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EDUCATION

- 1998 B.A. with honors; Skidmore College, Saratoga Springs, NY
2000 M.S., Mathematics; University of Massachusetts, Amherst, MA
2005 Ph.D., Biostatistics; University of Washington, Seattle, WA.

POSTGRADUATE TRAINING

- 2005-2007 Post-Doctoral Fellow, Department of Biostatistics, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD

FACULTY POSITIONS

- 2007-2011 Assistant Member, Vaccine and Infectious Disease Division and Division of Public Health Sciences, Fred Hutchinson Cancer Research Center, Seattle, WA
2008-2012 Affiliate Assistant Professor, Department of Biostatistics, University of Washington, Seattle, WA
2011-present Associate Member, Vaccine and Infectious Disease Division and Division of Public Health Sciences, Fred Hutchinson Cancer Research Center, Seattle, WA
2012-present Affiliate Associate Professor, Department of Biostatistics, University of Washington, Seattle, WA

HONORS, AWARDS, SCHOLARSHIPS

- 2000 Cardiovascular Biostatistics Training Grant, National Institutes of Health
2004 Student Paper Award, Section on Statistics and the Environment, American Statistical Association
2004 Student Poster Award, Department of Biostatistics, University of Washington
2005 Senior Student Award, Department of Biostatistics, University of Washington
2005 Student Conference Award, International Society for Clinical Biostatistics
2005 Gilbert S. Omenn Graduate Student Award for Academic Excellence, School of Public Health, University of Washington
2006 Young Investigator Award, Section on Statistical Epidemiology, American Statistical Association
2008 Travel Award, AIDS Vaccine Conference, Global HIV Vaccine Enterprise

PROFESSIONAL ORGANIZATIONS

- 2000-present American Statistical Association (AMSTAT)
2012-present International Biometrics Society (IBS)

TEACHING RESPONSIBILITIES

- 1998 University of Massachusetts, Department of Mathematics, Amherst, MA; Math 121

(Linear Methods), Teaching Assistant

1998-2000 University of Massachusetts, Department of Mathematics, Amherst, MA; Math 100 (Basic Math Skills), Instructor

1998-2000 University of Massachusetts, Department of Mathematics, Amherst, MA; Math 101 (Pre-Calculus Algebra), Instructor

1998-2000 University of Massachusetts, Department of Mathematics, Amherst, MA; Math 101 (Calculus II for the Life and Social Sciences), Instructor

2000-2002 Department of Biostatistics, University of Washington, Seattle, WA; Biost 502, (Introduction to Statistics in Health Sciences), Teaching Assistant

2000-2002 Department of Biostatistics, University of Washington, Seattle, WA; Biost 503 (Application of Statistics to Health Sciences), Teaching Assistant

2000-2002 Department of Biostatistics, University of Washington, Seattle, WA; Biost 511,512,513 (Medical Biometry I, II, III), Teaching Assistant

2000-2002 Department of Biostatistics, University of Washington, Seattle, WA; Biost 517 (Applied Biostat I), Teaching Assistant

2000-2002 Department of Biostatistics, University of Washington, Seattle, WA; Biost 537 (Survival Data Analysis in Epidemiology), Teaching Assistant

2000-2002 Department of Biostatistics, University of Washington, Seattle, WA; Biost 540 (Correlated Data Regression), Teaching Assistant

2006 Center for Devices and Radiological Health, Food and Drug Administration, Washington, D.C.; Statistical Methods for Evaluating Tests and Biomarkers in Medicine, Short Course Instructor

2006-2007 Department of Biostatistics, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD; Biost 622,623 (Statistical Methods in Public Health II, III), Teaching Assistant

2007 Department of Biostatistics, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD; Biost 550.711 (Methods in Clinical Research), Co-instructor

2007 Summer Institute in Statistical Genetics, Department of Biostatistics, University of Washington, Seattle, WA ; Evaluating Biomarker Performance , Short Course Co-instructor

2007 Joint Statistical Meetings, Salt Lake City, UT; Statistical Evaluation of Medical Tests and Biomarkers for Classification, Short Course Co-instructor

2008 Joint Statistical Meetings, Statistical Evaluation of Medical Tests and Biomarkers for Classification, Denver Co; Short Course Co-instructor

2013 University of Washington, Seattle, WA; Biostatistics Essentials for STD/HIV Research. Principles of STD/HIV Research, Short Course Co-instructor

2013 Albert Einstein College of Medicine, New York, NY; Development and Evaluation of Risk Prediction Models, Short Course Instructor

2014 Summer Institute in Statistics for Clinical Research, University of Washington, Seattle,

- 2015 WA ; Development and Evaluation of Risk Prediction Models, Short Course Co-instructor
 Summer Institute in Statistics for Clinical Research, University of Washington, Seattle, WA ; Development and Evaluation of Risk Prediction Models, Short Course Co-instructor
- 2015 University of Washington, Seattle, WA; Biostatistics Essentials for STD/HIV Research. Principles of STD/HIV Research, Short Course Co-instructor
- 2016 Summer Institute in Statistics for Clinical Research, University of Washington, Seattle, WA ; Discovering and Evaluating Biomarkers for Guiding Treatment: Methodology for Precision Medicine, Short Course Co-instructor
- 2016 University of Washington, Seattle, WA; Biostatistics Essentials for STD/HIV Research. Principles of STD/HIV Research, Short Course Co-instructor

