

CURRICULUM VITAE

NAME: Michael Patrick Fay

DATE AND PLACE OF BIRTH: November 21, 1963 Washington D.C.

CITIZENSHIP: United States of America

MARITAL STATUS: Married

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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.

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

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

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

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

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

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

1998 Visiting Statistician, St. John's Medical College, Bangalore, India.

1999-2004 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.

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

OTHER PROFESSIONAL EXPERIENCE:

2006-present Associate Editor for Biometrics

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

PEER-REVIEWED PUBLICATIONS (STATISTICAL):

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

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

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

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

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

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

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

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

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

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

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

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

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

Fay, MP, Follmann, DA. Designing Monte Carlo Implementations of Permutation or Bootstrap Hypothesis Tests. *American Statistician*, 56 (1), 63-70, 2002.

Fay, MP. Measuring a Binary Response's Range of Influence in Logistic Regression. *American Statistician*, 56 (1), 5-9, 2002.

Fay, MP, Pfeiffer, R, Cronin, KA, Feuer, EJ, Le, C. Age-Conditional Probabilities of Developing Cancer, *Statistics in Medicine* 22 (11) 1837-1848, 2003.

Kim, H-J, Fay, MP, Feuer, EJ, Yu, B, Barrett, MJ. Comparability of Joinpoint Regression Models, *Biometrics* 60 (4), 1005-1014, 2004.

Fay, MP. Estimating age conditional probability of developing disease from surveillance data. *Population Health Metrics* 2004, 2:6
(<http://www.pophealthmetrics.com/content/2/1/6>).

Midthune, DN, Fay MP, Clegg, LX, Feuer EJ. Modeling Reporting Delay and Reporting Error in Cancer Registry Data, *Journal of American Statistical Association*, 100: 61-69, 2005.

Fay, MP. Random Marginal Agreement Coefficients: Rethinking the Adjustment for Chance in Agreement Coefficients. *Biostatistics* 2005, 6(1): 171-180.

Fay MP, Lee, J-H. Measuring Agreement Between Two Statistics with Applications to Age-Standardization. *Journal of the Royal Statistical Society, Series A*, 2006, 169: 81-96.

Fay, MP, Tiwari, RC., Feuer, EJ. Zou, Z. Estimating Average Annual Percent Change for Disease Rates without Assuming Constant Change. *Biometrics* 2006, 62:847-854.

Fay, MP, Halloran, ME, Follmann, DA. Accounting for Variability in Sample Size Estimation with Applications to Nonadherence and Estimation of Variance and Effect Size. *Biometrics* 2007, 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. On using Truncated Sequential Probability Ratio Test Boundaries for Monte Carlo Implementation of Hypothesis Tests. *Journal of Computational and Graphical Statistics*. 2007, 16 (4): 946-967.

Fay, MP, Noubary, F, Saul, A. (2008). Robust Non-inferiority Tests for Potency of a Test Drug Against a Reference Drug. (to appear in *Statistics in Biopharmaceutical Research*).

Follmann, DA, Fay, MP, Proschan, MA. (2008). "Chop-lump tests for vaccine trials" (to appear in *Biometrics*).

PEER-REVIEWED PUBLICATIONS (MEDICAL):

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

Pias, P, Fay, MP, Yusuf, S. 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, 2001.

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

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

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

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

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

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

McPherson, T, Fay, MP, Singh, S, Penzer, R, Hay, R. Health workers' agreement in clinical description of filarial lymphedema. *American Journal of Tropical Medicine & Hygiene* 2006, 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. "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*, 2007, 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. KIT D816V-associated systemic mastocytosis with eosinophilia and FIP1L1/PDGFR α -associated chronic eosinophilic leukemia are distinct entities, *Journal of Allergy and Clinical Immunology*, Volume 120, Issue 3, September 2007, Pages 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. "Relapse following discontinuation of imatinib mesylate therapy for *FIP1L1/PDGFR α* -positive chronic eosinophilic leukemia: implications for optimal dosing" *Blood*, Nov 2007; 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. <http://www.plosone.org/doi/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. (2007) "Phase 1 Study of a Combination AMA1 Blood Stage Malaria Vaccine in Malian Children" PLoS ONE, 2008 Feb 13;3(2):e1563. doi:10.1371/journal.pone.0001563. <http://www.plosone.org/doi/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. 2008; 3(7): e2830. doi: 10.1371/journal.pone.0002830.

NON-PEER-REVIEWED PUBLICATIONS:

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

OTHER PUBLICATIONS:

Shih, JH, Fay, MP. 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.

Clegg, LX, Midthune, DN, Feuer, EJ, Fay, MP, Hankey, BF. ``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, 2000.

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

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

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

UNPUBLISHED MANUSCRIPTS:

Follmann, DA, Fay MP "Exact inference for complex clustered data using within-cluster resampling".

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. 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.

Fay, MP, Proschan, MA "Wilcoxon-Mann-Whitney or t-Test? On Assumptions for Hypothesis Tests and Multiple Interpretations of Decision Rules".

PRESENTATIONS AT NATIONAL OR INTERNATIONAL MEETINGS:

- 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 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 assumption for hypothesis tests and multiple interpretations of decision rules”.

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