

CURRICULUM VITAE

Michael Patrick Fay

5601 Fishers Lane, Room 4C40/ MSC 9820
Bethesda, MD 20892
Phone: (240) 669-5228
mfay@niaid.nih.gov

EDUCATION:

May 1987 - B.A. (Mathematics, minor:Physics), University of Virginia, Charlottesville, Virginia
August 1993 - Ph.D. (Biostatistics), Medical College of Virginia at Virginia Commonwealth University, Richmond, Virginia

POSITIONS HELD:

1991 Summer Intern, Pharmaceutical Research Associates, Charlottesville, Virginia.

- Provide SAS programming support and help writing reports.

1990-1992 Student Fellowship, Burroughs Wellcome Co., Research Triangle Park, North Carolina.

- Provide SAS programming support.

1992-1993 Student Co-director, Biostatistical Consulting Laboratory, Medical College of Virginia, Richmond, Virginia

- Meet with medical researchers, assess statistical needs and assign students to project.

1993 Guest Instructor, Medical College of Virginia, Richmond, Virginia.

1993 Statistician, Statistics Collaborative, Washington, D.C.

- Analyze data and write reports.

1994-1996 Intramural Research Training Award Fellow, Biometry Branch, Division of Cancer Prevention and Control, National Cancer Institute, NIH, Bethesda, Maryland.

- Work either collaboratively or independently to develop statistical methods relevant for cancer research

1996-1997 Senior Staff Fellow, Biometry Branch, Division of Cancer Prevention and Control, National Cancer Institute, NIH, Bethesda, Maryland.

- Work either collaboratively or independently to develop statistical methods relevant for cancer research

1998 (see Service section)

1999-2003 Mathematical Statistician, Statistical Modelling and Methods Section, Applied Research Branch, Division of Cancer Control and Population Sciences, National Cancer Institute, NIH, Bethesda, Maryland. On October 1, 1999, the section became Statistical Research and Applications Branch, Surveillance Research Program, DCCPS, NCI.

- Develop statistical methods, especially those relevant to cancer surveillance.
- Supervise contractors developing NCI software related to the statistical methods

that I helped develop. For example, chaired monthly conference calls between NCI researchers and contractors relating to the development of the Joinpoint software.

- Project officer on contract with Dr. Hyune-Ju Kim of Syracuse University.
- Supervise summer interns.

2004-present Mathematical Statistician, Biostatistics Research Branch, Office of Clinical Research, National Institute of Allergy and Infectious Diseases, NIH, Bethesda, Maryland.

- Provide statistical support for researchers in parasitic diseases at NIAID, including assistance in design of studies, analysis of results, and writing of scientific articles.
- Develop and publish in statistical journals new statistical methods.
- Supervise IRTA fellow (J. Kirk, 2010-2011) and summer intern (F. Noubary, 2006).
- Mentor Postdoc (Sungwook (Peter) Kim, 2014-2016)
- Provide advice to animal care and use committee.

EDITORIAL WORK:

2006-2010 Associate Editor for Biometrics

2014-present Associate Editor for Clinical Trials

AREAS OF INTEREST:

Hypothesis Testing, Interval Censored Data, Measures of Agreement, Age Adjusted Rates, Surveillance, Join Point Models, Malaria Vaccines.

PROFESSIONAL SOCIETIES:

American Statistical Association, International Biometrics Society, Institute of Mathematical Statistics

HONORS AND AWARDS:

1992-1993 Robert Wood Johnson Fellow

1993 Honorable mention, Student Presentation, Virginia Academy of Sciences Statistics Section

1993 Eastern North American Region Biometric Society Student Travel Award.

2001 NIH Merit Award: For developing novel methods and models for the presentation and analysis of the nation's population-based cancer statistics.

2010 Follmann, Fay, and Proschan (2009) awarded Best Paper in Biometrics by an IBS Member for 2009. Also selected in 2013 as one of 15 classic Biometrics papers.

2010 NIH Merit Award: For exemplary performance in the establishment of an outstanding collaborative environment with NIAID researchers involved in parasitic diseases.

- 2011 NIH Merit Award: For displaying exceptional leadership, communication, and collaborative skills to address mission-critical regulatory science needs for the development and use of medical countermeasures.
- 2017 NIH Merit Award: For exceptional leadership in the development of standard clinical trial endpoints to measure dengue disease severity in interventional clinical trials.
- 2019 Fellow of the American Statistical Association
- 2021 NCATS Director's Award: As part of Serosurvey Team. In recognition for working together to rapidly create a trans-NIH serosurvey clinical research program in March 2020 to assess the extent of SARS-CoV-2 spread in the community.
- 2021 NIH Director's Award: As part of COVID-19 Serosurvey Team. For establishing and analyzing the first representative US serosurvey of SARS-CoV-2, leading to identification of 17 million undiagnosed cases of COVID-19 as of summer 2020
- 2021 NIH Director's Award: As member of the Advancing COVID-19 Vaccines: ACTIV and HHS Collaborations. For outstanding efforts in the pursuit of efficacious vaccines to prevent COVID-19.

