

# CURRICULUM VITAE

## Jennifer Clark Nelson

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### 1. Biographical Information

Jennifer Clark Nelson, PhD  
Director of Biostatistics and Senior Investigator  
Biostatistics Division, Kaiser Permanente Washington Health Research Institute  
(formerly Group Health Research Institute)  
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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

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+) 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, 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
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 award, <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-present	Member, The American Statistical Association (ASA)
1999-present	Member, The International Biometric Society (WNA)R
2003-present	Member, Methodology Committee, Vaccine Safety Datalink collaboration, Centers for Disease Control and Prevention (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, Seattle WA
2008 & 2011	Member, Strategic Plan Committee, Group Health Research Institute, Seattle WA
2009-2012	Member, International Biometric Society Regional Advisory Board (WNA)R
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)
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	Invited panelist, Improving the efficiency of outcome validation in the Sentinel System, Duke-Margolis Center for Health Policy, Washington DC, May 17, 2018
2018	Invited panelist, Signal Detection Capabilities in the Sentinel System, Duke-Margolis Center for Health Policy, Bethesda MD, December 3, 2018
2018-2021	Invited member, Data Monitoring Committee, HEPLISAV-B Vaccine Post Marketing Surveillance Study, Southern California Permanente Medical Group
2019-2020	Invited member, Strategic Plan Steering Committee, School of Public Health, University of Washington, Seattle WA
2019-present	Executive Committee, FDA Sentinel Initiative Innovation Center
2019-2021	Invited member, Advisory Board, Sentinel Site Readiness for Maternal Immunization Active Safety Surveillance in Low & Middle Income Countries, The

Bill & Melinda Gates Foundation, Seattle WA  
 2020-2022 Council of Sections Representative, ASA Section on Statistics in Epidemiology  
 2020-4/2021 Invited member, mRNA-1273 (COVID-19 vaccine candidate) External Safety  
 Advisory Board, Moderna's COVID-19 vaccine program  
 5/2021-2023 Invited member, Advisory Committee on Immunization Practices (ACIP)  
 COVID-19 Vaccine Safety Technical (VaST) Subgroup, CDC, Atlanta GA  
 2021-present Member, International Biometric Society Regional Advisory Board (WNAR)  
 2022 Invited member, ASA Council of Sections Governing Board Nominations  
 Committee  
 2023-present Invited member, Advisory Committee on Immunization Practices (ACIP) COVID-19  
 Vaccines Working group, CDC, Atlanta GA  
 2023-2024 Member, Steering Committee for the 7<sup>th</sup> Seattle Symposium in Biostatistics,  
 University of Washington, Seattle WA

### 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, Seattle WA  
 2006-2008 Program Chair, Joint Statistical Meetings, ASA's Section in Epidemiology (chair-  
 elect 2006, chair 2007, past chair 2008)  
 2008-2014 & 2023-present Chair, Methodology Committee, CDC's Vaccine Safety Datalink collaboration  
 2009-2019 Co-Lead, Methods Core, FDA's Sentinel Initiative Coordinating Center  
 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, 1<sup>st</sup> 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, 2<sup>nd</sup> Seattle Symposium on Health Care Data Analytics: Learning  
 from electronic data to advance health & 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.  
 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 Mentor, ASA's Statistics in Epidemiology Section Mentoring Program  
 2018-present Associate Editor, *Vaccine*

### 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

- 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

#### 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
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.
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.
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.
22. **Nelson JC**, Jiang X-C, Tabas I, Tall A, Shea S. Plasma sphingomyelin and subclinical atherosclerosis: findings from the Multi-Ethnic Study of Atherosclerosis (MESA). *Am J Epidemiol*. 2006;163(10):903-912.
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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.
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.

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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.
32. Dublin S, Jackson ML, **Nelson JC**, Weiss NS, Larson E, Jackson LA. Statin use and risk of community-acquired pneumonia in the elderly: results of a population-based case-control study. *Brit Med J*. 2009; Jun 16;338:b2137.
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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.
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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.
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.
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.
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.
41. Jackson ML, **Nelson JC**, Jackson LA. Why do covariates defined by International Classification of Disease codes fail to remove confounding in pharmacoepidemiologic studies among seniors? *Pharmacoepidemiology and Drug Safety*. 2011; 20:858-865.