MENTORING

Mentees

- 2011-2014 Chaeryon Kang, Post-Doctoral Fellow, Fred Hutchinson Cancer Research Center
- 2015-2016 Jason Liang, Post-Doctoral Fellow, Fred Hutchinson Cancer Research Center

Graduate Committees and Advising

- 2007-2009 Yuying Jin, PhD Student, Department of Biostatistics, University of Washington; Research Assistant Advisor
- 2009 Jessie Wen Gu, PhD Student, Department of Biostatistics, University of Washington; Member of Dissertation Committee
- 2009-2011 Kelly Stratton, Masters Student, Department of Biostatistics, University of Washington; Academic Advisor
- 2009-2012 Erin Gabriel, PhD Student, Department of Biostatistics, University of Washington; Research Assistant Advisor and Member of Dissertation Reading Committee
- 2010-2013 David Prince, PhD Student, Department of Biostatistics, University of Washington; Academic Advisor
- 2011 Traci Bartz, Masters Student, Department of Biostatistics, University of Washington; Masters Thesis Advisor
- 2011 Sean Devlin, PhD Student, Department of Biostatistics, University of Washington; Member of Dissertation Committee
- 2011-2012 Clara Dominguez Islas, PhD Student, Department of Biostatistics, University of Washington; Research Assistant Advisor
- 2015-present Allison Meisner, PhD Student, Department of Biostatistics, University of Washington; Member of Dissertation Reading Committee
- 2016-present Tracey Marsh, PhD Student, Department of Biostatistics, University of Washington; Member of Dissertation Reading Committee
- 2016-present Ted Westling, PhD Student, Department of Biostatistics, University of Washington, Research Assistant Advisor

2017-present Jeremy Roth, PhD Student, Department of Biostatistics, University of Washington;
Member of Dissertation Committee

EDITORIAL RESPONSIBILITIES

Associate Editor

Journal of the National Cancer Institute (2015-present)

Diagnostic and Prognostic Research (2016-present)

Referee for the Following Journals (2015-present)

Biometrics

Biostatistics

Communications in Statistics

Contemporary Clinical Trials

Journal of the American Statistical Association

Journal of the National Cancer Institute

Journal of the Royal Statistical Society

PLOS ONE

Statistics in Medicine

PROFESSIONAL SERVICE

National

2017 SMC member for Phase I influenza vaccine study (Baylor College of Medicine)

2015, 2017 Ad-hoc grant reviewer for Medical Research Council (United Kingdom)

2016-present Member of Vaccines and Related Biological Products Advisory Committee, US Food and Drug Administration

2015-present Member of Research Oversight Committee for stroke proteomics project (Genome BC)

2015-present DSMB member for Phase II trial of Targeted Anticoagulation Therapy in Long-Term HIV Disease (University of Minnesota)

2014-present Co-chair, HIV Vaccine Trials Network (HVTN) efficacy trials working group

2014 Ad-hoc grant reviewer for Bill and Melinda Gates Foundation

Local

2007-2008 Organizer, SCHARP seminar series

2010 Member, VIDD faculty search committee

2010-2011 Member, UW Biostatistics affiliates and adjunct committee

2011-present Organizer, Fred Hutch/UW Biomarker Reading Group (bi-weekly meetings)

2012 Member, PHS faculty promotion committee

2012 Invited talk, Fred Hutch Development Office, Innovators Network Happy Hour

2012 Member, SWOG faculty search committee

2012-present Member, VIDD Staff scientist promotion committee

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| 2013 | Chair, VIDF faculty search committee |
| 2013 | Member, VIDF faculty promotion committee |
| 2013 | Invited talk, HIV Vaccine Trials Network (HVTN), HIV Vaccine Awareness Day Community Event |
| 2013-present | Co-organizer, Clinical Trials Affinity Group, VIDF and PHS (monthly meetings) |
| 2016 | Member, VIDF faculty search committee |

