

CURRICULUM VITAE Jennifer Clark Nelson

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1. Biographical Information

Jennifer Clark Nelson, PhD
Director of Biostatistics and Senior Investigator
Biostatistics Unit
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2. Education

B.A. (*summa cum laude*), Mathematics and Accounting, Luther College, Decorah, IA, 1994
M.S., Biostatistics, University of Washington, Seattle, WA, 1996
Ph.D., Biostatistics, University of Washington, Seattle, WA, 1999 (Advisor: Dr. Margaret Pepe)

3. Licensure

Not applicable

4. Professional Positions

1994-1997	Pre-doctoral Research Assistant Group Health Research Institute, Seattle, WA
1997-1999	Pre-doctoral Research Assistant Biostatistics Division, Fred Hutchinson Cancer Research Center, Seattle, WA
1999-2003	Research Scientist & Deputy Director, Multi-Ethnic Study of Atherosclerosis Department of Biostatistics, University of Washington, Seattle, WA
2003-present	Scientific Investigator (Assistant 2003-2009, Associate 2009-2014, Full 2014+) Biostatistics Unit, Kaiser Permanente Washington Health Research Institute, Seattle, WA
2004-present	Affiliate Professor (Assistant 2004-2010, Associate 2011-2015, Full 2016+) Department of Biostatistics, University of Washington, Seattle, WA
2014-present	Director of Biostatistics Biostatistics Unit, Kaiser Permanente Washington Health Research Institute, Seattle, WA

5. Honors, Awards, and Scholarships

1993-1994	CoSIDA GTE Academic All-American, Volleyball Luther College, Decorah, IA
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1994	National Collegiate Athletic Association (NCAA) Postgraduate Scholar Luther College, Decorah, IA
1994	Pi Mu Epsilon National Mathematics Honor Society Luther College, Decorah, IA
1994	Phi Beta Kappa National Honor Society Luther College, Decorah, IA
1994-1996	Achievement Rewards for College Scientists (ARCS) Fellowship University of Washington, Seattle, WA
1994-1999	National Institutes of Health Predoctoral Trainee in Cardiovascular Research Department of Biostatistics, University of Washington, Seattle, WA
1999	Outstanding Student Award Department of Biostatistics, University of Washington, Seattle, WA
2009	Margarette Kolczak Award for outstanding contributions in vaccine statistics Centers for Disease Control & Prevention (CDC), Atlanta, GA
2012	Best poster, Databases Special Interest Group International Conference on Pharmacoepidemiology, Barcelona, Spain
2013	Paper selected among the 2013 Articles of the Year <i>American Journal of Epidemiology</i> and the Society for Epidemiologic Research
2015	Best reviewer, <i>Pharmacoepidemiology and Drug Safety</i>
2019	Distinguished Alumni Service Award Luther College, Decorah, IA
2020	Fellow, American Statistical Association (ASA)

6. Other Professional Activities

Statistical Consultancies

1995	Cancer Center, University of Washington Medical Center, Seattle, WA
2003-2004	Department Family and Child Nursing, University of Washington, Seattle, WA
2003-2006	Divisions of Epidemiology and Medicine, Columbia University, New York, NY
2009	Global Clinical Safety & Pharmacovigilance, GlaxoSmithKline, Research Triangle Park, NC

Memberships

1999-2003	Member: Executive, Operations Committee, Ultrasound, and Computed Tomography Committees for NHLBI's Multi-Ethnic Study of Atherosclerosis Department of Biostatistics, University of Washington, Seattle, WA
1999-present	Member, The American Statistical Association (ASA)
1999-present	Member, The International Biometric Society (WJAR)
2003-present	Member, Methodology Committee, Vaccine Safety Datalink collaboration, CDC
2005-2007	Member, Executive Committee, ASA's Section in Epidemiology
2004-2007 & 2018-present	Member, Affiliate Faculty Appointments Committee, Department of Biostatistics University of Washington, Seattle, WA
2006-2018	Member, Vaccine Safety Datalink Annual Meeting Planning Committee
2007-2008 & 2012-2013	Member, Scientific Policy Committee, Group Health Research Institute
2008 & 2011	Member, Strategic Planning Committee, Group Health Research Institute
2009-2012	Member, International Biometric Society Regional Advisory Board (WJAR)
2010-2014	Invited member, Vaccines Subcommittee, International Society for Clinical Biostatistics (ISCB)

- 2013-2016 Invited member, Methods Scientific Advisory Committee, Reagan-Udall Foundation's Innovation in Medical Evidence Development and Surveillance (IMEDS) Program for the Food and Drug Administration (FDA)
- 2018-present Invited member, Data Monitoring Committee, HEPLISAV-B Vaccine Post Marketing Surveillance Study, Southern California Permanente Medical Group
- 2019-present Invited member, Strategic Plan Steering Committee, School of Public Health, University of Washington
- 2019-present Invited member, Advisory Board, Sentinel Site Readiness for Maternal Immunization Active Safety Surveillance in Low & Middle Income Countries, The Bill & Melinda Gates Foundation

Leadership

- 1999-2003 Chair, Quality Control Committee, Multi-Ethnic Study of Atherosclerosis, NHLBI
- 2006-2007 Chair, Affiliate Faculty Appointments Committee, Department of Biostatistics, University of Washington
- 2006-2008 Program Chair, Joint Statistical Meetings, ASA's Section in Epidemiology (chair-elect 2006, chair 2007, past chair 2008)
- 2008-2014 Chair, Methodology Committee, CDC's Vaccine Safety Datalink collaboration
- 2009-2019 Co-Lead, Methods Core, FDA's Sentinel Initiative to improve drug safety
- 2011-2013 Secretary, Vaccines Subcommittee, ISCB
- 2011 Co-Organizer, Vaccines Mini-Symposium at 32nd ISCB, Ottawa, Canada
- 2012 Co-Organizer, Vaccines Mini-Symposium at 33rd ISCB, Bergen, Norway
- 2013 Co-Organizer, Vaccines Mini-Symposium at 34th ISCB, Munich, Germany
- 2013-2014 Co-Chair, Vaccines Subcommittee, ISCB
- 2014 Co-Founder & Moderator, 1st Seattle Symposium on Health Care Data Analytics: Confronting statistical challenges of using electronic health record data to conduct health research, September 28-30, Seattle WA
- 2015 Invited Moderator, America's Health Insurance Plans (AHIP) Roundtable: From Personalized Medicine to Population Health – Maximizing the Value of Data, December 3, Washington D.C.
- 2016 Co-Organizer, 2nd Seattle Symposium on Health Care Data Analytics: Learning from electronic data to advance health and health care, October 23-25, Seattle WA.
- 2016 Organizer, WNAR-invited session on "Statistical methods to improve drug and vaccine safety surveillance using big health care data," XXVIIIth International Biometric Conference (IBC), July 10-15, Victoria B.C.
- 2017 Invited participant, Roundtable on "Integrating patient-reported health data and electronic health records data for pragmatic health research," Hosted by Duke Clinical Research Institute and the NIH, September 14, Bethesda MD
- 2018 Organizer, Invited session on "Improving the use of propensity score methods in large health care databases with rare outcomes," ASA's International Conference on Health Policy Statistics, January 10-12, Charleston SC
- 2018 Invited panelist, Improving the efficiency of outcome validation in the Sentinel System, Duke-Margolis Center for Health Policy, Washington DC, May 17, 2018
- 2018 Mentor, ASA's Statistics in Epidemiology Section Mentoring Program
- 2018 Invited panelist, Signal Detection Capabilities in the Sentinel System, Duke-Margolis Center for Health Policy, Bethesda MD, December 3, 2018
- 2018-present Associate Editor, *Vaccine*
- 2019-present Executive Committee, FDA Sentinel Initiative Innovation Center
- 2020-present Council of Sections Representative, ASA Section on Statistics in Epidemiology

Journal referee

Journal of Computational and Graphical Statistics, Statistics in Medicine, American Journal of Epidemiology, Epidemiology, Journal of Clinical Epidemiology, Pharmacoepidemiology and Drug Safety, Circulation, Vaccine, American Journal of Preventive Medicine, Journal of Infectious Diseases, Archives of Pediatrics & Adolescent Medicine, BMC Medical Research Methodology