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.
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. 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.
45. **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.
46. 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.
47. 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.
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53. \*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.
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- and risk of local reactions in children one through six years of age. *Pediatrics*. 2013;131(2):283-9.
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  63. 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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  65. Hambidge SJ, Newcomer SR, Narwaney KJ, Glanz J, Daley MF, Xu S, Shoup JA, Rowhani-Rahbar A, Klein NP, Lee GM, **Nelson JC**, Lugg M, Naleway AL, Nordin JD, Weintraub E, DeStefano. Timely versus delayed early childhood vaccination and seizures. *Pediatrics*. 2014 Jun;133(6);e1492-9.
  66. **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.
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  68. Bell C, Chakravarty A, Gruber S, Heckbert SR, Levenson M, Martin D, **Nelson JC**, Pinheiro S, Psaty BM, Reich CG, Schneeweiss S, Shoaibi A, Toh S, Walker AM. Characteristics of study design and elements that may contribute to the success of electronic safety monitoring systems. *Pharmacoepidemiol Drug Saf*. 2014 Nov;23(11):1223-5.
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#### 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*. 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
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6. Larson EB, **Nelson JC**. Commentary: In older adults, use of recombinant zoster vaccine was associated with Guillain-Barre syndrome. *Annals of Internal Medicine*. 2021 Mar 1;

#### 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](http://www.mini-sentinel.org/methods/methods_development).
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  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](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](http://www.mini-sentinel.org/methods/methods_development).
  11. Razzaghi H, Meghani M, Pingali C, Crane B, Naleway A, Weintraub E, Kenigsberg TA, Lamias MJ, Irving SA, Kauffman TL, Vesco KK, Daley MF, DeSilva M, Donahue J, Getahun D, Glenn S, Hambidge SJ, Jackson L, Lipkind HS, **Nelson JC**, Zerbo O, Oduyebo T, Singleton JA, Patel SA. COVID-19 Vaccination Coverage Among Pregnant Women During Pregnancy - Eight Integrated Health Care Organizations, United States, December 14, 2020-May 8, 2021. *MMWR Morb Mortal Wkly Rep*. 2021 Jun 18;70(24): 895-899. PMID: 34138834; PMCID: PMC8220952.
  12. Pingali C, Meghani M, Razzaghi H, Lamias MJ, Weintraub E, Kenigsberg TA, Klein NP, Lewis N, Fireman B, Zerbo O, Bartlett, J, Goddard K, Donahue J, Hanson K, Naleway A, Kharbanda EO, Yih WK, **Nelson JC**, Lewin BJ, Williams JTB, Glanz JM, Singleton JA, Patel SA (2021). COVID-19 Vaccination Coverage Among Insured Persons Aged ≥16 Years, by Race/Ethnicity and Other Selected Characteristics - Eight Integrated Health Care Organizations, United States, December 14, 2020-May 15, 2021. *MMWR. Morb Mortal Wkly Rep*. 2021 Jul 16;70(28), 985–990.