BIBLIOGRAPHY

Refereed Research Articles

1. Pepe MS, **Janes H**, Longton G, Leisenring W, Newcomb P. Limitations of the odds ratio in gauging the performance of a diagnostic, prognostic, or screening marker. *Am J Epidemiol*. 2004;159(9):882-90.
2. **Janes H**, Pepe M, Kooperberg C, Newcomb P. Identifying target populations for screening or not screening using logic regression. *Stat Med*. 2005;24(9):1321-38.
3. **Janes H**, Sheppard L, Lumley T. Case-crossover analyses of air pollution exposure data: Referent selection strategies and their implications for bias. *Epidemiology*. 2005;16(6):717-26.
4. **Janes H**, Sheppard L, Lumley T. Overlap bias in the case-crossover design, with application to air pollution exposures. *Stat Med*. 2005;24(2):285-300.
5. **Janes H**, Pepe M. The optimal ratio of cases to controls for estimating the classification accuracy of a biomarker. *Biostatistics*. 2006;7(3):456-68.
6. **Janes H**, Dominici F, Zeger SL. Trends in air pollution and mortality: An approach to the assessment of unmeasured confounding. *Epidemiol*. 2007;18(4):416-23.
7. Pepe MS, **Janes H**. Insights into latent class analysis of diagnostic test performance. *Biostatistics*. 2007;8(2):474-84.
8. Eftim SE, Samet JM, **Janes H**, McDermott A, Dominici F. Fine particulate matter and mortality: A comparison of the six cities and American Cancer Society cohorts with a medicare cohort. *Epidemiol*. 2008;19(2):209-16.
9. **Janes H**, Pepe MS. Matching in studies of classification accuracy: Implications for analysis, efficiency, and assessment of incremental value. *Biometrics*. 2008;64(1):1-9.
10. **Janes H**, Pepe MS. Adjusting for covariates in studies of diagnostic, screening, or prognostic markers: An old concept in a new setting. *Am J Epidemiol*. 2008;168(1):89-97.
11. **Janes H**, Sheppard L, Shepherd K. Statistical analysis of air pollution panel studies: An illustration. *Ann Epidemiol*. 2008;18(10):792-802.

12. McElrath MJ, De Rosa SC, Moodie Z, Dubey S, Kierstead L, **Janes H**, Defawe OD, Carter DK, Hural J, Akondy R, Buchbinder SP, Robertson MN, Mehrotra DV, Self SG, Corey L, Shiver JW, Casimiro DR. HIV-1 vaccine-induced immunity in the test-of-concept Step study: A case-cohort analysis. *Lancet*. 2008;372(9653):1894-905. PMID: 2774110.
13. Pepe MS, Feng Z, **Janes H**, Bossuyt PM, Potter JD. Pivotal evaluation of the accuracy of a biomarker used for classification or prediction: Standards for study design. *J Natl Cancer Inst*. 2008;100(20):1432-8. PMID: 2567415.
14. Pepe MS, **Janes H**. Gauging the performance of SNPs, biomarkers, and clinical factors for predicting risk of breast cancer. *J Natl Cancer Inst*. 2008;100(14):978-9. PMID: 3132154.
15. **Janes H**, Pepe MS, Gu W. Assessing the value of risk predictions by using risk stratification tables. *Ann Intern Med*. 2008;149(10):751-60. PMID: 3091826.
16. **Janes H**, Longton G, Pepe M. Accommodating covariates in ROC analysis. *Stata J*. 2009;9(1):17-39. PMID: 2758790.
17. **Janes H**, Pepe MS. Adjusting for covariate effects on classification accuracy using the covariate-adjusted receiver operating characteristic curve. *Biometrika*. 2009;96(2):371-82. PMID: 3371718.
18. Pepe M, Longton G, **Janes H**. Estimation and comparison of receiver operating characteristic curves. *Stata J*. 2009;9(1):1. PMID: 2774909.
19. **Janes H**, Dominici F, Zeger S. On quantifying the magnitude of confounding. *Biostatistics*. 2010;11(3):572-82. PMID: 2883302.
20. Seaman MS, **Janes H**, Hawkins N, Grandpre LE, Devoy C, Giri A, Coffey RT, Harris L, Wood B, Daniels MG, Bhattacharya T, Lapedes A, Polonis VR, McCutchan FE, Gilbert PB, Self SG, Korber BT, Montefiori DC, Mascola JR. Tiered categorization of a diverse panel of HIV-1 Env pseudoviruses for assessment of neutralizing antibodies. *J Virol*. 2010;84(3):1439-52. PMID: 2812321.
21. Barnabas RV, Wasserheit JN, Huang Y, **Janes H**, Morrow R, Fuchs J, Mark KE, Casapia M, Mehrotra DV, Buchbinder SP, Corey L. Impact of herpes simplex virus type 2 on HIV-1 acquisition and progression in an HIV vaccine trial (the Step study). *J Acquir Immune Defic Syndr*. 2011;57(3):238-44. PMID: 3446850.
22. Fitzgerald DW, **Janes H**, Robertson M, Coombs R, Frank I, Gilbert P, Loufty M, Mehrotra D, Duerr A. An Ad5-vectored HIV-1 vaccine elicits cell-mediated immunity but does not affect disease progression in HIV-1-infected male subjects: Results from a randomized placebo-controlled trial (the Step study). *J Infect Dis*. 2011;203(6):765-72. PMID: 3119328.
23. **Janes H**, Pepe MS, Bossuyt PM, Barlow WE. Measuring the performance of markers for guiding treatment decisions. *Ann Intern Med*. 2011;154(4):253-9. PMID: 3085402.
24. Janssens AC, Ioannidis JP, Bedrosian S, Boffetta P, Dolan SM, Dowling N, Fortier I, Freedman AN, Grimshaw JM, Gulcher J, Gwinn M, Hlatky MA, **Janes H**, Kraft P, Melillo S, O'Donnell CJ, Pencina MJ, Ransohoff D, Schully SD, Seminara D, Winn DM, Wright CF, van Duijn CM, Little J, Khoury MJ. Strengthening the reporting of genetic risk prediction studies (GRIPS): Explanation and elaboration. *Eur J Hum Genet*. 2011;19(5):18 p preceding 494. PMID: 3083630.
25. Pepe MS, **Janes H**. Commentary: Reporting standards are needed for evaluations of risk reclassification. *Int J Epidemiol*. 2011;40(4):1106-8. PMID: 3156371.