Ad hoc reviewer

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| 2014 | Meeting abstracts, International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE) |
| 2012 | Analysis plan, Developing and evaluating methods for record linkage and reducing bias in patient registries, Agency for Healthcare Research and Quality |
| 2017 | Methodological report, Causal Inference for Effectiveness Research in Using Secondary Data, Patient Centered Outcomes Research Institute (PCORI) |
| 2017 | Short course proposal, Statistical Analysis of Large Administrative Health Databases, Banff International Research Station (BIRS) |

7. Bibliography

*Denotes mentored work of student

†Denotes mentored work of junior scientist

a) Peer-reviewed research articles

1. McBride CM, Curry SJ, Grothaus LC, **Nelson JC**, Lando HL and Pirie PL. Partner smoking status and pregnant smoker's perceptions of support for and likelihood of smoking cessation. *Health Psychol* 1998;17:63-69.
2. Hellerstedt WL, Pirie PL, Lando HL, Curry SJ, McBride CM, Grothaus LC, and **Nelson JC**. Differences in preconceptional and prenatal behaviors in women with intended and unintended pregnancies. *Am J Public Health* 1998;88(4):663-666.
3. McBride CM, Curry SJ, Lando HL, Pirie PL, Grothaus LC, and **Nelson JC**. Prevention of relapse in women who quit smoking during pregnancy. *Am J Pub Hlth* 1999;89(5):706-711.
4. Ludman EJ, McBride CM, **Nelson JC**, Curry SJ, Grothaus LC, Lando HL, and Pirie PL. Stress, depressive symptoms, and smoking cessation among pregnant women. *Health Psychol* 2000;19(1):21-27.
5. **Nelson JC**, Pepe MS. Statistical description of interrater variability in ordinal ratings. *Stat Methods Med Res* 2000;9(5):475-496.
6. Rautaharju PM, **Nelson JC**, Kronmal RA, Zhang Z, Robbins J, Gottdiener J, Furberg CD, Manolio T, and Fried L. Usefulness of T-axis deviation as an independent risk indicator for incident cardiac events in older men and women free from coronary heart disease (the Cardiovascular Health Study). *Am J Cardiol* 2001;88(2):118-123.
7. Yanez ND III, Kronmal RA, **Nelson JC**, Alonzo TA. Analyzing change in clinical trials using quasi-likelihood. *J Applied Stat* 2002;29(8):1135-1145.
8. Bild DE, Bluemke DA, Burke GL, Detrano R, Diez Roux AV, Folsom AR, Greenland P, Jacobs Jr. DR, Kronmal RA, Liu K, **Nelson JC**, O'leary D, Saad MF, Shea S, Szklo M, Tracy RP. The Multi-Ethnic Study of Atherosclerosis (MESA): Objectives and Design. *Am J Epidemiol* 2002;156(9):871-881.

9. Robbins J, **Nelson JC**, Rautaharju PM, and Gottdiener J. The association between the length of the QT interval and mortality in the Cardiovascular Health Study. *Am J Med* 2003;115(9):689–694.
10. Carr JJ, **Nelson JC**, Wong ND, McNitt-Gray M, Arad Y, Jacobs DR Jr, Sidney S, Bild DE, Williams OD, Detrano RC. Calcified coronary artery plaque measurement with cardiac CT in population-based studies: standardized protocol of the Multi-Ethnic Study of Atherosclerosis (MESA) and Coronary Artery Risk Development in Young Adults (CARDIA). *Radiology* 2005;234(1):35-43.
11. **Nelson JC**, Kronmal RA, Carr JJ, McNitt-Gray MF, Wong ND, Loria C, Goldin JG, Williams OD, Detrano R. Measuring coronary calcium on CT images adjusted for attenuation differences. *Radiology* 2005; 235(2): 403-414.
12. Lydon-Rochelle MT, Holt VL, Cardenas V, **Nelson JC**, Easterling TR, Gardella C, Callaghan WM. The reporting of pre-existing maternal medical conditions and complications of pregnancy on birth certificates and in hospital discharge data. *Am J Obstet Gynecol* 2005;193(1):125-134.
13. Jackson LA, Neuzil KM, Whitney CG, Starkovich P, Dunstan M, Yu O, **Nelson JC**, Feikin DR, Shay DK, Baggs J, Carste B, Nahm MH, Carlone G. Safety of varying dosages of 7-valent pneumococcal protein conjugate vaccine in seniors previously vaccinated with 23-valent pneumococcal polysaccharide vaccine. *Vaccine* 2005;23(28):3697–3703.
14. Detrano RC, Anderson M, **Nelson JC**, Wong ND, Carr JJ, McNitt-Gray M, Bild DE. Coronary calcium measurements: effect of CT scanner type and calcium measure on rescan reproducibility--MESA study. *Radiology* 2005;236: 477-484.
15. Lydon-Rochelle MT, Cardenas V, **Nelson JC**, Tomashek KM, Mueller BA, Easterling TR. Validity of maternal and perinatal risk factors reported on fetal death certificates. *Am J Public Health* 2005;95(11):1948-1951. Epub 2005 Sep 29.
16. Lydon-Rochelle MT, Holt VL, **Nelson JC**, Cardenas V, Gardella C, Easterling TR, Callaghan WM. Accuracy of reporting maternal in-hospital diagnoses and intrapartum procedures in Washington State linked birth records. *Pediatr Perinat Epidemiol* 2005;19: 460-471.
17. Jackson LA, **Nelson JC**, Whitney CG, Neuzil KM, Benson P, Malais D, Baggs J, Mullooly J, Black S, Shay DK. Assessment of the safety of a third dose of pneumococcal polysaccharide vaccination in the Vaccine Safety Datalink population. *Vaccine* 2006;24(2): 151-156. Epub 2005 Aug 10.
18. Rautaharju PM, Ge S, **Nelson JC**, Larsen EKM, Psaty BM, Furberg CD, Zhang Z, Robbins J, Gottdiener JS, Chaves PHM. Comparison of mortality risk for electrocardiographic abnormalities in men and women with and without coronary heart disease (from the Cardiovascular Health Study). *Am J Cardiol* 2006;97:309-315. Epub 2005 Dec 1.
19. Jackson LA, Dunstan M, Starkovich P, Dunn J, Yu O, **Nelson JC**, Rees T, Zavitkovsky A. Prophylaxis with acetaminophen or ibuprofen for prevention of local reactions to the fifth DTaP vaccination: a randomized, controlled trial. *Pediatrics* 2006;117: 620-625.
20. Jackson LA, Jackson M, **Nelson JC** Neuzil KM, Weiss NS. Evidence of bias in estimates of influenza vaccine effectiveness in seniors. *Int J Epidemiol* 2006;35: 337-344.
21. Jackson LA, **Nelson JC**, Benson P, Neuzil KM, Reid RJ, Psaty BM, Heckbert SR, Larson EB, Weiss NS. Functional status is a confounder of the association of influenza vaccine and risk of all cause mortality in seniors. *Int J Epidemiol* 2006;35:345-352. Epub 2005 Dec 20.
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23. Neuzil KM, Jackson LA, **Nelson JC**, Klimov A, Cox N, Bridges CB, Dunn J, DeStefano F, Shay D. Immunogenicity and reactogenicity of 1 versus 2 doses of trivalent inactivated