MENTORING:

- 2002 Ji-Hyun Lee, Statistical Research Assistant, SRAB, NCI.
- 2006 Farzad Noubary, Summer Intern, NIAID
- 2010-2011 Jennifer L. Kirk, Postbaccalaureate Intramural Research Training Award Fellow, NIAID.
- 2014-2016 Sungwook (Peter) Kim, Postdoctoral Fellow, NIAID

SERVICE:

- Byar Award Committee, ASA Biometrics Section (2020, 2022)
- Associate Program Chair, ENAR, 2019
- Supervised high school interns, 2018
- Science fair judge for Washington Statistical Society (2006-2015, 2018).
- Chaired sessions at Joint Statistical meetings and ENAR.
- 2014 Extended Advisory Board Member, FastVac.
- March 2015: NASA Human Exploration Research Opportunities (HERO) Immunology/Microbiology Review Panel.
- 1998 – Volunteer Visiting Statistician (January to October), St. John's Medical College, Bangalore, India.
 - Provide statistical support for researchers at the medical college. Including help with all statistical aspects of scientific research, including data collection, software design, statistical design and analysis.
 - Teach short courses in statistics to faculty and students.
- Review papers for statistical journals and other scientific journals

TEACHING:

- 2009-2012 Tutorials on Interval Censored Data Analysis: 2009 at DIA (Drug Information Association) Progression-Free Survival Oncology Workshop,

2009 Webinar for DIA, 2010 at useR Conference, 2010 at National Cancer Institute, Biometric Research Branch, 2012 at Centers for Disease Control and Prevention, Atlanta, GA.
2014 Team Taught, Introduction to Statistics, Manuscript Writing Workshop, Jakarta, Indonesia.

BOOK:

Fay, M., & Brittain, E. (2022). *Statistical Hypothesis Testing in Context: Reproducibility, Inference, and Science*. Cambridge: Cambridge University Press.

PEER-REVIEWED PUBLICATIONS (STATISTICAL):

Fay, MP, Gennings, C. (1996). Nonparametric Two-Sample Tests for Repeated Ordinal Responses. *Statistics in Medicine* **15**, 429-442.

Fay, MP. (1996). Rank Invariant Tests for Interval Censored Data under the Grouped Continuous Model. *Biometrics* **52**, 811-822.

Fay, MP, Feuer, EJ. (1997). Confidence Intervals for Directly Standardized Rates: A Method Based on the Gamma Distribution. *Statistics in Medicine* **16**, 791-801.

Fay, MP, Feuer, EJ. (1997). A Semiparametric Estimate of Extra-Poisson Variation for Vital Rates. *Statistics in Medicine* **16**, 2389-2401.

Fay, MP, Shih, JH. (1998). Permutation Tests using Estimated Distribution Functions. *Journal of the American Statistical Association* **93**, 387-396, March.

Fay, MP, Graubard, BI, Freedman, LS, Midthune, DN. (1998). Conditional Logistic Regression with Sandwich Estimators: Application to a Meta-Analysis. *Biometrics* **54**, 195-208.

Fay, MP. (1999). Comparing Several Score Tests for Interval Censored Data. *Statistics in Medicine* **18**, 273-285 (Correction: **18**, 2681, 1999).

Shih, JH, Fay, MP. (1999). A Class of Permutation Tests for Stratified Survival Data. *Biometrics* **55**, 1156-1161.

Fay, MP. (1999). Approximate Confidence Intervals for Rate Ratios from Directly Standardized Rates with Sparse Data. *Communications in Statistics, Theory and Methods* **28**, 2141-2160.

Kim, H-J, Fay, MP, Feuer, EJ, Midthune, DN. (2000). Permutation Tests for Joinpoint Regression with Applications to Cancer Rates. *Statistics in Medicine* **19**, 335-351 (correction: **20**: 655, 2001).

Fay, MP, Graubard, BI. (2001). Small-Sample Adjustments for Wald-type Tests using Sandwich Estimators. *Biometrics* **57**, 1198-1206.

- Fay, MP, Follmann, DA. (2002). Designing Monte Carlo Implementations of Permutation or Bootstrap Hypothesis Tests. *American Statistician* **56** (1), 63-70.
- Fay, MP. (2002). Measuring a Binary Response's Range of Influence in Logistic Regression. *American Statistician* **56** (1), 5-9.
- Fay, MP, Pfeiffer, R, Cronin, KA, Feuer, EJ, Le, C. (2003). Age-Conditional Probabilities of Developing Cancer. *Statistics in Medicine* **22** (11), 1837-1848.
- Kim, H-J, Fay, MP, Feuer, EJ, Yu, B, Barrett, MJ. (2004). Comparability of Joinpoint Regression Models, *Biometrics* **60** (4), 1005-1014.
- Fay, MP. (2004). Estimating age conditional probability of developing disease from surveillance data. *Population Health Metrics* **2**:6
(<http://www.pophealthmetrics.com/content/2/1/6>).
- Midthune, DN, Fay MP, Clegg, LX, Feuer EJ. (2005). Modeling Reporting Delay and Reporting Error in Cancer Registry Data, *Journal of American Statistical Association* **100**: 61-69.
- Fay, MP. (2005). Random Marginal Agreement Coefficients: Rethinking the Adjustment for Chance in Agreement Coefficients. *Biostatistics* **6**(1), 171-180.
- Fay MP, Lee, J-H. (2006). Measuring Agreement Between Two Statistics with Applications to Age-Standardization. *Journal of the Royal Statistical Society, Series A* **169**, 81-96.
- Fay, MP, Tiwari, RC., Feuer, EJ. Zou, Z. (2006). Estimating Average Annual Percent Change for Disease Rates without Assuming Constant Change. *Biometrics* **62**,847-854.
- Fay, MP, Halloran, ME, Follmann, DA. (2007). Accounting for Variability in Sample Size Estimation with Applications to Nonadherence and Estimation of Variance and Effect Size. *Biometrics* **63**, 465-474.
- Fay, MP, Huang, C-Y, Twum-Danso, NAY. (2007). Monitoring Rare Serious Adverse Events from a New Treatment and Testing for a Difference from Historical Controls. *Clinical Trials* **4**,598-610.
- Fay, MP, Kim, H-J, and Hachey, M. (2007). On using Truncated Sequential Probability Ratio Test Boundaries for Monte Carlo Implementation of Hypothesis Tests. *Journal of Computational and Graphical Statistics* **16** (4), 946-967.
- Fay, MP, Noubary, F, Saul, A. (2009). Robust Non-inferiority Tests for Potency of a Test Drug Against a Reference Drug. *Statistics in Biopharmaceutical Research* **1**(3):291-300.