26. Abu-Raddad LJ, Barnabas RV, **Janes H**, Weiss HA, Kublin JG, Longini IM, Jr., Wasserheit JN, the HIVVLWG. Have the explosive HIV epidemics in sub-Saharan Africa been driven by higher community viral load? *AIDS*. 2012. PMID: 3725236.
27. Haynes BF, Gilbert PB, McElrath MJ, Zolla-Pazner S, Tomaras GD, Alam SM, Evans DT, Montefiori DC, Karnasuta C, Sutthent R, Liao HX, DeVico AL, Lewis GK, Williams C, Pinter A, Fong Y, **Janes H**, DeCamp A, Huang Y, Rao M, Billings E, Karasavvas N, Robb ML, Ngauy V, de Souza MS, Paris R, Ferrari G, Bailer RT, Soderberg KA, Andrews C, Berman PW, Frahm N, De Rosa SC, Alpert MD, Yates NL, Shen X, Koup RA, Pitisuttithum P, Kaewkungwal J, Nitayaphan S, Rerks-Ngarm S, Michael NL, Kim JH. Immune-correlates analysis of an HIV-1 vaccine efficacy trial. *N Engl J Med*. 2012;366(14):1275-86. PMID: 3371689.
28. Huang Y, Gilbert PB, **Janes H**. Assessing treatment-selection markers using a potential outcomes framework. *Biometrics*. 2012;68(3):687-96. PMID: 3417090.
29. **Janes H**, Frahm N, DeCamp A, Rolland M, Gabriel E, Wolfson J, Hertz T, Kallas E, Goepfert P, Friedrich DP, Corey L, Mullins JI, McElrath MJ, Gilbert P. MRKAd5 HIV-1 Gag/Pol/Nef vaccine-induced T-cell responses inadequately predict distance of breakthrough HIV-1 sequences to the vaccine or viral load. *PLoS One*. 2012;7(8):e43396. PMID: 3428369.
30. **Janes H**, Friedrich DP, Krambrink AM, Smith RJ, Kallas E, Horton H, Casimiro DR, Carrington M, Geraghty D, Gilbert PB, McElrath J, Frahm N. Vaccine-induced Gag-specific T cells are associated with reduced viremia after HIV infection. *J Infect Dis*. 2013;208(8):1231-9. PMID: 23878319.
31. Moodie Z, **Janes H**, Huang Y. New clinical trial designs for HIV vaccine evaluation. *Curr Opin HIV AIDS*. 2013;8(5):437-42. PMID: 23872613.
32. **Janes H**, Pepe MS, Huang Y. A framework for evaluating markers used to select patient treatment. *Med Decis Making*. 2014;34(2):159-67. PMID: 23811760.
33. Hammer SM, Sobieszczyk ME, **Janes H**, Karuna ST, Mulligan MJ, Grove D, Koblin BA, Buchbinder SP, Keefer MC, Tomaras GD, Frahm N, Hural J, Anude C, Graham BS, Enama ME, Adams E, DeJesus E, Novak RM, Frank I, Bentley C, Ramirez S, Fu R, Koup RA, Mascola JR, Nabel GJ, Montefiori DC, Kublin J, McElrath MJ, Corey L, Gilbert PB, HVTN 505 Study Team. Efficacy trial of a DNA/rAd5 HIV-1 preventive vaccine. *N Engl J Med*. 2013;369(22):2083-92. PMID: 4030634.
34. **Janes H**, Gilbert P, Buchbinder S, Kublin J, Sobieszczyk ME, Hammer SM. In pursuit of an HIV vaccine: Designing efficacy trials in the context of partially effective non-vaccine prevention modalities. *AIDS Res Hum Retroviruses*. 2013;29(11):1513-23. PMID: 3809388.
35. Kerr KF, Wang Z, **Janes H**, McClelland RL, Psaty BM, Pepe MS. Net reclassification indices for evaluating risk prediction instruments: A critical review. *Epidemiol*. 2014;25(1):114-21. PMID: 24240655.
36. **Janes H**, Brown MD, Pepe MS, Huang Y. An approach to evaluating and comparing biomarkers for patient treatment selection. *Int J Biostat*. 2014;10(1):99-121. PMID: PMC4341986.
37. Pepe MS, **Janes H**, Li CI. Net risk reclassification p values: valid or misleading? *J Natl Cancer Inst*. 2014;106(4):dju041. PMID: 3982889.
38. Huang Y, Laber E, **Janes H**. Characterizing expected benefits of biomarkers in treatment selection. *Biostatistics*. 2014;16(2):383-99.