- influenza vaccine in vaccine-naïve 5-8-year-old children. *J Infect Dis.* 2006;194(8):1032-1039. Epub 2006 Sep 11.
24. Lydon-Rochelle MT, Holt V, **Nelson JC**, Cardenas V. Induction of labor in the absence of standard medical indication: incidence and correlates. *Med Care.* 2007; 45(6):505-12.
 25. Jackson ML, **Nelson JC**, Chen RT, Davis RL, Jackson LA. Vaccines and changes in coagulation parameters in adults on chronic warfarin therapy: a cohort study. *Pharmacoepidemiol Drug Saf.* 2007; 16(7):790-796. Epub 2007 Feb 8.
 26. Jackson LA, Neuzil KM, Nahm MH, Whitney CG, Yu O, **Nelson JC**, Starkovich PT, Dunstan M, Carste B, Shay DK, Baggs J, Carlone GM. Immunogenicity of varying dosages of 7-valent pneumococcal polysaccharide-protein conjugate vaccine in seniors previously vaccinated with 23-valent pneumococcal polysaccharide vaccine. *Vaccine.* 2007; 25:4029-4037.
 27. Jackson LA, Starkovich P, Dunstan M, Yu O, **Nelson JC**, Dunn J, Rees T, Zavitkovsky A, Maus D, Froeschle JE, Decker M. Prospective assessment of the effect of needle length and injection site on the risk of local reactions to the 5th Diphtheria-Tetanus-Acellular Pertussis vaccination. *Pediatrics.* 2008;121:e646-e652.
 28. **Nelson JC**, Jackson ML, Yu O, Whitney CG, Bounds L, Bittner R, Zavitkovsky A, Jackson LA. Impact of the introduction of pneumococcal conjugate vaccine on rates of community acquired pneumonia in children and adults. *Vaccine.* 2008; 26:4947-54. Epub 2008 Jul 25.
 29. Jackson ML, **Nelson JC**, Weiss NS, Neuzil KM, Barlow W, Jackson LA. Influenza vaccination and risk of community-acquired pneumonia in immunocompetent elderly people: a population-based, nested case-control study. *Lancet.* 2008; 372:398-405.
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 31. Jackson ML, **Nelson JC**, Jackson LA. Risk factors for community-acquired pneumonia in immunocompetent seniors. *J Am Geriatrics Society.* 2009; 57:882-8.
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 33. Jackson LA, Yu O, **Nelson JC**, Belongia EA, Hambidge SJ, Baxter R, Naleway A, Nordin J, Baggs J, Iskander J. Risk of medically attended local reactions following diphtheria toxoid containing vaccines in adolescents and young adults: a Vaccine Safety Datalink study. *Vaccine.* 2009; 27:4912-6. Epub 2009 Jun 28.
 34. **Nelson JC**, Bittner RCL, Bounds L, Zhao S, Baggs J, Donahue JG, Hambidge SJ, Jacobsen SJ, Klein NP, Naleway AL, Zangwill KM, Jackson LA. Compliance with multiple-dose vaccine schedules among older children, adolescents, and adults: results from a Vaccine Safety Datalink Study. *Am J Public Health* 2009 Oct;99 Suppl 2:S389-97.
 35. Jackson LA, Yu O, Belongia EA, Hambidge SJ, **Nelson JC**, Baxter R, Naleway A, Gay C, Nordin J, Baggs J, Iskander J. Frequency of medically attended adverse events following tetanus and diphtheria toxoid vaccine in adolescents and young adults: a Vaccine Safety Datalink study. *BMC Infect Dis.* 2009;9:165.
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 37. †Yu O, **Nelson JC**, Bounds L, Jackson LA. Classification algorithms to improve the accuracy of identifying patients hospitalized with community-acquired pneumonia using administrative data. *Epidemiol Infect.* 2011;139:1296-1306. Epub 2010 Nov 19;1-11.
 38. Jackson LA, Yu O, **Nelson JC**, Dominguez CP, Peterson D, Baxter R, Hambidge SJ, Naleway AL, Belongia EA, Nordin JD, Baggs J for the Vaccine Safety Datalink Team.

- Injection site and risk of medically attended local reactions to the acellular pertussis vaccine. *Pediatrics* 2011;127(3):e581-e587. Epub 2011 Feb 7.
39. Xu S, Zhang L, **Nelson JC**, Zeng C, Mullooly J, McClure D, Glanz J. Identifying optimal risk windows for self-controlled case series studies of vaccine safety. *Statistics in Medicine* 2011;30(7):742-752. Epub 2010 Nov 30.
 40. Jackson LA, Peterson D, Dunn J, Hambidge SJ, Dunstan M, Starkovich P, Yu, O, Benoit J, Dominguez-Islas CP, Carste, B, Benson P, **Nelson JC**. A randomized placebo-controlled trial of acetaminophen for prevention of post-vaccination fever in infants. *PLoS ONE* 2011; 6(6): e20102.
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 42. Li L, Kulldorff M, **Nelson JC**, Cook AJ. A propensity score-enhanced sequential analytic method for comparative drug safety surveillance. *Statistics in Biosciences*. 2011; 3(1):45-62. doi: 10.1007/s12561-011-9034-5.
 43. Weiner SD, Jin Z, Cushman M, **Nelson JC**, Saad M, Di Tullio MR, Homma S. Brachial artery endothelial function and coagulation factors in the Multi-Ethnic Study of Atherosclerosis (MESA). *J Amer Coll Cardiol*. 2011; 57(14s1):E1414-E1414.
 44. **Nelson JC**, Cook AJ, Yu O, Zhao S, Jackson LA, Psaty BM. Methods for observational post-licensure medical product safety surveillance. *Statistical Methods in Medical Research*. 2015; 24(2):177-193. Epub 2011 Dec 2.
 45. Dublin S, Walker RL, Jackson ML, **Nelson JC**, Weiss NS, Von Korff M, Jackson LA. Use of opioids or benzodiazepines and risk of pneumonia in older adults: a population-based case-control study. *Journal of the American Geriatrics Society*. 2011; 59(10):1899-907. doi: 10.1111/j.1532-5415.2011.03586.x. Epub 2011 Sep 13.
 46. **Nelson JC**, Cook AJ, Yu O, Zhao S, Dominguez C, Fireman B, Greene S, Jacobsen SJ, Weintraub E, Jackson LA. Challenges in the design and analysis of sequentially-monitored post-licensure safety surveillance studies using observational health care utilization data. *Pharmacoepidemiology and Drug Safety*. 2012; 21 Suppl 1:62-71. doi: 10.1002/pds.2324.
 47. †Cook AJ, Wellman RD, Marsh T, Li L, Heckbert S, Heagerty P, Tiwari RC, **Nelson JC**. Statistical approaches to group sequential monitoring of post-marketing safety surveillance data: Current state of the art for use in the Mini-Sentinel surveillance project. *Pharmacoepidemiology and Drug Safety*. 2012; 21 Suppl 1:72-81. doi: 10.1002/pds.2320.
 48. Maclure M, Fireman B, **Nelson JC**, Hua W, Shoaibi A, Paredes A, Madigan D. When should case-only designs be used for safety monitoring of medical products? *Pharmacoepidemiology and Drug Safety*. 2012; 21 Suppl 1:50-61. doi: 10.1002/pds.2330.
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- Atherosclerosis (MESA). *Journal of the American College of Cardiology: Cardiovascular Imaging*. 2012;5:358-366.
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 54. *Zhao S, Cook AJ, Jackson LA, **Nelson JC**. Statistical performance of group sequential testing methods for post-licensure medical product safety surveillance: a simulation study. *Statistics and Its Interface*. 2012; 5:381-390.
 55. **Nelson JC**, Yu O, Dominguez C, Cook AJ, Peterson D, Greene SK, Yih K, Daley MF, Jacobsen SJ, Klein NP, Weintraub E, Jackson LA. Adapting group sequential methods to observational post-licensure safety surveillance: Results of a pentavalent combination DTaP-IPV-Hib (Pentacel) vaccine safety study. *Am J Epidemiol*. 2013; Jan 15;177(2):131-41. doi: 10.1093/aje/kws317
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 57. Glanz JM, Newcomer SR, Narwaney KJ, Hambidge SJ, Daley MF, Wagner NM, McClure DL, Xu S, Rowhani-Rahbar A, Lee GM, **Nelson JC**, Donahue JG, Naleway AL, Nordin JD, Lugg MM, Weintraub ES. A population-based cohort study of undervaccination in 8 managed care organizations across the United States. *JAMA Pediatr*. 2013; 167(3):274-81. doi: 10.1001/jamapediatrics.2013.502.
 58. Dublin S, Baldwin E, Walker RL, Christensen LM, Haug PJ, Jackson ML, **Nelson JC**, Ferraro J, Carrell D, Chapman WW. Natural language processing to identify pneumonia from radiology reports. *Pharmacoepidemiol Drug Saf*. 2013. Apr 1. doi: 10.1002/pds.3418.
 59. †Jackson ML, **Nelson JC**. The “test-negative case-control” design for estimating influenza vaccine effectiveness. *Vaccine*. 2013; 31(17):2165-8. doi: 10.1016/j.vaccine.2013.02.053.
 60. **Nelson JC**, Marsh T, Bittner RCL, Lumley T, Larson EB, Jackson LA, Jackson ML. Validation sampling can reduce bias in healthcare database studies: an illustration using influenza vaccination effectiveness. *J Clin Epidemiol*. 2013; 66(8): S110-121.
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 63. Xu S, Zeng C, Newcomer S, **Nelson JC**, Glanz J. Use of fixed effects models to analyze self-controlled case series data in vaccine safety studies. *J Biom Biostat*. 2012 Apr 19;Suppl 7:006.
 64. Xu S, Newcomer SR, **Nelson JC**, Chan L, McClure D, Pan Yi, Zeng C, Glanz J. Signal detection of adverse events with imperfect confirmation rates in vaccine safety studies using self-controlled case series design. *Biometrical Journal* 2014 May;56(3):513-25.
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- Weintraub E, DeStefano. Timely versus delayed early childhood vaccination and seizures. *Pediatrics* 2014 Jun;133(6):e1492-9. doi: 10.1542/peds.2013-3429
67. **Nelson JC**, Shortreed S, Yu O, Peterson D, Baxter R, Fireman B, Lewis N, McClure D, Weintraub E, Xu S, Jackson LA on behalf of the Vaccine Safety Datalink project. Integrating database knowledge and epidemiological design to improve the implementation of data mining methods to evaluate vaccine safety in large healthcare databases. *Stat Analysis Data Mining* 2014 Oct;7(5):337-351. doi:10.1002/sam.11232
 68. Weiner SD, Ahmed HN, Jin Z, Cushman M, Herrington DM, **Nelson JC**, Di Tullio MR, Homma S. Systemic inflammation and brachial artery endothelial function in the Multi-Ethnic Study of Atherosclerosis (MESA). *Heart* 2014 Jun;100(11):862-6. doi: 10.1136/heartjnl-2013-304893.
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92. Shi X, Wellman R, Heagerty P, **Nelson JC**, Cook AJ. Safety surveillance and the estimation of risk in select populations: flexible methods to control for confounding while targeting marginal comparisons. *Stat Med*. 2019 Dec 10. doi: 10.1002/sim.8410. [Epub ahead of print].
93. Shi X, Miao W, **Nelson JC**, Tchetgen E. Multiply Robust Causal Inference with Double Negative Control Adjustment for Categorical Unmeasured Confounding (in press *Journal of the Royal Statistical Society: Series B*)
94. Gruber S, Fireman B, Zhang Z, Wellman R, Franklin J, Izem R, **Nelson JC**, Wyss R, Maro J, Murray C, Toh S, Gagne J, Amsden LB, Schneeweiss S. Consequences of depletion of susceptibles for hazard ratio estimators based on propensity scores (in press *Epidemiology*)