Follmann, DA, Fay, MP, Proschan, MA. (2009). Chop-lump tests for vaccine trials. *Biometrics* **65**, 885-893.

Follmann, DA, Fay, MP (2010). Exact Inference for Complex Clustered Data Using Within Cluster Resampling. *Journal of Biopharmaceutical Statistics* **20**(4) 850-869.

Fay, MP. (2010). Confidence intervals that match Fisher's exact or Blaker's exact tests. *Biostatistics* **11**, 373-374.

Proschan, MA, Brittain, EH, and Fay, MP (2010). Does Treatment Effect Depend on Control Event Rate? Revisiting a Meta-analysis of Suicidality and Antidepressant Use in Children. *Clinical Trials* **7**, 109-117.

Fay, MP, Proschan, MA (2010). Wilcoxon-Mann-Whitney or t-Test? On Assumptions for Hypothesis Tests and Multiple Interpretations of Decision Rules. *Statistics Surveys* **4**:1-39 (available at <http://projecteuclid.org/euclid.ssu/1266847666>).

Fay, MP, Shaw, PA (2010). "Exact and Asymptotic Weighted Logrank Tests for Interval Censored Data: The interval R package. *Journal of Statistical Software*. Vol 36, Issue 2, 1-34 (available at <http://www.jstatsoft.org/v36/i02>).

Fay, MP (2010). Two-sided Exact Tests and Matching Confidence Intervals for Discrete Data. *R Journal* **2**(1) 53-58. (available at http://journal.r-project.org/archive/2010-1/RJournal_2010-1_Fay.pdf.)

Follmann, D, Fay, M (2012). Bounds on the effect of vaccine induced immune response on outcome. *International Journal of Biostatistics* Vol 8, Iss. 2, Article 3.

Fay, MP and Shih JH. (2012). Weighted Logrank Tests for Interval Censored Data when Assessment Times Depend on Treatment. *Statistics in Medicine* **31**, 3760-3772.

Brittain, EH, Fay, MP, and Follmann, DA. (2012). A Valid Formulation of the Analysis of Non-inferiority Trials under Random Effects Meta-Analysis. *Biostatistics* **13**(4): 637-649.

Fay, MP, Brittain, E, and Proschan, MA. (2013). Pointwise Confidence Intervals for a Survival Distribution for Right Censored Data with Small Samples or Heavy Censoring. *Biostatistics* **14**(4): 723-736.

Kirk, JL, and Fay MP. (2014). An Introduction to Practical Sequential Inferences via Single Arm Binary Response Studies Using the binseqtest R Package. *American Statistician* **68**(4)" 230-242.

Fay, MP, Proschan, MA and Brittain, E (2015). Combining One-Sample Confidence Procedures for Inference in the Two-Sample Case. *Biometrics*. **71**: 146-156.

Fogarty, C. B., Fay, M. P., Flegg, J. A., Stepniewska, K., Fairhurst, R. M., & Small, D. S. (2015). Bayesian hierarchical regression on clearance rates in the presence of “lag” and “tail” phases with an application to malaria parasites. *Biometrics*. 71: 751-759.

Fay, MP, and Brittain, EH (2016). Finite Sample Pointwise Confidence Intervals for a Survival Distribution with Right-Censored Data. *Statistics in Medicine*. 35: 2726-2740.

Shaw, PA, and Fay, MP (2016). A rank test for bivariate event time outcomes when one event is a surrogate. *Statistics in Medicine*. 53(19) 3413-3423.

Fay, MP, and Follmann, DA. (2016). Non-inferiority Tests for Anti-Infective Drugs using Control Group Quantiles. *Clinical Trials*, 13(6): 632-640.

Scott, JM, deCamp, A, Juraska, M, Fay, MP, Gilbert, PB (2017). Finite-Sample Corrected GEE for Assessment of Population Average Treatment Effects in Stepped Wedge Cluster Randomized Trials. *Statistical Methods in Medical Research*. 26(2): 583-597. DOI: 10.1177/0962280214552092.

Fay, MP and Kim, S (2017). Confidence intervals for directly standardized rates using mid-p gamma intervals. *Biometrical Journal*, 59(2): 377-387.