39. Kang C*, **Janes H**, Huang Y. Combining biomarkers to optimize patient treatment recommendations. *Biometrics*. 2014;70(3):695-707. PMID: 4248022.
40. Li SS, Gilbert PB, Tomaras GD, Kijak G, Ferrari G, Thomas R, Pyo C-W, Zolla-Pazner S, Montefiori D, Liao H-X, Nabel G, Pinter A, Evans DT, Gottardo R, Dai JY, **Janes H**, Morris D, Fong Y, Edlefsen PT, Li F, Frahm N, Alpert MD, Prentice H, Rerks-Ngarm S, Pitisuttithum P, Kaewkungwal J, Nitayaphan S, Robb ML, Connell RJ, Haynes BF, Michael NL, Kim JH, McElrath MJ, Geraghty DE. FCGR2C polymorphisms associate with HIV-1 vaccine protection in RV144 trial. *J Clin Invest*. 2014;124(9):3879-90. PMID: 4151214.
41. Gartland AJ, Li S, McNevin J, Tomaras GD, Gottardo R, **Janes H**, Fong Y, Morris D, Geraghty DE, Kijak GH, Edlefsen PT, Frahm N, Larsen BB, Tovanabutra S, Sanders-Buell E, deCamp AC, Margaret CA, Ahmed H, Goodridge JP, Chen L, Konopa P, Nariya S, Stoddard JN, Wong K, Zhao H, Deng W, Maust BS, Bose M, Howell S, Bates A, Lazzaro M, O'Sullivan A, Lei E, Bradfield A, Ibitamuno G, Assawadarachai V, O'Connell RJ, deSouza MS, Nitayaphan S, Rerks-Ngarm S, Robb ML, Sidney J, Sette A, Zolla-Pazner S, Montefiori D, McElrath MJ, Mullins JI, Kim JH, Gilbert PB, Hertz T. Analysis of HLA A*02 Association with Vaccine Efficacy in the RV144 HIV-1 Vaccine Trial. *J Virol*. 2014;88(15):8242-55. PMID: 4135964.
42. **Janes H**, Pepe MS, McShane LM, Sargent DJ, Heagerty PJ. The fundamental difficulty with evaluating the accuracy of biomarkers for guiding treatment. *J Nat Cancer Inst*. 2015;107(8): pii: djv157. PMID: 4609557.
43. Huang Y, Karuna ST, **Janes H**, Frahm N, Nason M, Edlefsen PT, Kublin JG, Corey L, McElrath MJ, Gilbert PB. Use of placebos in Phase 1 preventive HIV vaccine clinical trials. *Vaccine*. 2015;33(5):74952. PMID: 4554766.
44. **Janes H**, Brown MD, Pepe MS. Designing a study to evaluate the benefit of a biomarker for selecting patient treatment. *Stat Med*. 2015;34(27):3503-15. PMID: 4626364.
45. Huang Y, Follmann D, Nason M, Zhang L, Huang Y, Mehrotra DV, Moodie Z, Metch B, **Janes H**, Keefer MC, Churchyard G, Robb ML, Fast PE, Duerr A, McElrath MJ, Corey L, Mascola JR, Graham BS, Sobieszczyk ME, Kublin JG, Robertson M, Hammer SM, Gray G, Buchbinder SP, Gilbert PB. Effect of rAd5-vector HIV-1 preventive vaccines on HIV-1 acquisition: A participant-level meta-analysis of randomized trials. *PLOS ONE*. 2015;10(9):e0136626. PMID: 4558095.
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47. **Janes H**, Tovanabutra S, Herbeck JT, Frahm N, Duerr A, Hural J, Corey L, Self SG, Buchbinder S, McElrath JM, O'Connell RJ, Paris R, Rerks-Ngarm S, Nitayaphan S, Pitisuttithum P, Kaewkungwal J, Robb ML, Michael NM, Mullins JI, Kim JH, Gilbert PB, Rolland M. HIV-1 infections with multiple founders are associated with higher viral loads. *Nat Med*. 2015;21(10):1139-41. PMID: 4598284.
48. Huang Y, Diaz Granados C, **Janes H**, Huang Y, deCamp A, Metch B, Grant SP, Sanchez B, Phogat S, Tomaras GD, McElrath J, Kublin J, Corey L, Gilbert PB. Selection of HIV vaccine candidates for concurrent testing in an efficacy trial. *Curr Opin Virol*. 2016;17:57-65. PMID: 4902743.
49. Gilbert PB, **Janes H**, Huang Y. Power/sample size calculations for assessing correlates of risk in clinical efficacy trials. *Stat Med*. 2016;35(21):3745-59. PMID: 4965346.