#### e) Submitted manuscripts

1. Williams JTB, Kurlandsky K, Breslin K, Cruz H, Stein A, Shoup JA, Reifler LM, Daley MF, Lewin B, Goddard K, Henninger ML, **Nelson JC**, Vazquez-Benitez G, Hanson KE, Fuller CC, Weintraub E, McNeil MM, Hambidge SJ. Religion, religious service attendance, and COVID-19 attitudes and self-reported vaccination within the Vaccine Safety Datalink.
2. Bann M, Hazlehurst B, Carrell D, Bann M, Slaughter M, Cronkite D, Gruber S, **Nelson JC**, Ball R, Floyd J. A comparison of manual and automated approaches to developing computable algorithms for identifying acute pancreatitis.
3. Yu X, Zhai Y, Hazlehurst B, Williamson BD, Cai T, **Nelson JC**, Heagerty PJ, Shi X. Comparing medical code endorsement between healthcare systems using privacy-enhancing tests.
4. Shi X, Zhai Y, Yu X, Li X, Hazlehurst BL, Nyongesa DB, Sapp DS, Williamson BD, Carrell DS, Healy L, Cushing-Haugen KL, Wong J, Wang SV, Floyd JS, Shattuck K, McGown S, Alam S, Bright P, Hernández-Muñoz JJ, Li J, Ma Y, Stojanovic D, Raman SR, Davis SE, Cai T, **Nelson JC**, Heagerty PJ. Harmonizing Electronic Health Record Data Across FDA Sentinel Initiative Data Partners Using Privacy-Protecting Unsupervised Learning: Case Study and Lessons Learned
5. Denoble AE, Vazquez-Benitez G, Sheth SS, Ackerman CM, DeSilva MB, Zhu J, Daley MF, Getahun D, Klein NP, Vesco KK, Irving SA, **Nelson JC**, Williams JTB, Hambidge SJ, Donahue JG, Weintraub ES, Kharbanda EO, Lipkind HS. COVID-19 Vaccination and Stillbirth in the Vaccine Safety Datalink: A Case-Control Study.
6. Williams JTB, Kurlandsky K, Breslin K, Durfee J, Stein A, Shoup J, Reifler LM, Daley MF, Lewin B, Goddard K, Henninger ML, **Nelson JC**, Vasquez-Benitez G, Hanson KE, Fuller CC, Weintraub E, McNeil MM, Hambidge SJ. COVID-19 Vaccination Status and Attitudes among Pregnant and Recently Pregnant Vaccine Safety Datalink Members during the first Omicron Wave
7. Stein AB, Williams JTB, Hurley LP, Breslin K, Kurlandsky K, **Nelson JC**, Fuller CC, Crane B, Hanson KE, Glenn SC, Jazwa Am, Reifler LM. Accuracy of COVID-19 vaccination self-report compared with data from electronic health records for pregnant and non-pregnant adults.
8. Sheth SS, Vazquez-Benitez G, DeSilva MB, Zhu J, Seburg E, Denoble AE, Daley MF, Getahun D, Klein NP, Vesco KK, Irving SA, Nelson JC, Williams JTB, Hambidge SJ, Donahue JG, Weintraub ES, Lipkind HS, Kharbanda EO. COVID-19 Vaccination and Spontaneous Abortion in the Vaccine Safety Datalink: a Case-Control Study.
9. Williamson B, Krakauer C, Johnson E, Gruber S, Shepherd B, van der Laan M, Lumley T, Lee H, Hernandez Munoz J, Zhao F, Dutcher S, Desai R, Simon G, Shortreed S, **Nelson J**, Shaw Pam. Assessing treatment effects in observational data with missing confounders: A comparative study of practical doubly-robust and traditional missing data methods
10. Williams JTB, Kurlandsky K, Breslin K, Durfee J, Stein A, Shoup J, Reifler LM, Daley MF, Lewin B, Goddard K, Henninger ML, **Nelson JC**, Vasquez-Benitez G, Hanson KE, Fuller CC, Weintraub E, McNeil MM, Hambidge SJ. Religious Service Attendance, COVID-19 Vaccine Attitudes, and COVID-19 Vaccination Status: A Vaccine Safety Datalink Member Survey, 2022-23

## 8. Patents and Other Intellectual Property (not applicable)

## 9. Funding History

### a) Funded projects

1. Multiple Principal Investigator (0.10 FTE): Sentinel Innovation Center Master Plan and Maintenance, 2019-2023. Funded by the FDA (Principal Investigator, Darren Toh, PhD; Harvard Medical School). Direct costs: \$249,935.



2. Co-Investigator (0.35 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 (0.10 FTE): Adult Changes in Thought (ACT) U19 Program, 2021-2026. Funded by the National Institute on Aging (Multiple Principal Investigators: Linda McEvoy, PhD; Paul Crane, MD; Andrea LaCroix PhD). Direct costs: \$55M.
4. Task Order Co-Investigator (0.03 FTE): Empirical Application of the Sentinel EHR and Claims Data Partner Network to Address Active Risk Identification and Analysis (ARIA) Insufficient Inferential Requests, 2023-2024. Funded by the FDA (Task Order Principal Investigator, Sascha Dublin, MD, PhD; Sentinel Contract Principal Investigator: Darren Toh, PhD; Harvard Medical School). Direct costs: \$420,000.
5. Task Order Co-Investigator (0.05 FTE): Sentinel Innovation Center Subset Calibration Methods, 2023-2024. Funded by the FDA (Task Order Principal Investigator, Pamela Shaw, PhD; Sentinel Contract Principal Investigator: Darren Toh, PhD; Harvard Medical School). Direct costs: \$393,087.