Shih, JH, and Fay, MP (2017). Pearson’s Chi-square test and rank correlation inferences for clustered data. *Biometrics* 73(3): 822-834.

Swihart, BJ, Fay, MP, and Miura, K. (2018). Statistical Methods for Standard Membrane Feeding Assays to Measure Transmission Blocking or Reducing Activity in Malaria. *Journal of the American Statistical Association*. 113(522): 534-545.

Fay, MP, Sachs, MC, and Miura, K. (2018). Measuring Precision in Bioassays: Rethinking Assay Validation. *Statistics in Medicine*. 37:519-529.

Gabriel, EE, Nason, M, Fay, MP, and Follmann, DA (2018). A boundary-optimized rejection region test for the two-sample binomial problem. *Statistics in Medicine* 37:1047-1058.

Fay, MP, Brittain, EH, Shih, JH, Follmann, DA, Gabriel, EE (2018). Causal Estimands and Confidence Intervals Associated with Wilcoxon-Mann-Whitney Tests in Randomized Experiments. *Statistics in Medicine*. 37(20): 2923-2937.

Fay, MP and Malinovsky, Y (2018). Confidence intervals of the Mann-Whitney parameter that are compatible with the Wilcoxon-Mann-Whitney test. *Statistics in Medicine* 37:3991-4006.

Greenland, S, Fay, MP, Brittain, EH, Shih, JH, Follmann, DA, Gabriel, EE, and Robins,

JM. (2020). On Causal Inferences for Personalized Medicine: How Hidden Causal Assumptions Led to Erroneous Causal Claims About the D-Value. *American Statistician*, 74(3), pp.243-248.

Follmann, D, Fay, MP, Hamasaki, T, and Evans, S (2020). Analysis of ordered composite endpoints. *Statistics in Medicine* 39: 602-616.

Fay, MP, and Lumbard, K (2021). Confidence intervals for difference in proportions for matched pairs compatible with exact McNemar's or sign tests. *Statistics in Medicine* 40(5): 1147-1159. (<http://dx.doi.org/10.1002/sim.8829>).

Kim, S, Fay, MP, and Proschan, MA. (2021). Valid and Approximately Valid Confidence Intervals for Current Status Data. *Journal of the Royal Statistical Society, Series B* 83:438-452 (<http://doi.org/10.1111/rssb.12422>).

Fay, MP, and Hunsberger, SA. (2021). Practical Valid Inferences for the Two-Sample Binomial Problem. *Statistics Surveys*, 15: 72-110 ([DOI: 10.1214/21-SS131](https://doi.org/10.1214/21-SS131)).

Fay, MP, Proschan, MA, Brittain, EH, and Tiwari, R. (2022). "Interpreting P-values and Confidence Intervals using Well-Calibrated Null Preference Priors." *Statistical Science* ([to appear](#)).

PEER-REVIEWED PUBLICATIONS (MEDICAL/BIOLOGICAL):

Fay, MP, Freedman, LS, Clifford, C, Midthune, DN. (1997). Effects of Different Types and Amounts of Fat on the Development of Mammary Tumors in Rodents: A Review. *Cancer Research* **57**, 3979-3988.

Fay, MP., Freedman, LS. (1997). Meta-Analyses of Dietary Fats and Mammary Neoplasms in Rodent Experiments. *Breast Cancer Research and Treatment* **46**(2-3):215-223.

Sampath, S, Fay, MP, Pais, P. (1999). Use of the logistic organ dysfunction system to study mortality in an Indian intensive care unit. *National Medical Journal of India* 12(6), 258-261.

Pias, P, Fay, MP, Yusuf, S. (2001). Increased Risk of Acute Myocardial Infarction Associated with Beedi and Cigarette Smoking in Indians: Final Report on Tobacco Risks from a Case-Control Study. *Indian Heart Journal* Nov-Dec, **53**: 731-735.

Warren, JL, Brown, M, Fay, MP, Schussler, N, Potosky, AL, Riley, GF. (2002). Costs of Treatment for Elderly Women with Early Stage Breast Cancer in Fee-for-Service Settings. *Journal of Clinical Oncology* **20**(1), 307-316.

Clegg, LX, Feuer, EJ, Midthune, DN, Fay MP, Hankey BF. (2002). Impact of Reporting Delay and Reporting Error on Cancer Incidence Rates and Trends. *Journal of the National Cancer Institute* **94** (20), 1537-1545.

Radimer, KL, Ballard-Barbash, R, Miller, JS, Fay, MP, Schatzkin, A, Troiano, RP, Kreger, BE, Splansky, GL. (2004). Weight change and the risk of late onset breast cancer in the original Framingham cohort. *Nutrition and Cancer* **49** (1), 7-13.

Faden, VB, Fay, MP. (2004). Trends in Drinking among Americans Age 18 and Younger: 1975-2002. *Alcoholism: Clinical and Experimental Research* **28** (9), 1388-1395.

Cronin, KA, Yu, B, Krapcho, M, Miglioretti, DL, Fay, MP, Izmirlian, G, Ballard-Barbash, R, Geller, BM, Feuerm EJ. (2005). Modeling the dissemination of mammography in the United States. *Cancer Causes and Control* **16**, 701-712.