50. Kerr K, Brown MD, Zhu K, **Janes H**. Assessing the clinical impact of risk prediction models with decision curves: Guidance for correct interpretation and appropriate use. *J Clin Onc*. 2016;34(21):2534-40. PMID: 4962736.
51. Pepe MS, **Janes H**, Li CL, Bossuyt PM, Feng Z, Hilden J. Early phase studies of biomarkers: What target sensitivity and specificity values might confer clinical utility? *Clin Chem*. 2016;62(5):737-42. PMID: 5003106.
52. Gilbert PB⁺, Huang Y⁺, **Janes H**⁺. Modeling vaccine trials of the future. *Curr Opin HIV AIDS*. 2016;11(5):620-27. PMID: 5077275.
53. Hanscom B, **Janes H**, Guarino PD, Huang Y, Brown ER, Chen YQ, Hammer SM, Gilbert PB, Donnell DJ. Brief Report: Preventing HIV-1 infection in women using oral pre-exposure prophylaxis: A meta-analysis of current evidence. *J Acquir Immune Defic Syndr*. 2016;73(5):606-8. PMID: 5175411.
54. Huang Y, Gilbert P, Fong R, **Janes H**. Statistical methods for down-selection of treatment regimens based on multiple endpoints, with application to HIV vaccine trials. *Biostatistics*. 2016. Sep 20 [Epub ahead of print].
55. Huang Y, Zhang L, **Janes H**, Frahm N, Isaacs A, Kim JH, Montefiori DM, McElrath J, Tomaras GD, Gilbert PB. Predictors of durable immune responses six months after the last vaccination in preventive HIV vaccine trials. *Vaccine*. 2017;35(8):1184-93. PMID: 5319823.
56. **Janes H**, Cohen K, Frahm N, DeRosa S, Sanchez B, Hural J, Magaret C, Karuna C, Bentley R, Gottardo G, Finak G, Grove D, Shen M, Graham B, Koup R, Mulligan M, Koblin B, Buchbinder S, Keefer M, Adams E, Anude C, Corey L, Sobieszczyk M, Hammer S, Gilbert PB, McElrath MJ. Higher T cell responses induced by DNA/rAd5 HIV-1 preventative vaccine are associated with lower HIV-1 infection risk in an efficacy trial. *J Infect Dis*. 2017. Feb 12 [Epub ahead of print].

Manuscripts under Review

1. **Janes H**, Brown MD, Cramer MR, Miller DP, Barlow WE. Adjusting for prognostic clinical factors in evaluating markers for guiding use of chemotherapy for treating estrogen-receptor-positive, node-positive breast cancer. *Contemp Clin Trials*.
2. Dai J*, Liang J, LeBlanc M, Prentice R, **Janes H**. Case-only approach to identifying markers predicting treatment effects on the relative risk scale. *Biometrics*.
3. Kang C*, **Janes H**, Tajik P, Groen H, Mol MJB, Koopmans CM, Broekhuijsen K, Zwertbroek E, van Pampus MG, Franssen MTM. Evaluation of biomarkers for treatment selection using individual participant data meta-analysis. *Stat Med*.

Letters to the Editor and Non-Refereed Contributions

1. **Janes H**, Sheppard L, Lumley T. Do subject characteristics modify the effects of particulate air pollution on daily mortality among the elderly? Letter to the Editor. *J Occup Environ Med*. 2005;47(6):543.
2. Lumley T, **Janes H**, Sheppard L. Cox models for ecologic time-series data? Letter to the Editor. *Environ Health Perspect*. 2006;114(12):A690-1. PMID: 1764157.
3. **Janes H**, Dominici F, Zeger S. Letter to the editor. Response to Dr.s. Pope and Burnett: Partitioning evidence of association between air pollution and mortality. *Epidemiol*. 2007;18(4):427-8.

4. Pepe MS, **Janes H**, Gu JW. Letter to the editor regarding article, "Use and misuse of the receiver operating characteristic curve in risk prediction". *Circulation*. 2007;116(6):e132.
5. **Janes H**, Pepe MS, Gu W. Assessing the value of risk predictions by using risk stratification tables. *Ann Intern Med*. 2008;149(10):751-60. PMID: 3091826.
6. **Janes H**, Pepe MS, Gu W. Are Risk Stratification Tables the Best Way to Evaluate Model Performance? Response. *Ann Intern Med*. 2009;150(6):428.
7. **Janes H**, Pepe M. Letter to the editor re: "Clinical usefulness of the Framingham cardiovascular risk profile beyond its statistical performance: The Tehran lipid and glucose study". *Am J Epidemiol*. 2013;177(8):864-5. PMID: 23524037.
8. **Janes H**. Letter to the editor. *Biostatistics*. 2013;14(4):807-8. PMID: 3841383.
9. Kang C*, **Janes H**, Huang Y. Rejoinder: Combining biomarkers to optimize patient treatment recommendations. *Biometrics*. 2014: May 30; [Epub ahead of print]. PMID: 4247994.
10. Kerr KF, Brown M, **Janes H**. Reply to A.J. Vickers et al. *J Clin Oncol*. 2017;35(4):473-75.
11. **Janes H**. Book Review: Analysis of Biomarker Data: A Practical Guide. *Biometrics* (in press).
12. Kerr K, **Janes H**. First things first: Risk model performance metrics should reflect the clinical application. *Stat Med*. (in press).