b) Other peer-reviewed scholarly publications

1. Dublin S, Weiss NS, **Nelson JC**, and Jackson ML. Statins and outcomes in patients with pneumonia: potential sources of bias. *British Medical Journal*. Epub 2006 Nov 17. A response to Majumdar SR et al, "Statins and outcomes in patients admitted to hospital with community acquired pneumonia: population based prospective cohort study." *BMJ* 2006; 333:999
2. Jackson ML, Weiss NS, **Nelson JC**, Jackson LA. To rule out confounding, observational studies of influenza vaccine need to include analyses during the 'preinfluenza' period. *Archives Internal Medicine* 2007; 167(14):1553-4; author reply 1554-5. A response to Spaude KA et al, "Influenza vaccination and risk of mortality among adults hospitalized with community-acquired pneumonia." *Arch Int Med* 2007; 167(1):53-9.
3. **Nelson JC**, Jackson ML, and Jackson LA. Effectiveness of influenza vaccine: To the editor. *N Engl J Med* 2007; 357(26):2728-9. A response to Nichol KL et al, "Effectiveness of influenza vaccine in the community-dwelling elderly." *N Engl J Med* 2007; 357(14):1373-81.
4. Jackson LA, **Nelson JC**. Association between statins and mortality: To the editor. *Journal of Infectious Diseases*; Epub 2012, May 8. doi: 10.1093/infdis/jis344.

c) Books and book chapters

Not applicable

d) Other non-peer-reviewed scholarly publications

1. Gagne J, Fireman B, Ryan P, Maclure M, Gerhard T, Toh D, Rassen JA, **Nelson JC**, and Schneeweiss S. (2010) Taxonomy for monitoring methods within a medical product safety surveillance system: Year 1 report of the Mini-Sentinel Taxonomy Project Workgroup. Available at http://www.mini-sentinel.org/methods/methods_development.
2. Cook AJ, Wellman RD, Tiwari RC, Li L, Heckbert S, Marsh T, Heagerty P and **Nelson JC**. (2011) Statistical approaches for group sequential monitoring of postmarketing safety surveillance data. An Overview and simulation evaluation of methods applicable to the Mini-Sentinel surveillance pilot: Report of the Mini-Sentinel Sequential Methods Project Workgroup. Available at http://www.mini-sentinel.org/methods/methods_development.

3. Madigan D, Fireman B, Maclure M, Simpson S, Hua W, Paredes A, **Nelson JC**, and Shoaibi A. Case-based methods: Report of the Mini-Sentinel Case-Based Methods Project Workgroup. Available at http://www.mini-sentinel.org/methods/methods_development
4. Cook AJ, Wellman RD, Marsh T, Tiwari RC, Nguyen MD, Russek-Cohen E, Jiang Z and **Nelson JC**. (2012) Statistical methods for estimating causal risk differences in the distributed data setting for postmarket safety outcomes: Report of the Mini-Sentinel Sequential Monitoring with Causal Inference Project Workgroup. Available at http://www.mini-sentinel.org/methods/methods_development.
5. Gagne J, **Nelson JC**, Fireman B, Seeger JD, Toh D, Gerhard T, Rassen JA, Shoaibi A, Reichman M, and Schneeweiss S. (2012) Taxonomy for monitoring methods within a medical product safety surveillance system: Year 2 report of the Mini-Sentinel Taxonomy Workgroup. Available at http://www.mini-sentinel.org/methods/methods_development
6. Cook AJ, Wellman RD, Shoaibi A, Tiwari RC, Boudreau D, Goonesekera S, Marsh TL, and **Nelson JC**. (2013) Demonstrate feasibility of new Mini-Sentinel group sequential monitoring methods in a distributed setting by implementing them in practice: Report of the Mini-Sentinel Group Sequential Methods Development Workgroup. Available at http://www.mini-sentinel.org/methods/methods_development.
7. Dublin S, Walker R, Rutter C, **Nelson JC**, Fireman B, Graham D, Psaty B, Setoguchi S, and Shoaibi A. (2014) Collecting Supplemental Information via Two-Phase Study Designs to Investigate Signals Arising from Medication Safety Surveillance Activities: Report of the Mini-Sentinel 2-phase Methods Development Workgroup. Available at http://www.mini-sentinel.org/methods/methods_development.
8. Cook AJ, Wellman RD, Shoaibi A, Tiwari RC, Heckbert SR, Li L, Izem R, Zhang R, and **Nelson JC**. (2014) Safety signaling methods for survival outcomes to control for confounding in the Mini-Sentinel Distributed Database: Report of the Mini-Sentinel Survival Methods Workgroup. Available at http://www.mini-sentinel.org/methods/methods_development
9. Carnahan RC, Gagne JJ, **Nelson JC**, Fireman B, Wang S, Shoaibi A, Reichman M, Zhang R, Levenson M, Graham D, Tiwari R, Southworth MR, Archdeacon P, Chakravarty A, Goulding M, Brown J, Fuller C, Toh D, Chrischilles E. Mini-Sentinel Prospective Routine Observational Monitoring Program Tools (PROMPT): Rivaroxaban Surveillance: Report of the Rivaroxaban Surveillance Workgroup. Available at: http://www.mini-sentinel.org/work_products/Assessments/Mini-Sentinel_PROMPT_Rivaroxaban-Surveillance-Plan.pdf.
10. **Nelson JC**, Boudreau D, Wellman R, Yu O, Cook AJ, Maro J, Ouellet-Hellstrom R, Floyd J, Heckbert S, Pinheiro S, Reichman R, Shoaibi A. (2015) Improving surveillance planning methods for routine assessments that use regression adjustment or weighting to control confounding: Report of the Working on Mini-Sentinel Prospective Routine Observational Monitoring Program Tools for Regression and Weighting Methods. Available at: http://www.mini-sentinel.org/methods/methods_development.