McPherson, T, Persaud, S, Singh, S, Fay, MP, Addiss, D, Nutman, TB, Hay, R. (2006). Interdigital lesions and frequency of acute dermatolymphangioadenitis in filarial lymphoedema. *British Journal of Dermatology* **154** (5), 933-941.

McPherson, T, Fay, MP, Singh, S, Penzer, R, Hay, R. (2006). Health workers' agreement in clinical description of filarial lymphedema. *American Journal of Tropical Medicine & Hygiene* **74**(3), 500-504.

Malkin, E., Long, C.A., Stowers, A.W., Zou, L., Singh, S., MacDonald, N., Narum, D.L., Miles, A.P., Orcutt, A., Muratova, O., Moretz, S.E., Zhou, H., Diouf, A., Fay, M., Tierney, E., Leese, P., Mahanty, S., Miller, L.H., Saul, A., Martin, L.B. (2007). Phase 1 Study of Two Merozoite Surface Protein 1 (MSP1₄₂) Vaccines for *Plasmodium falciparum* Malaria. *PLoS Clinical Trials* **2**(4): e12.doi:10.1371/journal.pctr.0020012.

Martin, JE, Pierson, TC, Hubka, S, Rucker, S, Gordon, IJ, Enama, ME, Andrews, CA, Xu, Q, Davis, B, Nason, M, Fay, M, Koup, RA, Bailer, RT, Gomez, PL, Mascola, JR, Chang, JG, Nabel, GJ, Graham, BS, and VRC 302 Study Team. (2007). A West Nile Virus DNA Vaccine is safe and Induces Neutralizing Antibody in Healthy Adults in a Phase I Clinical Trial. *Journal of Infectious Diseases* **196** (Dec 15), 1732-1740.

Maric, I, Robyn, J, Metcalfe, DD, Fay, MP, Carter, M, Wilson, T, Fu, W, Stoddard, J, Scott, L, Hartsell, M, Kirshenbaum, A, Akin, C, Nutman, TB, Noel, P, and Klion, AD. (2007). KIT D816V-associated systemic mastocytosis with eosinophilia and FIP1L1/PDGFR α -associated chronic eosinophilic leukemia are distinct entities. *Journal of Allergy and Clinical Immunology* **120**(3), 680-687.

Saul A, Fay MP (2007). Human Immunity and the Design of Multi-Component, Single Target Vaccines. *PLoS ONE* **2**(9): e850. doi:10.1371/journal.pone.0000850

Klion, AD, Robyn, J, Maric, I, Fu, W, Schmid, L, Lemery, S, Noel, P, Law, M, Hartsell, M, Fay, MP, Dunbar, C, Nutman, TB. (2007). Relapse following discontinuation of imatinib mesylate therapy for *FIP1L1/PDGFR*A-positive chronic eosinophilic leukemia: implications for optimal dosing. *Blood* **110**, 3552-3556.

Dicko, A, Diemert, DJ, Sagara, I, Sogoba, M, Niambele, MB, Assadou, MH, Guindo, O, Kamate, B, Baby, M, Sissoko, M, Malkin, EM, Fay, MP, Thera, MA, Miura, K, Dolo, A, Diallo, DA, Mullen, GE, Long, CA, Saul, A, Doumbo, O, and Miller, LH. (2007) Impact of a *Plasmodium falciparum* AMA1 vaccine on antibody responses in adult Malians. *PLoS ONE* **2**(10):e1045. doi:10.1371/journal.pone.0001045.

Dicko, A, Sagara, I, Ellis, RD, Miura, K, Guindo, O, Kamate, B, Sogoba, M, Niambele, MB, Sissoko, M, Baby, B, Dolo, A, Mullen, GE, Fay, MP, Pierce, M, Diallo, DA, Saul, A, Miller, LH, Doumbo, OK. (2008). Phase 1 Study of a Combination AMA1 Blood Stage Malaria Vaccine in Malian Children. *PLoS ONE* **3**(2):e1563. doi:10.1371/journal.pone.0001563.

Joy, DA, Gonzalez-Ceron, L., Carlton, JM, Gueye, A, Fay, M, McCutchan, TF, Su, X-Z (2008). Local Adaptation and Vector-Mediated Population Structure in *Plasmodium Vivax* Malaria. *Molecular Biology and Evolution* **25**, 1245-1252.

Lisk, G, Pain, M, Gluzman, IY, Kambhampati, S, Furuya, T, Su, X-z, Fay, MP, Goldberg, DE, Desai, SA (2008). Changes in PSAC Reduce Leupeptin Uptake and Can Confer Drug Resistance in *Plasmodium falciparum*-Infected Erythrocytes. *Antimicrobial Agents and Chemotherapy* **52** (7), 2346-2354.

Kimblin, N, Peters, N, Debrabant, A, Secundino, N, Egen, J, Lawyer, P, Fay, MP, Kamhawi, S, Sacks, D. (2008). Quantification of the infectious dose of *Leishmania major* transmitted to the skin by single sand flies. *Proceedings of the National Academy of Sciences* **105**,10125-10130.

Wu, Y, Ellis, RD, Shaffer, D, Fontes, E, Malkin, EM, Mahanty, S, Fay, MP, Narum, D, Rausch, K, Miles, AP, Aebig, J, Orcutt, A, Muratova, O, Song, G, Lambert, L, Zhu, D, Miura, K, Long, C, Saul, A, Miller, LH, Durbin, AP. (2008). Phase 1 trial of malaria transmission blocking vaccine candidates Pfs25 and Pvs25 formulated with Montanide ISA 51. *PLoS ONE* **3**(7): e2636, doi:10.1371/journal.pone.0002636.