Books and Book Chapters

1. **Janes H**, Margaret A. "Statistical evaluation of diagnostic tests." In: *Laboratory Diagnosis of Viral Infections, Fourth Edition*, Ed: Jerome KR. Informa Healthcare, New York (2010), 9-18.
2. Pepe MS, **Janes H**. Methods for evaluating prediction performance of biomarkers and tests. In: *Risk Assessment and Evaluation of Predictions*. Eds: Cai T, Gail M, Gandy A, Lee MLT, Pfeiffer R, Satten G. Springer, New York (2013), 107-142.

* Indicates work led by student/post-doc under mentorship of H. Janes

+ Indicates equal contributions

ABSTRACTS

1. **Janes H**, Mehrotra D, Duerr A, Gilbert P, Buchbinder S, Robertson M, Fitzgerald D, HIV Vaccine Trials Network (HVTN). Vaccine Effects on HIV-1 Progression in the STEP Study. *AIDS Vaccine*, Cape Town, South Africa (2008).
2. Frahm N, DeRosa S, Defawe O, Carter D, **Janes H**, Moodie Z, Noonan L, Duerr A, Fitzgerald D, Kublin J, Buchbinder S, Robertson M, Casimiro D, McElrath MJ, HIV Vaccine Trials Network (HVTN). HIV infected cases have lower pre-infection Ad5-specific T-cell response rates than non-cases after Ad5/HIV vaccination in the Step trial. *AIDS Vaccine*, Cape Town, South Africa (2008).
3. Barnabas R, Huang Y, **Janes H**, Morrow R, Fuchs J, Mark K, Casapia M, Mehrotra D, Buchbinder S, Corey L, Wasserheit J and the NIAID HIV Vaccine Trials Network. HSV-2 is associated with HIV acquisition among both placebo and vaccine recipients in the STEP trial of the Merck Adenovirus 5 (MRKAd5) HIV-1 vaccine. International AIDS Society Conference, Cape Town, South Africa (2009).

4. Frahm N, **Janes H**, Friedrich D, Slichter C, Smith R, Site PI author, Geraghty D, Self S, McElrath J and the NIAID HIV Vaccine Trials Network (HVTN). Beneficial effects of protective HLA class I allele expression on HIV viral load are not mediated through increased vaccine-induced immunity. AIDS Vaccine, Atlanta, GA (2010).
5. **Janes H**, Gilbert PB, Frahm N, Rolland M, DeCamp A, Gabriel E, Wolfson J, Mullins J, McElrath J. Integrated analysis of immunogenicity, viral sequence, and viral load data in the step study. AIDS Vaccine, Bangkok, Thailand (2011).
6. Li S, Gilbert PB, Tomaras GD, Kijak G, Ferrari G, Thomas R, Zolla-Pazner S, Evans DT, Li Y, Gottardo R, Dai JY, **Janes H**, Morris D, Fong Y, Edlefsen PT, Li F, Magaret CA, Frahm N, Alpert MD, Rerks-Ngarm S, Pitisuttithum P, Kaewkungwal J, Nitayaphan S, Robb ML, O'Connell RJ, Michael NL, Kim JH, McElrath MJ, Geraghty DE. Association of FcγRIIC Polymorphism with Vaccine Efficacy and Correlates of HIV-1 Infection Risk in RV144. AIDS Vaccine, Barcelona, Spain (2013).
7. Hammer S, Sobieszczyk M, **Janes H**, Gilbert P, Karuna S, Grove D, Ramirez S, Bentley C, Anude C, Mulligan M, Koblin B, Buchbinder S, Keefer M, Hural J, McElrath J, Frahm N, Tomaras G, Enama M, Broder G, Maynard J, Wakefield S, Holt R, DeJesus E, Frank I, Novak R, Martinez A, Kublin J, Corey L, and the HIV Vaccine Trials Network . HVTN 505: Efficacy of a Multi-Gene DNA Prime/Recombinant Adeno 5 (rAd5) Vector Boost Vaccine in Men & Transgender Women (TGW) Who Have Sex with Men. AIDS Vaccine, Barcelona, Spain (2013).
8. **Janes H**, Tovanabutra S, Herbeck J, Rerks-Ngarm S, Robb M, Michael N, Gilbert P, Kim J, Rolland M. HIV-1 infections with multiple founders are associated with higher viral loads. Conference on Retroviruses and Opportunistic Infections (CROI), Seattle, WA (2015).
9. **Janes H**, Cohen K, Sobieszczyk M, Frahm N, Karuna S, Sanchez B, Magaret C, Adams E, Hammer S, Gilbert P, McElrath J. Vaccine-Induced CD8+ T Cell Immunity Strongly Predicts Lower HIV Infection Risk in HVTN 505. R4P, Chicago, IL (2016).