#### **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.
  31. Site Principal investigator (0.05 FTE): Shingrix vaccine surveillance, 2018-2019. Funded by GlaxoSmithKline (Principal Investigator, Jeff Brown ScD). Direct costs: \$16,105.
  32. 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.
  33. 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.
  34. 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.
  35. Co-investigator (0.03 FTE): Adult Changes in Thought (ACT) U01 study. Funded by the National Institute on Aging (Principal Investigators, Eric Larson, MD and Paul Crane, MD). Direct costs: \$10.3M.
  36. Site Principal investigator (0.05 FTE): Enhancing Causal Inference in the Sentinel system: An Evaluation of Targeted Learning and Propensity Scores for Confounding Control in Drug Safety, 2020-2022. Funded by the FDA (Principal Investigator, Richard Platt, MD, MSc; Harvard Medical School). Direct costs: \$21,692.
  37. Task Order Co-Principal Investigator (0.10 FTE): The Sentinel Operations Center Learning Phenotype Laboratory, Phase 3, 2021-2023. Funded by the FDA (Principal Investigator, Richard Platt, MD, MSc; Harvard Medical School). Direct costs: \$424,991.

**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. 5<sup>th</sup> 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. 29<sup>th</sup> 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. 2<sup>nd</sup> 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. 13<sup>th</sup> Vaccine Congress, Bangkok, Thailand, September 15-18, 2019.
56. \***Nelson JC**. University of Washington biostatistics students and alums 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.
57. \***Nelson JC**. Precision health in the age of data science: Learning from observational data (invited panelist). Sixth Seattle Symposium in Biostatistics, University of Washington, Department of Biostatistics, Seattle WA, November 21-23, 2020.
58. \***Nelson JC**. Real-World Evidence (RWE) study estimands (invited discussant). Forum on the Integration of Observational and Randomized Data (FIORD), Washington D.C., November 6-7, 2023.
59. \***Nelson JC**. Linked-claims EHR data: Sentinel System's efforts at improving causal inference & broadening queries. 15<sup>th</sup> Annual Sentinel Initiative Public Workshop, Washington D.C., November 8, 2023.
60. \***Nelson JC**. Statistical methods for improving post-licensure vaccine safety surveillance. FDA-CBER Biologics Effectiveness and Safety (BEST) virtual seminar series, November 20, 2024.
61. \***Nelson JC**. Statistical methods for improving post-licensure vaccine safety surveillance. Department of Biostatistics and Medical Informatics at UW-Madison, November 22, 2024.

## 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.  
Epidemiology 533: Pharmacoepidemiology, Department of Epidemiology, University of Washington, Seattle, WA, Guest Lecturer on Methods for post-licensure medical product safety surveillance, March 30, 2022.  
Epidemiology 533: Pharmacoepidemiology, Department of Epidemiology, University of Washington, Seattle, WA, Guest Lecturer on Methods for post-licensure medical product safety surveillance, April 4, 2024.

**c) Independent study and reading**

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
2024	Matthew Peng, Department of Statistics, University of Washington, Seattle WA
2024	Charlotte Hong, 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, Co-Chair Master's Thesis Committee



2020-2021 Department of Biostatistics, University of Washington, Seattle WA  
Iris Emerman, 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

2016-2020 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)

2018-2020 Eric Johnson, MS Collaborative Biostatistician Supervisor  
Biostatistics Unit, Kaiser Permanente Washington Health Research Institute,  
Seattle, WA

2019-present Maricela Cruz, PhD Investigator Biostatistician Primary Mentor  
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

2020-present Rod Walker, MS Collaborative 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

2017-2018 Department of Epidemiology, University of Washington, Seattle, WA  
 Katherine Tan, Reading Committee Member for Doctoral Dissertation

2019-2022 Department of Biostatistics, University of Washington, Seattle, WA  
 Ernesto Ulloa, Reading Committee Member for Doctoral Dissertation

2020-present Department of Biostatistics, University of Washington, Seattle, WA  
 Lola Arakaki, Committee Member for Doctoral Dissertation

2023-present Department of Epidemiology, University of Washington, Seattle, WA  
 Graham Crawbuck, Committee Member for Doctoral Dissertation

2023-present Department of Epidemiology, 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

2015-2022 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