e) Submitted manuscripts

1. Cook AJ, Wellman RD, Marsh TL, Tiwari RC, Nguyen MD, Russek-Cohen E, Jiang Z, **Nelson JC**. A group sequential method to estimate causal risk differences in an observational distributed health care database setting.
2. Berrueta M, Bardach A, Ciaponni A, Xiong X, Stergachis A, Zarea S, Buekens P, Scoping Review Collaboration Group (including **Nelson JC**). Maternal and neonatal data collection systems in low- and middle-income countries: scoping review protocol. [version 1; peer review: awaiting peer review]. *Gates Open Res* 2020, 4:18 (<https://doi.org/10.12688/gatesopenres.13106.1>)

3. Panagiotakopoulos L, McCarthy NL, Tepper N, Kharbanda EO, Lipkind H, Vazquez-Benitez G, McClure DL, Greenberg V, Getahun D, Glanz J, Naleway A, Klein NP, Nelson JC, Weintraub ES. Evaluating stillbirths after maternal immunization in the Vaccine Safety Datalink.

8. Patents and Other Intellectual Property

Not applicable

9. Funding History

a) Funded projects

1. Multiple Principal investigator (0.10 FTE): Sentinel Innovation Center, 2019-2023. Funded by the FDA (Principal Investigator, Richard Platt, MD, MSc; Harvard Medical School). Direct costs: \$249,935.
2. Co-Investigator (0.30 FTE): Vaccine Safety Datalink Infrastructure Task Order, 2017-2022. Funded by the CDC (Principal Investigator, Lisa Jackson, MD, MPH). Direct costs: ~\$2.3M.
3. Co-Investigator (0.05 FTE): Influenza Vaccine Effectiveness Center, 2016-2021. Funded by the CDC (Principal Investigator: Michael Jackson, PhD; U01IP001037). Direct Costs: \$3,161,462.
4. Task Order Co-Principal Investigator (0.10 FTE): The Sentinel Operations Center Learning Phenotype Laboratory, Phase 1, 2018-2020. Funded by the FDA (Principal Investigator, Richard Platt, MD, MSc; Harvard Medical School). Direct costs: \$424,991.
5. Task Order Co-Principal Investigator (0.10 FTE): The Sentinel Operations Center Learning Phenotype Laboratory, Phase 2: 2019-2021. Funded by the FDA (Principal Investigator, Richard Platt, MD, MSc; Harvard Medical School). Direct costs: \$528,484.
6. Co-investigator (0.10 FTE): Aging eyes and aging brains in studying Alzheimer's disease: modern ophthalmic data collection in the Adult Changes in Thought (ACT) study, 2019-2023. Funded by the National Institute on Aging (Principal Investigator, Cecilia Lee, MD, MS). Direct costs: \$3.9M.
7. Co-investigator (0.03 FTE): Adult Changes in Thought (ACT) study. Funded by the National Institute on Aging (Principal Investigators, Eric Larson, MD and Paul Crane, MD). Direct costs: \$10.3M.
8. Site Principal investigator (0.05 FTE): Shingrix vaccine surveillance, 2018-2019. Funded by GlaxoSmithKline (Principal Investigator, Jeff Brown ScD). Direct costs: \$16,105.

b) Completed projects

1. Senior Statistician and Co-Investigator (0.25 FTE from 8/99-8/03): Cardiovascular Health Study Morbidity and Mortality Follow-up - Coordinating Center, 1/1/88-5/31/05. Funded by the National Heart Lung and Blood Institute (Principal Investigator, Richard Kronmal, PhD). Direct costs: \$18,576,105.
2. Deputy Director and Co-Investigator (0.75 FTE 8/99-8/03): Subclinical Cardiovascular Disease Study – Coordinating Center (alternate name: Multi-Ethnic Study of Atherosclerosis, MESA), 1/15/99-8/14/09. Funded by the National Heart Lung and Blood Institute (Principal Investigator, Richard Kronmal, PhD). Direct costs: \$11,699,997.
3. Co-Investigator (0.10 FTE): Impact of Introduction of Pneumococcal Conjugate Vaccine on Pneumonia in Adults, 10/1/2003-09/30/2005. Funded by the CDC (Principal Investigator, Lisa Jackson, MD, MPH). Direct costs: \$169,763.

4. Principal Investigator (0.20 FTE): Review of Statistical Methods for Post-Marketing Medical Product Safety Surveillance, 9/19/2008-3/18/2009. Funded by the FDA. (Principal Investigator, Jennifer Nelson, PhD). Direct costs: \$98,000.
5. Co-Investigator (0.10 FTE): Prospective Drug Safety Surveillance using Sequential Analytic Methods: Two Approaches for Confounding Adjustment, 8/1/09-12/31/09. Funded by Observational Medical Outcomes Partnership and the Foundation for the National Institutes of Health (Principal Investigator, Lingling Li, PhD; Harvard Medical School). Direct costs: \$27,269.
6. Co-Investigator (0.05 FTE): Efforts to Develop the Sentinel Initiative (Protocol for Active Surveillance of Medical Product-Related Acute Myocardial Infarction task order), 4/1/2010-7/31/2011. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$14,092.
7. Co-Investigator (0.20 FTE): Efforts to Develop the Sentinel Initiative (Sequential Testing Methods Development task order), 4/1/2010-7/31/2011. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$177,642.
8. Co-Investigator (0.05 FTE): Efforts to Develop the Sentinel Initiative (Case-Based Methods Development task order), 2/1/2010-2/28/2011. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School).
9. Co-Investigator (0.20 FTE): Efforts to Develop the Sentinel Initiative (Causal Inference and Sequential testing Methods Development task order), 1/1/2011-12/31/2011. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$170,000.
10. Consultant/Mentorship Advisory Committee (0.00 FTE): Pharmacoepidemiology in the elderly -- medications, pneumonia risk, and confounding. Career Development Award (9/15/2007-8/31/2013). Funded by the National Institute on Aging (Principal Investigator, Sascha Dublin, MD, PhD; Mentor, Eric Larson, MD, PhD). Direct costs: \$800,000.
11. Co-Investigator and Methodology Chair (0.70 FTE): Vaccine Safety Datalink Project, 10/1/02-9/30/12. Funded by the CDC (Principal Investigator, Lisa Jackson, MD, MPH). Direct costs: \$13,011,994
12. Co-Investigator (0.20 FTE): Efforts to Develop the Sentinel Initiative (Application of new sequential testing methods task order), 6/1/2012-5/31/2013. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$231,062.
13. Co-Investigator (0.10 FTE): Efforts to Develop the Sentinel Initiative (Two-phase sampling methods development task order), 9/1/2012-8/31/2013. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$148,157.
14. Co-Investigator (0.05 FTE): Vaccine Hesitancy Intervention—Provider, 7/2011-7/2013. Funded by the Group Health Foundation, Gates Foundation (Principal Investigator, David Grossman MD). Direct Costs: \$799,871.
15. Task Order Principal Investigator (0.20 FTE): Efforts to Develop the Sentinel Initiative (Improvements to Prospective Routine Observational Monitoring Program Tools-- PROMPT), 2/1/2014-8/31/2015. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$493,089.
16. Co-Investigator (0.10 FTE): Efforts to Develop the Sentinel Initiative (Safety signaling follow-up methods task order), 5/1/2015-10/31/2015. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$8,038.
17. Site Principal Investigator (0.05 FTE): Efforts to Develop the Sentinel Initiative (Joint IMEDS-Mini Sentinel methods task order), 9/30/2013-10/31/2014. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$33,381.
18. Site Principal Investigator (0.05 FTE): Efforts to Develop the Sentinel Initiative (Protocol for active surveillance of rivaroxaban task order), 9/23/2013-3/15/2015. Funded by the FDA