Peters, NC, Egen, JG, Secundino, N, Debrabant, A, Kimblin, N, Kamhawi, S, Lawyer, P., Fay, MP, Germain, RN, Sacks, D. (2008). In vivo imaging reveals an essential role for neutrophils in Leishmaniasis transmitted by sand flies. *Science* **321** (5891): 970-974.

Mullen, GED, Ellis, RD, Miura, K, Malkin, E, Nolan, C, Hay, M, Fay, MP, Saul, A, Zhu, D, Rausch, K, Mortetz, S, Zhou, H, Long, CA, Miller, LH, Treanor, J. (2008). Phase 1 trial of AMA1-C1/Alhydrogel plus CPG 7909: an asexual blood-stage vaccine for *Plasmodium falciparum* malaria. *PLoS ONE* **3**(8): e2940 doi:10.1371/journal.pone.0002940.

Lyon, JA, Angov, E. , Fay, MP, Sullivan, JS, Girourd, AS, Robinson, SJ, Bergmann-Leitner, ES, Duncan, EH, Darko, CA, Collins, WE, Long, CA, Barnwell, JW. (2008). Protection induced by *Plasmodium falciparum* MSP142 is strain specific, antigen and adjuvant dependent, and correlates with antibody responses. *PLoS ONE*. **3**(7), e2830. doi: 10.1371/journal.pone.0002830.

Raj, DK, Mu, J, Jiang, H, Kabat, J, Singh, S, Sullivan, M, Fay, MP, McCutchan, TF, Su, X (2009). Disruption of a *Plasmodium falciparum* multidrug resistance-associated protein (PfMRP) alters its fitness and transport of antimalarial drugs and glutathione. *Journal of Biological Chemistry* **284**, 7687-7696.

Miura, K, Zhou, H, Diouf, A, Moretz, SE, Fay, MP, Miller, LH, Martin, LB, Ellis, RD, Muller, GED, Long, CA. (2009). Anti-Apical Membrane Antigen 1 antibody is more effective than anti-Merozoite Surface Protein 1₄₂ antibody in inhibiting *Plasmodium falciparum* growth as measured by in vitro Growth Inhibition Assay. *Clinical and Vaccine Immunology* **16**, 963-968.

Coulibaly, YI, Dembele, B, Diallo, AA, Lipner, EM, Doumbia, SS, Coulibaly, SY, Konate, S, Diallo, DA, Yalcouye, D, Doumbo, OK, Traore, AK, Keita, AD, Fay MP, Traore, SF, Nutman, TB, Klion, AD. (2009). Efficacy of doxycycline for the treatment of *Mansonella perstans* infection: an open label, randomized trial with and without the addition of single dose ivermectin and albendazole. *New England Journal of Medicine* **361**(15):1448-58.

Sa, JM, Twu, O, Hayton, K, Reyes, S, Fay, MP, Ringwald, P, Wellems, TE (2009). Geographic Patterns of *Plasmodium falciparum* Drug Resistance Distinguished by Differential Responses to Amodiaquine and Chloroquine. *Proc Natl Acad Sci USA* **106**(45): 18883-9.

Sagara, I, Ellis, RD, Dicko, A, Niamele, MB, Kamate B, Guindo O, Sissoko MS, Fay MP, Guindo MA, Kante O, Saye R, Miura K, Long C, Mullen GE, Pierce M, Martin LB, Rausch K, Dolo A, Diallo DA, Miller LH, Doumbo OK (2009). A randomized and controlled Phase 1 study of the safety and immunogenicity of the AMA1-C1/Alhydrogel((R))+CPG 7909 vaccine for *Plasmodium falciparum* malaria in semi-immune Malian adults. *Vaccine* **27**(52), 7292-8.

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NON-PEER-REVIEWED PUBLICATIONS:

Fay, MP, Midthune, DN, Graubard, BI, Freedman, LS. (1999). Meta Analyses using Conditional Logistic Regression with Sandwich Estimators. Proceedings of the Biopharmaceutical Section, American Statistical Association.

OTHER PUBLICATIONS:

Clegg, LX, Midthune, DN, Feuer, EJ, Fay, MP, Hankey, BF. (2000). "Section XXIX: Cancer Incidence Rates Adjusted for Reporting Delay" in Ries, LAG, Eisner, MP,

Kosary, CL, Hankey, BF, Clegg, LX, Edwards, BK (eds). *SEER Cancer Statistics Review, 1973-1997*, National Cancer Institute. NIH Pub. No. 00-2789. Bethesda, MD.

U.S. Cancer Statistics Working Group. (2002). *United States Cancer Statistics: 1999 Incidence*. Atlanta (GA): Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute.

Ries LAG, Eisner MP, Kosary CL, Hankey BF, Miller BA, Clegg L, Mariotto A, Fay MP, Feuer EJ, Edwards BK (eds). (2003). *SEER Cancer Statistics Review, 1975-2000*, National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/csr/1975_2000.