INVITED PRESENTATIONS *(only includes presentations given by H. Janes)*

1. Overlap bias in the case-crossover design, with application to air pollution exposures. Department of Biostatistics, University of Washington, Seattle, WA (2004).
2. Overlap bias in the case-crossover design, with application to air pollution exposures. Environmental Biostatistics and Epidemiology Working Group, Department of Biostatistics, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD (2005).
3. Adjusting for covariate effects on classification accuracy: Implications for analysis, efficiency and assessment of incremental value. Student conference award presentation at the 26th annual conference of the International Society for Clinical Biostatistics, Szeged, Hungary (2005).
4. Adjusting for covariate effects on classification accuracy: Implications for analysis, efficiency and assessment of incremental value. Department of Biostatistics, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD (2005).
5. Adjusting for covariate effects on classification accuracy: Implications for analysis, efficiency and assessment of incremental value. Division of Epidemiology, Statistics and Prevention Research, National Institute of Child Health and Human Development, Rockville, MD (2006).

6. Matching in studies of classification accuracy: Implications for analysis, efficiency and assessment of incremental value. Division of Cancer Treatment and Diagnosis, Biometric Research Branch, National Cancer Institute, Rockville, MD (2006).
7. Matching in studies of classification accuracy: Implications for analysis, efficiency and assessment of incremental value. Division of Cancer Treatment and Diagnosis, Biometric Research Branch, National Cancer Institute, Rockville, MD (2006).
8. Matching in studies of classification accuracy: Implications for analysis, efficiency and assessment of incremental value. Annual meeting of the Western North American Region of the International Biometric Society, Irvine, CA (2007).
9. On quantifying the magnitude of confounding. Annual meeting of the American Public Health Association, Washington, DC (2007).
10. Covariate adjustment in studies of classification accuracy: An old concept in a new setting. Oregon Health and Science University, Portland, OR (2007).
11. Calculating disease risk: Evaluating risk prediction models using risk stratification tables. Annual meeting of the Eastern North American Region of the International Biometric Society, San Antonio, TX (2009).
12. Calculating disease risk: Evaluating risk prediction models using risk stratification tables. International Chinese Statistical Association Applied Statistics Symposium, San Francisco, CA (2009).
13. Assessing the clinical value of risk prediction tools. HuGENet Workshop: Strengthening the reporting of genetic risk prediction studies, Centers for Disease Control and Prevention, Atlanta, GA (2009).
14. Statistical methods for evaluating markers for treatment selection. Annual meeting of the Western North American Region of the International Biometric Society, Seattle, WA (2010).
15. Statistical methods for evaluating markers for treatment selection. Joint Statistical Meetings, Vancouver, Canada (2010).
16. Designing studies to evaluate biomarkers for selecting patient treatment. Conference on risk assessment and evaluation of predictions, Silver Spring, MD (2011).
17. A statistical perspective on the RV144 immune correlates analysis. HIV Vaccine Trials Network Full Group Meeting, Seattle, WA, Plenary Presentation (2011).
18. Designing studies to evaluate biomarkers for selecting patient treatment. Annual meeting of the Eastern North American Region of the International Biometric Society, Washington, DC (2012).
19. Incorporating covariates in assessing the performance of markers for treatment selection. Annual meeting of the Eastern North American Region of the International Biometric Society, Orlando, FL (2013).
20. Designing HIV vaccine efficacy trials in the PrEP era. Workshop on clinical trial design for long-acting PrEP agents at the Aaron Diamond AIDS Research Center, New York City, NY (2013).
21. Designing a phase III HIV vaccine efficacy trial. Annual meeting of the International Society for Clinical Biostatistics, Munich, Germany (2013).
22. HVTN 505: Immunogenetics, HIV infection and viral load. HIV Vaccine Trials Network Full Group Meeting, Washington, DC, Plenary Presentation (2014).

23. Methods for evaluating biomarkers for guiding therapy. Fifth Seattle Symposium in Biostatistics, Seattle, WA (2015).
24. The challenge in making inference about a biomarker's predictive capacity. International Chinese Statistical Association Annual Meeting, Fort Collins, CO (2015).
25. The challenge in making inference about a biomarker's predictive capacity. Joint Statistical Meetings, Seattle, WA (2015).
26. Evaluating biomarkers for guiding therapy. Biostatistics Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, Bethesda, MD (2016).
27. Evaluating biomarkers for guiding therapy. Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY (2016).
28. Evaluating biomarkers for guiding therapy. Department of Biostatistics, University of Michigan, Ann Arbor, MI (2016).
29. A framework for evaluating precision prevention. Annual meeting of the Eastern North American Region of the International Biometric Society. Washington, DC (2017).