- (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$13,732.
19. Site Principal Investigator and Methods Core Co-lead (0.25 FTE): Efforts to Develop the Sentinel Initiative (Mini-Sentinel Coordinating Center): 9/23/09-9/22/15. Funded by the FDA (Principal Investigator, Richard Platt, MD, MSc; Harvard Medical School). Direct costs: \$1,143,180.
 20. Co-Investigator (0.10 FTE): Efforts to Develop the Sentinel Initiative (Safety signaling methods for survival outcomes to control for confounding), 9/1/2013-1/31/2015. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$216,053.
 21. Site PI and Co-Investigator (0.10 FTE): Efforts to Develop the Sentinel Initiative (Roadmap to evaluating the performance of Sentinel analytic modules using simulation experiments), 6/1/2015-12/31/2015. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$29,698.
 22. Co-Investigator (0.10 FTE): Efforts to Develop the Sentinel Initiative (Protocol for Selected Medications and Sudden Death), 10/22/2013-2/21/2016. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$334,947.
 23. Co-Investigator (0.10 FTE): Efforts to Develop the Sentinel Initiative (Comparison of safety signaling methods for survival outcomes to control for confounding, Phase 2), 5/1/2015-11/30/2016. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$281,486.
 24. Site PI and Co-Investigator (0.10 FTE): Efforts to Develop the Sentinel Initiative (Evaluating the performance of Mini-Sentinel analytic modules using simulation experiments), 12/1/2015-6/30/2016. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$87,769.
 25. Site PI and Co-Investigator (0.05 FTE): Efforts to Develop the Sentinel Initiative (FDA/Mini-Sentinel/IMEDS Sequential Surveillance White Paper), 4/2016-3/2017. Funded by the FDA (Principal Investigator, Richard Platt MD, MSc; Harvard Medical School). Direct costs: \$150,000.
 26. Co-Investigator (0.03 FTE): Racial/ethnic disparities in alcohol outcomes and health services, 9/2015 - 8/2017. Funded by the National Institute on Alcohol Abuse and Alcoholism (Principal Investigator: Joseph Glass, PhD; 1R03AA023639-01A1). Direct annual costs: \$50,000.
 27. Co-Investigator (0.10 FTE): Oral Health 4 Life: Integrating Oral Health Promotion & Tobacco Quitline Counseling, 8/1/2014-6/30/2018. Funded by the National Institute of Dental and Craniofacial Research (Principal Investigator: Jennifer McClure, PhD; 1U01DE024462-01) Direct costs: \$1,692,537.
 28. Co-Investigator (0.05 FTE): Vaccine Therapy and Evaluation Unit (VTEU), 2007-2017. Funded by the National Institute of Allergy and Infectious Diseases (Principal Investigator: Lisa Jackson, MD, MPH; HHSN272200800004C). Direct Costs: \$19,180,401.
 29. Site Principal Investigator (0.25 FTE): Coordinating Center for Opioids Post-Marketing Requirement Observational Study 1B, 9/1/16-1/31/19. Funded by the Campbell Alliance, Ltd (Principal Investigator, Mary Ann McBurnie, PhD; Kaiser Permanente Center for Health Research). Direct costs: \$2.35M.
 30. Site Principal Investigator and Methods Core Co-Lead (0.10 FTE): The Sentinel Initiative Coordinating Center: 9/23/15-9/22/19. Funded by the FDA (Principal Investigator, Richard Platt, MD, MSc; Harvard Medical School). Direct annual costs: ~\$65,000.

c) Pending applications

Not applicable at this time.

10. Conferences and Symposiums

Like presentations grouped. *Denotes invited presentation

1. **Nelson JC.** A new descriptive method for exploring interrater variability in ordinal ratings. International Biometric Society (WNAR) Annual Meeting, San Diego, CA, July 1998.
2. **Nelson JC** and Pepe MS. Describing interrater variability in ordinal ratings. International Biometric Society (ENAR) Annual Meeting, Atlanta, GA, March 1999.
3. ***Nelson JC** and Pepe MS. A graphical methodology for describing interrater variability in ordinal assessments among many raters. Southern Methodist University, Dallas, TX, April 1999.
4. **Nelson JC.** Graphical description of interrater variability in ordinal data. Group Health Research Institute, Seattle, WA, June 2003.
5. **Nelson JC** and Pepe MS. Modeling and Estimating Interrater Variability in Ordinal Assessments Among Many Raters. International Biometric Society (WNAR) Annual Meeting, Fairbanks, AK, June 2005.
6. **Nelson, JC,** Whitney, CG, Yu, O, Jackson, ML, Scott, T, Bounds, L, Zavitkovsky A, Jackson, LA. Impact of the Introduction of Pneumococcal Conjugate Vaccine on Rates of Community Acquired Pneumonia. 5th International Symposium on Pneumococci and Pneumococcal Diseases, Alice Springs, Central Australia, April 2006.
7. **Nelson, JC,** Jackson LA, Jackson ML, Weiss NS. Methodological issues and strategies to reduce bias in observational studies of influenza vaccination effectiveness in the elderly. Conference on Statistical Methods in Epidemiology and Observational Studies In Honor of Norman E. Breslow, Seattle, WA, August 2006.
8. **Nelson, JC,** Jackson ML, Weiss NS, Jackson LA. A method to assess bias in observational studies of influenza vaccination effectiveness in the elderly. Joint Statistical Meetings, Salt Lake City, UT July 2007.
9. Bittner RCL, **Nelson JC.** Use of propensity score calibration to reduce unmeasured confounding bias. University of Washington Biostatistics Retreat, Bainbridge Island, WA, September 2007.
10. **Nelson JC.** Strategies to reduce bias in estimates of influenza vaccine effectiveness in observational studies. Seattle Influenza Meetings, Seattle, WA, March 2008.
11. Zhao S, Cook AJ, **Nelson JC.** Statistical performance of group sequential methods for evaluating vaccine and drug safety. Joint Statistical Meetings, Denver, CO Aug 2008.
12. **Nelson JC.** Performance of Group Sequential Methods for Active Post-Licensure Medical Product Safety Surveillance Using Observational Health Care Databases. Poster presentation and Databases Special Interest Group award-winner at 28th International Conference on Pharmacoepidemiology and Therapeutic Risk Management, Barcelona, Spain, August 23-26, 2012.
13. **Nelson JC,** Cook AC, Zhao S. Extending group sequential methods to observational medical product safety surveillance. Eastern North American Region of the International Biometrics Society Meetings, San Antonio TX; March 18, 2009.
14. ***Nelson, JC.** Design and analysis considerations for post-marketing vaccine safety surveillance studies. Pediatric Academic Societies Annual Meeting, Baltimore MD; May 2-5, 2009.
15. ***Nelson, JC.** Evaluation of existing methods for safety signal identification for the Sentinel Initiative. Food and Drug Administration CBER/CDER/CDRH Joint Rounds, Silver Spring MD; May 6, 2009.