Shih, JH, Fay, MP. (2004). A Class of Permutation Tests for Some Two-Sample Survival Data Problems. Chapter 8 in *Advances in Clinical Trial Biostatistics*, Editor: Geller, N 2004. Marcel Dekker, Inc.: New York.

Fay, MP, Feuer, EJ (2007). Authors' Reply. *Statistics in Medicine*. 26 (9): 2133-2135.

Proschan, MA, Brittain, EH, Fay, MP (2010). Response to commentary. *Clinical Trials* 7:120.

Fay MP (2012). Discussion on "Probabilistic index models" by O Thas, J DeNeve, L Clement, and JP Ottoy. *Journal of the Royal Statistical Society Series B*. **74**,658-659.

Fay, MP and Hunsberger, SA. (2013). Practical Issues on Using Weighted Logrank Tests with Interval Censored Events in Clinical Trials. Chapter 13 in *Interval-Censored Time-to-Event Data: Methods and Applications*, Chen, D-G, Sun, J, and Peace, KE (editors) Chapman and Hall/CRC.

Fay, M. P. (2013). An alternative property for evaluating sample size for normal data using preliminary data. *Clinical Trials*, 10(6), 990-991.

Gabriel, EE, Nason, M, Fay, M, and Follmann, D (2018). Response to Letter by Antonio Martin Andres on 'A boundary-optimized rejection region test for the two-sample binomial problem' *Statistics in Medicine* 37(14):2303-2306.

Fay, MP (2020). Software Review: Small Sample Inferences with Kaplan-Meier Estimates with R packages bpcp. *Lifetime Data Science Newsletter*. Vol 5, Issue 1, 6-7.

UNPUBLISHED MANUSCRIPTS:

Follmann, DA, and Fay, MP (2021). Vaccine Efficacy at a Point in Time. medrxiv
<https://doi.org/10.1101/2021.02.04.21251133>

Follmann, DA, Fay, MP, Magaret, C, and Gilbert, P (2021). Estimation of Vaccine Efficacy for Variants that Emerge After the Placebo Group is Vaccinated. medrxiv
<https://doi.org/10.1101/2021.08.31.21262908>

SOFTWARE:

Worked with the team on the development of the Joinpoint and DevCan software for cancer surveillance at the National Cancer Institute. Also developed (with E. Feuer) confidence interval method for age-adjusted rates used in SEER*Stat. (see <https://surveillance.cancer.gov/tools/>).

Author and maintainer on CRAN of the following R packages: asht, binseqtest (with JL Kirk), bpcp, choplump, csci, exact2x2, exactci, hbim, interval, MChstest, nivm, perm, rateratio.test, saws, ssanv.

Coauthor of following R package on CRAN: testassay.

Maintainer of the following R package on CRAN: csci.

PRESENTATIONS:

- 1993 Contributed Talk, 1993 Spring Meetings, ENAR, “Ordered Multinomial Population Scores: A Generalization of Midrank Scores”
- 1995 Contributed Talk, 1995 Joint Statistical Meetings, “Rank Invariant Tests for Interval Censored Data under the Grouped Continuous Model”
- 1996 Contributed Talk, 1996 Joint Statistical Meetings, “Hypothesis Tests using Estimated Distribution Functions”
- 1997 Contributed Talk, 1997 Spring Meetings, ENAR, “Conditional Logistic Regression with Sandwich Estimators: Application to a Meta-Analysis”
- 1999 (Special) Contributed Talk, 1999 Joint Statistical Meetings, “Meta Analyses using Conditional Logistic Regression with Sandwich Estimators”
- 2000 Contributed Talk, 2000 Spring Meetings, ENAR, “Small Sample Adjustments for Wald-type Tests using Sandwich Estimators”
- 2002 Contributed Talk, 2002 Spring Meetings, ENAR, “Designing Monte Carlo Implementations of Permutation or Bootstrap Hypothesis Tests”
- 2004 Contributed Talk, 2004 Joint Statistical Meetings, “Rethinking the Adjustment for Chance in Agreement Coefficients”
- 2005 Fay, M.P., Halloran, M.E., Follmann, D.A., Diemert, D., Dicko, A., Thera, M., Sagara, I., Klion, A., Doumbo, O., Saul, A. (2005). The Design of a Phase 2 Malaria Vaccine Trial Based on a Cohort Study. Poster presented at 4th MIM Pan-African Malaria Conference.
- 2006 Invited Talk, 2006 Spring Meetings, ENAR, “Accounting for Variability in Sample Size Estimation with Applications to a Malaria Vaccine Trial”
- 2006 Invited Talk, 2006 Joint Statistical Meetings, “Accounting for Variability in Sample Size Estimation with Application to a Malaria Vaccine Phase II Trial”
- 2007 Fay, M.P., Huang, C-Y., Twum-Danso, N.A.Y. (2007). Monitoring Rare Serious Adverse Events from a New Treatment and Testing for a Difference from a Baseline Rate. Poster presented at 2007 EMR-IBS conference, Eilat, Israel.

