)
- 37. "Potential Efficiency of Cluster Randomization with Crossover", WNAR, Flagstaff, AZ (Jun 2006)
- 38. *"Statistical issues in designing unblinded randomized controlled studies for non-pharmaceutical therapy focusing on massage and yoga interventions for neck and back pain", JSM, Miami, FL (Aug 2011)
- 39. "Web-based Team Care to Improve Hypertension Control the e-BP* study and BEYOND: Long-term Results", GHRI Seminar Series, Seattle, WA (Oct 2013)
- 40. *"Improving Pragmatic Clinical Trials: Lessons Learned from the NIH Collaboratory Biostatistics Core", University of Penn 8th Annual Conference on Statistical Issues in Clinical Trials, Philadelphia, PA (Apr 2015)
- 41. "Improving Pragmatic Clinical Trials: Lessons Learned from the NIH Collaboratory Biostatistics Core", NIH Collaboratory Grand Rounds Webinar (Jun 2015)
- 42. "Pragmatic Clinical Trial Challenges: Lessons Learned from the NIH Collaboratory Biostatistics Core", GHRI Seminar Series (Oct 2015)
- 43. *"Pragmatic Clinical Trial Challenges: Lessons Learned from the NIH Collaboratory Biostatistics Core", Seattle Symposium on Health Care Data Analytics, Seattle, WA (Oct 2016)
- 44. "Lessons Learned from the NIH Collaboratory Biostatistics Core up to 2016", NIH Collaboratory Grand Rounds Webinar (Dec 2016)
- 45. *"Pragmatic Clinical Trial Challenges: Lessons Learned from the NIH Collaboratory Biostatistics and Design Core", Georgia CTSA BERD Research Forum, Advances & Challenges in Pragmatic Trials, Morehouse School of Medicine, Atlanta, GA (Sep 2018)
- 46. *"Assessing Bias when Evaluating Data Completeness when using EHR data", Pragmatic Clinical Trial Think Tank, Washington DC (Jan 2019)
- "Design and Analysis of Embedded Pragmatic Clinical Trials within Health Care Systems: Lessons Learned from the NIH Collaboratory", Dept. of Biostatistics, University of Washington, Seattle, WA (May 2019)
- *"Protecting Patient Privacy: Distributed Analyses for Multi-site Observational Studies", JSM, Baltimore, MD (Jul 2017)

- 49. *"The Role of Health Care Data analytics in Health Policy Decision-making", JSM Speaker Lunch Session, Seattle, WA (Aug 2015)
- 50. *"Design and Analysis to Address Potential Calendar Time Bias in Subgroup Analyses of RCTs: BIA and COVID", WNAR, Fort Collins, CO (Jun 2024) Like presentations grouped; * indicates invited presentation

11. PROFESSIONALLY-RELATED COMMUNITY SERVICE:

- Science Club for Girls, Cambridge MA, Spring 2004, Mentor-Scientist for K-1st Graders.
- Community for Youth, Seattle WA, Sept 2017-June 2020, Mentor for underserved high school teens.

12. TEACHING HISTORY:

Formal Courses

- BIO/STAT 533: Linear Regression, Spring 2016
- BIO 582: Student Seminar, Winter 2019

Guest Lecturer Courses

Dept. of Health Services, University of Washington • Advanced Health Services Research Methods I, Special Topic: Spatial Statistics, Nov. 2007

Dept. of Biostatistics, University of Washington

• Advanced Health Services Research Methods I, Special Topic: Causal Inference, Feb. 2016

Teaching Assistant Courses

- Spatial Statistics (R and ArcGIS), Fall 2004
- Applied Longitudinal Analysis (SAS), Fall 2003 and 2004
- Regression and ANOVA (STATA), Spring 2003 and 2004
- Basics in Statistical Inference, Fall 2001 and 2002

13. ADVISING and FORMAL MENTORING:

a) PhD Dissertation, chair

- Xu Shi, Dept. of Biostatistics, Univ. of Washington, Grad.: Jun 2017.

b) Masters Theses, chair

- Kelly Stratton, Dept. of Biostatistics, Univ. of Washington, Grad.: Aug 2012.

- c) Mentored Scientists and Postdocs
 - H. Molly Grow MD, Fellow, Seattle Childrens Hospital, Fall 2006 to Fall 2008
 - Anju Aggarwal PhD, Research Associate, Dept. of Nutrition, Univ of Washington, Fall 2007 to Summer 2010
 - Rebecca Seguin PhD, Postdoc, Women's Health post-doctoral fellow, Fall 2009 to Spring 2011
 - Rebecca Seguin PhD, K01 Award Recipient, Advisory board member, Fall 2012 to Summer 2014
 - Dori Rosenberg PhD, K01 Award Recipient, Mentorship committee member, Fall 2014 to Spring 2016
- d) MS and PhD Committees in non-chair roles:
 - PhD Committee:
 - Colleen Sitlani, Dept. of Biostatistics, Univ. of Washington, Grad.: June 2011.

Master Committee:

- Lei Wang, Dept. of Biostatistics, Univ. of Washington, Grad.: Dec 2017.
- e) Other Advising/Mentoring

Research Assistants

- Paramita Saha, Fall 2005 to Spring 2006
- Colleen Sitlani, Fall 2006 to Fall 2007
- Siobhan Everson-Stewart, Fall 2006 to Spring 2008
- Shanshan Zhao, Fall 2007 to Fall 2009
- Kelly Stratton, Fall 2010 to Summer 2012
- Xu Shi, Spring 2015 to Summer 2017

Biostatistician Supervisor

- Melissa Anderson MS, Jan. 2009 to Mar 2022
- Robert Wellman MS, Oct 2009 to Present
- Onchee Yu MS, Oct 2014 to Present

Dept. of Biostatistics, Harvard University

Curriculum Vitae

- $-\,$ Jing Zhou PhD, Oct 2017 to Apr 2020 $\,$
- $-\,$ Maricela Cruz PhD, Jan 2020 to Mar 2022
- Rod Walker MS, Jan 2020 to Mar 2022
- $-\,$ Yu-Ru Su PhD, Jan 2020 to Mar 2022
- $-\,$ Yates Coley PhD, Jan 2020 to Present
- Weiwei Zhu MS, Jan 2020 to Present
- Abisola Idu MS, Jan 2020 to Present
- -Brian Williamson PhD, Sep 2021 to Present
- $-\,$ Chloe Krakauer PhD, Mar 2023 to Present
- f) Academic Advising

14. OTHER PERTINENT INFORMATION AS NEEDED:

Not Applicable