16. ***Nelson JC.** Evaluation of existing methods for safety signal identification for the Sentinel Initiative. 2nd Annual Sentinel Initiative Public Workshop hosted by the Engelberg Center for Health Care Reform at Brookings. Washington D.C.; January 11, 2010.
17. ***Nelson JC.** Signal Detection Methods for Active Post-Licensure Safety Surveillance. Think Tank: Methods, Tools, and Scientific Operations for The Sentinel Network, Engelberg Center for Health Care Reform at Brookings (convened in collaboration with the Centers for Educations and Research on Therapeutics (CERTs); Washington D.C.; May 7, 2009.
18. ***Nelson JC.** Discussion of Statistical Methods for Drug Safety Surveillance Using Electronic Health Care Databases. Joint Statistical Meetings, Vancouver BC; August 1, 2010.
19. ***Nelson JC.** Sequential methods for observational post-licensure medical product safety surveillance. Third International Workshop in Sequential Methodologies, Stanford University, Palo Alto, CA; June 13-15, 2011.
20. **Nelson JC, Cook AC, Yu O, Zhao S, Jackson LA.** Challenges in designing a sequentially-monitored observational study of post-licensure vaccine safety. Western North American Region of the International Biometrics Society Meetings, Seattle WA; June 21, 2010.
21. **Nelson JC, Cook AC, Yu O, Zhao S, Jackson LA.** Challenges in designing a sequentially-monitored observational study of post-licensure vaccine safety. International Biometrics Society Meetings, Florianopolis, Santa Catarina, Brazil; December 10, 2010.
22. **Nelson JC.** Challenges in conducting sequentially monitored medical product safety studies using electronic health care utilization data. International Conference on Pharmacoepidemiology & Therapeutic Risk Management, Chicago IL; August 16, 2011.
23. ***Nelson JC.** The Vaccine Safety Datalink's near real-time safety surveillance system and challenges in designing sequentially-monitored vaccine safety studies. International Workshop in Pharmacoepidemiology and Biostatistics sponsored by the University of Washington, Group Health Research Institute, Institute of Basic Research in Clinical Medicine, China Academy of Chinese Medical Sciences, and VA Seattle Medical Center; Seattle, WA; December 2-4, 2011.
24. ***Nelson JC.** An overview of methodological challenges in the U.S. FDA and CDC postmarket active surveillance systems. The First International Workshop on Safety Surveillance of Post-market Chinese Medicine Injection. China Academy of Chinese Medical Sciences, Beijing, China; April 7-8, 2012.
25. ***Nelson JC.** Challenges in the design and analysis of sequentially-monitored postmarket safety surveillance evaluations using electronic observational health care data. Presentation at the 33rd International Society for Clinical Biostatistics, Bergen, Norway, August 19-23, 2012
26. ***Nelson JC.** Methodological challenges for sequential medical product safety surveillance using observational healthcare data. Department of Biostatistics and Epidemiology, Perelman School of Medicine, University of Pennsylvania. Philadelphia, PA. May 9, 2013.
27. ***Nelson JC and Cook AJ.** Methodological challenges in conducting post-licensure drug and vaccine safety surveillance using large electronic healthcare databases. Biostatistics and Biomathematics Program, Public Health Sciences Division, Fred Hutchinson Cancer Research Center. Seattle, WA, January 29, 2014.
28. ***Nelson JC.** Methodological challenges in conducting post-licensure drug and vaccine safety surveillance using large electronic healthcare databases. Department of Statistics, University of Washington. Seattle, WA, April 14, 2014.
29. ***Nelson JC.** Challenges in using large electronic healthcare databases to conduct post-licensure drug and vaccine safety surveillance. Data Management Association of Puget Sound Spring 2014 Conference, Seattle, WA, May 14, 2014.

30. ***Nelson JC**. Methodological challenges in conducting post-licensure drug and vaccine safety surveillance using large electronic healthcare databases. DIA (Develop, Innovate, Advance)/FDA Statistics 2015 Forum, Bethesda, MD, April 20, 2015.
31. ***Nelson JC**. Statistical challenges in post-market drug and vaccine safety surveillance using electronic health records. Central European Network of the International Biometric Society's (CEN-IBS) Joint Conference on Biometrics & Biopharmaceutical Statistics, Vienna, Austria, August 28 – September 1, 2017.
32. ***Nelson JC**, Schneeweiss S. Expert Workshop: Setting priorities for methods research and development for active medical product surveillance hosted by the Engelberg Center for Health Care Reform at Brookings. Washington D.C.; June 3, 2011.
33. **Nelson JC**. Developing better evidence on medical product safety: FDA's Mini-Sentinel Program, Methodological Activities and Highlights. AcademyHealth Annual Research Meeting, Seattle WA; June 13, 2011.
34. ***Nelson JC**. Exploring the use of validation sample methods to reduce confounding bias in health care database estimates of influenza vaccination effectiveness in seniors. 4th Comparative Effectiveness Research Symposium "From Efficacy to Effectiveness". Presentation at the AHRQ DEcIDE Methods Symposium. Rockville, MD. June 12-13, 2012.
35. *Marsh T, **Nelson JC**. Validation sampling to reduce bias in healthcare database studies. 29th International Conference on Pharmacoepidemiology and Therapeutic Risk Management, Montreal, Canada, August 25-28, 2013.
36. ***Nelson JC**. Expert Workshop: "Overcoming the Statistical Challenges to the Reuse of Data within the Mini-Sentinel Distributed Database" hosted by the Engelberg Center for Health Care Reform at Brookings. Washington D.C.; September 5, 2012.
37. ***Nelson JC** and Madigan D. Collaborations supporting active surveillance research. Fifth Annual Sentinel Initiative Public Workshop hosted by the Engelberg Center for Health Care Reform at Brookings. Washington D.C.; January 31, 2013.
38. ***Nelson JC** and Cook AJ. Overview of distributed data methods and analyses within the HMO Research Network. Patient Centered Outcomes Research Institute (PCORI) Workshop: Distributed Analysis in Healthcare Data Networks. Washington D.C.; December 4, 2014.
39. ***Nelson JC**. Group sequential methods for vaccine pharmacovigilance. Methods for evaluating vaccine effectiveness and safety satellite workshop. Sydney, Australia; October 28, 2014.
40. ***Nelson JC**. Overview of systems for active post-marketing medical product surveillance in the USA. Keynote address at the Vaccine safety seminar on active surveillance for adverse events following immunization, hosted by the National Centre for Immunisation Research & Surveillance, Sydney, Australia; October 29, 2014.
41. ***Nelson JC**. Using large healthcare databases in the USA to assess vaccine safety. Keynote address at the Vaccine safety seminar on active surveillance for adverse events following immunization, hosted by the National Centre for Immunisation Research & Surveillance, Sydney, Australia; October 29, 2014.
42. ***Nelson JC**, Cook AJ, and Heagerty P. The role of health care data analytics in health policy decision-making. Invited Speaker Luncheon, Section on Health Policy Statistics, Joint Statistical Meetings, Seattle WA, August 13, 2015.
43. **Nelson JC**. Adapting group sequential methods to observational drug and vaccine safety surveillance studies that use large electronic healthcare databases. Joint Statistical Meetings, Seattle WA, August 13, 2015.
44. ***Nelson JC**. Precision medicine and the role of big data. Roundtable: From personalized medicine to population health – maximizing the value of data, America's Health Insurance Plans, Washington D.C., December 3, 2015.

45. ***Nelson JC.** Generating policy-relevant statistical evidence in sequentially monitored vaccine and drug safety evaluations using electronic health record data. Joint Statistical Meetings, Chicago, IL, August 4, 2016.
46. ***Nelson JC.** Connecting the data to the science: A biostatistician's role in advancing drug safety knowledge. 2nd Seattle Symposium in Health Care Data Analytics, Seattle WA, October 25, 2016.
47. ***Nelson JC.** Timely quantification of policy-relevant vaccine and drug safety evidence: What can we achieve using electronic health care data networks? Conference on risk modeling, management, and mitigation in health sciences, Centre de recherches mathématiques, Université de Montréal, December 11-13, 2017
48. ***Nelson JC.** Use of propensity score methods in multi-site safety data networks: current practice and challenges. ASA's International Conference on Health Policy Statistics, Charleston SC, January 10-12, 2018.
49. ***Nelson JC.** The role of electronic health record data in vaccine policy decisions. Clinical Trials Affinity Group (CTAG), Fred Hutchinson Cancer Research Center, Seattle WA, March 26, 2018.
50. ***Nelson JC.** Statistical considerations in multi-site vaccine safety evaluations. Stakeholder meeting on Maternal Interventions Vigilance Harmonization in Low & Middle income countries (Bill & Melinda Gates foundation), Amsterdam, The Netherlands, May 1-2, 2018.
51. ***Nelson JC.** Real-world biostatistics: perspectives from an alum. University of Washington, Department of Biostatistics Colloquium, Seattle WA, November 8, 2018.
52. ***Nelson JC.** Sequential surveillance in the Vaccine Safety Datalink: Interim analysis results for a recombinant Zoster vaccine. Advisory Committee on Immunization Practices, Zoster Working Group, February 11, 2019.
53. ***Nelson JC.** How big data can lead to safer drugs and vaccines. World Vaccine Congress 2019, Washington DC, April 14-15, 2019.
54. ***Nelson JC.** Challenges for randomized trial-based sequential methods in real-world settings. American College of Epidemiology Annual Meeting, Pasadena CA, September 9, 2019.
55. ***Nelson JC.** Sequential design and analysis considerations when using electronic health care data to rapidly quantify new vaccine safety evidence. 13th Vaccine Congress, Bangkok, Thailand, September 15-18, 2019.
56. ***Nelson JC.** University of Washington biostatistics students making an impact in drug and vaccine safety science. University of Washington, Department of Biostatistics Seminar (for prospective student visit days), Seattle WA, February 27, 2020.