- 2008 Contributed Talk, 2008 Joint Statistical Meetings, “Wilcoxon-Mann-Whitney or t-test? On assumptions for hypothesis tests and multiple interpretations of decision rules”.
- 2009 Contributed Talk 2009 Joint Statistical Meetings, “Exact and Asymptotic Weighted Logrank Tests for Interval-Censored Data: A Review and New R package”.
- 2010 Contributed Talk 2010 ENAR Meetings, “Confidence intervals that match Fisher’s exact or Blaker’s exact tests”.
- 2010 Contributed Talk useR! 2010 conference. “Two-sided Exact Tests and Matching Confidence Intervals for Discrete Data”.
- 2010 Invited Talk: Biostatistics Department of MCV at Virginia Commonwealth University: “On Unifying Inferences from Exact Tests and Confidence Intervals for 2x2 Tables”
- 2010 Talk to DMID advisory Committee on Anthrax Vaccines: “Further Explorations of the Anthrax Animal Vaccine Data”
- 2011 Invited Talk: “Software Validation and Some Personal Experience with R Packages: Creation, Testing, and Use” at 4th Annual FDA/MTLI Medical Device and IVD Statistical Issues Workshop
- 2011 Invited Talk: “Statistical Approaches to endpoint validation” at 7th Biennial Symposium, International Eosinophil Society, Pre-symposium workshop. Quebec City.
- 2011 Contributed Talk: “Weighted Logrank Tests for Interval Censored Data When Assessment Times Are Related to Treatment but Not to Event Time” Joint Statistical Meetings
- 2011 Contributed Talk: “Inferences from Tests of Biodefense Vaccines” FDA/Industry Statistics Workshop.
- 2012 Invited Talk: “Weighted Logrank Tests for Interval Censored Data When Assessment Times Depend on Treatment” George Washington University Biostatistics Center
- 2012 Invited Talk: “Graphing and Testing Interval Censored Time to Event Data: Practical Aspects of Using the interval R package” American Statistical Association Conference on Statistical Practice.
- 2012 Contributed Talk: “Pointwise confidence intervals for a survival distribution for right censored data with small samples or heavy censoring”. Eastern North American Region of International Biometric Society.
- 2012 Invited Talk: “Using Anthrax Vaccine Induced Antibodies to Predict Survival of Animals and Humans” DBPAP, CBER, FDA.
- 2013 Invited Talk: “Weighted Logrank Tests for Interval-Censored Data when Assessment Depends on Treatment” ICSA/ISBS Conference
- 2013 Contributed “Speed” Talk/Poster: “Two-Sample Test for Differences in Survival at a Fixed Time Point with Small Sample Sizes” Joint Statistical Meetings, Montreal, Canada.
- 2014 Topic Contributed Talk: “Two Sample Inferences for Differences in Survival at a Fixed Time Point with Small Sample Sizes” Joint Statistical Meetings, Boston.
- 2015 Invited Talk: “Nonparametric Methods for Interval Censored Data”. Johns Hopkins Biostatistics.
- 2015 Contributed Talk: “Finite Sample Confidence Intervals for a Survival Distribution with Right-Censored Data” Joint Statistical Meetings, Seattle, Washington.
- 2015 Invited Talk: “Combining One Sample Confidence Interval Procedures in the Two Sample Case” University of Pennsylvania.

- 2016 Invited Talk: “Combining One Sample Confidence Interval Procedures in the Two Sample Case” NIH/NICHD Biostatistics and Bioinformatics Branch.
- 2016 Invited Talk: “Combining One-Sample Confidence Interval Procedures for Valid Non-Asymptotic Inference in the Two-Sample Case” Fusion Learning and BFF Inferences and Statistical Foundations. Rutgers University.
- 2016 Contributed Talk: “Noninferiority Tests for Anti-infective Drugs Using Control Quantiles” Joint Statistical Meetings, Chicago, IL.
- 2016 Invited Talk: “Some Statistical Issues with Animal Models” Animal Model Development Workshop, NIH/NIAID.
- 2017 Invited Talk: “Combining One Sample Confidence Interval Procedures in the Two Sample Case” NIH/NHLBI Office of Biostatistics Research.
- 2017 Contributed Talk: “A Hypothesis Testing Framework for Validating an Assay for Precision” ENAR of Biometrics Society Meetings. Washington DC.
- 2017 Contributed Talk: “A Hypothesis Testing Framework for Validating an Assay for Precision” 2017 Joint Statistical Meetings. Baltimore, MD.
- 2018 Invited Talk: “Combining One Sample Confidence Interval Procedures in the Two Sample Case” University of Maryland, Baltimore County., Department of Mathematics and Statistics.
- 2018 Invited Talk: “Creating Confidence Intervals that are Unified with Tests: Why is it so Hard?”, Albuquerque ASA Spring Meeting, Santa Fe, NM.
- 2018 Contributed Talk: “Causal Estimands and Confidence Intervals Associated with Wilcoxon-Mann-Whitney Tests in Randomized Experiments” Joint Statistical Meetings, VanCouver, BC, Canada.
- 2019 Invited Talk (and invited session organizer): “Confidence Intervals and Causal Inference with the Mann-Whitney Parameter that are Compatible with the Wilcoxon-Mann-Whitney Test” ENAR, Philadelphia, PA.
- 2019 Contributed Talk: “Interpreting P-Values and Confidence Intervals Using Well-Calibrated Null Preference Priors” Joint Statistical Meetings, Denver, CO.
- 2020 Invited Talk: “Compatible Confidence Intervals with Two-Sample Exact Binomial Tests or the Wilcoxon-Mann-Whitney Tests” NIH/NHLBI Office of Biostatistics Research. (October 20, 2020).

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