11. Professionally-Related Community Service

Not applicable

12. Teaching History

a) Formal courses

Biostatistics 511: Medical Biometry I, Department of Biostatistics, University of Washington, Seattle, WA, Teaching Assistant, Summer 1996.

Biostatistics 511: Medical Biometry I, Department of Biostatistics, University of Washington, Seattle, WA, Teaching Assistant, Summer 1997.

Using Electronic Healthcare Data for Comparative Safety and Effectiveness Research, Summer Institute in Statistics for Clinical Research, Department of Biostatistics, University of Washington, Seattle, WA, Instructor, June 27, 2014.

b) Other teaching

Epidemiology 533: Pharmacoepidemiology, Department of Epidemiology, University of Washington, Seattle, WA, Guest Lecturer on Methods for post-licensure medical product safety surveillance, May 17, 2010.

Epidemiology 533: Pharmacoepidemiology, Department of Epidemiology, University of Washington, Seattle, WA, Guest Lecturer on Methods for post-licensure medical product safety surveillance, April 30, 2012.

Epidemiology 533: Pharmacoepidemiology, Department of Epidemiology, University of Washington, Seattle, WA, Guest Lecturer on Methods for post-licensure medical product safety surveillance, April 21, 2014.

Epidemiology 533: Pharmacoepidemiology, Department of Epidemiology, University of Washington, Seattle, WA, Guest Lecturer on Methods for post-licensure medical product safety surveillance, April 20, 2016.

Epidemiology 533: Pharmacoepidemiology, Department of Epidemiology, University of Washington, Seattle, WA, Guest Lecturer on Methods for post-licensure medical product safety surveillance, May 9, 2018.

Epidemiology 533: Pharmacoepidemiology, Department of Epidemiology, University of Washington, Seattle, WA, Guest Lecturer on Methods for post-licensure medical product safety surveillance, April 1, 2020.

c) Independent study

2006 Rachel Bittner, Department of Biostatistics, University of Washington, Seattle WA

2011 Kelly Stratton, Department of Biostatistics, University of Washington, Seattle WA

2020 Iris Emerman, Department of Biostatistics, University of Washington, Seattle WA

13. Advising and Formal Mentoring

a) Master's theses, chair

2006-2007 Rachel Bittner, Chair Master's Thesis Committee
Department of Biostatistics, University of Washington, Seattle WA

2011-2012 Kelly Stratton, Chair Master's Thesis Committee
Department of Biostatistics, University of Washington, Seattle WA

b) Mentored scientists and postdocs

2004-2007 Sascha Dublin, Member of K-award Postdoctoral Fellowship Advisory Board
Health Services Research & Development, VA Puget Sound, Seattle, WA

2000-2003 Melissa Anderson, Research Scientist Supervisor
Department of Biostatistics, University of Washington, Seattle, WA

2001-2003 Do Peterson, Research Scientist Supervisor
Department of Biostatistics, University of Washington, Seattle, WA

2003-2017 Onchee Yu, MS Collaborative Biostatistician Supervisor
Biostatistics Unit, Kaiser Permanente Washington Health Research Institute,
Seattle, WA

2009-2017 Laura Ichikawa, MS Collaborative Biostatistician Supervisor
Biostatistics Unit, Kaiser Permanente Washington Health Research Institute,

- Seattle, WA
- 2009-2014 Do Peterson, MS Collaborative Biostatistician Supervisor
Biostatistics Unit, Kaiser Permanente Washington Health Research Institute,
Seattle, WA
- 2014-2018 Melissa Anderson, MS Collaborative Biostatistician Supervisor
Biostatistics Unit, Kaiser Permanente Washington Health Research Institute,
Seattle, WA
- 2015-present Jennifer Bobb, PhD Investigator Biostatistician Supervisor
Biostatistics Unit, Kaiser Permanente Washington Health Research Institute,
Seattle, WA
- 2015-2016 Fei Wan, PhD Investigator Biostatistician Supervisor
Biostatistics Unit, Kaiser Permanente Washington Health Research Institute,
Seattle, WA
- 2016-present Yates Coley, PhD Investigator Biostatistician Supervisor
Biostatistics Unit, Kaiser Permanente Washington Health Research Institute,
Seattle, WA
- 2018-2019 Roberta De Vito, PhD Postdoctoral Research Fellow, Princeton University,
Princeton NJ (part of ASA's Statistics in Epidemiology Mentoring Program)
- 2018-present Eric Johnson, MS Collaborative Biostatistician Supervisor
Biostatistics Unit, Kaiser Permanente Washington Health Research Institute,
Seattle, WA
- 2019-present Maricela Cruz, PhD Investigator Biostatistician Supervisor
Biostatistics Unit, Kaiser Permanente Washington Health Research Institute,
Seattle, WA
- 2019-present Yu-Ru Su, PhD Investigator Biostatistician Supervisor
Biostatistics Unit, Kaiser Permanente Washington Health Research Institute,
Seattle, WA

c) Master's and PhD committee in non-chair role

- 2004-2007 Michael Jackson, Member of Doctoral Dissertation Committee
Department of Epidemiology, University of Washington, Seattle, WA
- 2017-2018 Katherine Tan, Reading Committee Member for Doctoral Dissertation
Department of Biostatistics, University of Washington, Seattle, WA
- 2019-present Ernesto Ulloa, Reading Committee Member for Doctoral Dissertation
Department of Biostatistics, University of Washington, Seattle, WA

d) Other mentoring

- 2005-2006 Kenneth Wu, Graduate Research Assistantship Supervisor
Department of Biostatistics, University of Washington, Seattle, WA
- 2006-2007 Rachel Bittner, Graduate Research Assistantship Supervisor
Department of Biostatistics, University of Washington, Seattle, WA
- 2007 Tanya Granston, Graduate Research Assistantship Supervisor
Department of Biostatistics, University of Washington, Seattle, WA
- 2007-2010 Shanshan Zhao, Graduate Research Assistantship Supervisor
Department of Biostatistics, University of Washington, Seattle, WA
- 2009-2011 Clara Dominguez-Islas, Graduate Research Assistantship Supervisor
Department of Biostatistics, University of Washington, Seattle, WA

2011-2013 Kelly Stratton, Graduate Research Assistantship Supervisor
Department of Biostatistics, University of Washington, Seattle, WA
2015-present Ernesto Ulloa, Graduate Research Assistantship Supervisor
Department of Biostatistics, University of Washington, Seattle, WA
2017-2019 Chloe Krakauer, Graduate Research Assistantship Supervisor
Department of Biostatistics, University of Washington, Seattle, WA

e) Academic Advising

2008-2009 Karen Liu, Graduate Academic Advisor
Department of Biostatistics, University of Washington, Seattle, WA
2009-2013 Alison Kosel, Graduate Academic Advisor
Department of Biostatistics, University of Washington, Seattle, WA
2010-2014 Tracey Marsh, Graduate Academic Advisor
Department of Biostatistics, University of Washington, Seattle, WA