CURRICULUM VITAE

MICHAEL AARON ROSENBLUM, PhD, MS

PROFESSIONAL DATA

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Pronouns: he/him/his

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EDUCATION AND TRAINING

Ph.D./2004 Massachusetts Institute of Technology, Cambridge, Massachusetts. Applied Math.

1999 Fulbright Scholar, École Normale Supérieure, Paris, France. Probability Theory.

M.S./1998 Stanford University, Stanford, California. Math.

B.S./1998 Stanford University, Stanford, California. Symbolic Systems.

Postdoctoral Training

2007-2009 Center for AIDS Prevention Studies (CAPS), University of California, San Francisco
Advisors: Mark van der Laan and David Bangsberg

2006-2007 Division of Biostatistics, School of Public Health, University of California, Berkeley
Advisor: Mark van der Laan

2005-2006 Department of Computer Science, University of California, Berkeley
Technology and Infrastructure for Emerging Regions (TIER) Project: implemented low-cost, wireless networks connecting rural health centers to hospitals in India.

PROFESSIONAL EXPERIENCE

Johns Hopkins University (JHU)

Associate Professor of Biostatistics, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, 2015-present.
Leadership roles in the Department of Biostatistics: Inclusion, Diversity, Anti-Racism, and Equity (IDARE) Leader (2020-present), Graduate Student Program Co-chair (2020-present), Co-organizer of the Causal Inference Working Group (2010-present).

Assistant Professor of Biostatistics, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, 2009-2015.

Other Non-JHU Professional Experience

Adjunct Faculty Member, Department of Math and Statistics, Dalhousie University, Halifax, Canada, 2015-2020. Taught causal inference and clinical trials methods to faculty/students.

PROFESSIONAL ACTIVITIES

Society Membership and Leadership

International Biometric Society Eastern North American Region (ENAR) Representative to the Joint Statistical Meetings (JSM) Program Committee, 2018-2019
Council of Section Representative, Statistics in Epidemiology Section of the American Statistical Association, 2011-2013
Founder and Statistical Consultant, Evolution Trial Design, Inc., 2015-present
Statistical Consultant for Target Analytics, 2008-2009

Symposia Organized

Inaugural Ross-Royall Symposium: From Individuals to Populations, Department of Biostatistics, Johns Hopkins Bloomberg School of Public Health (JHBSPH), 2016
Symposium on Statistical Methods in Clinical Trials and Regulatory Science, JHBSPH, 2015

Conference Sessions Organized (Invited Sessions)

Society for Clinical Trials Annual Meeting, Baltimore, MD, 2020
American Statistical Association, Biopharmaceutical Section, Regulatory-Industry Statistics Workshop, Washington, D.C., 2018 and 2020
International Biometric Society (ENAR) 2012, 2014, 2015, 2020, 2021
Joint Statistical Meetings (JSM) 2021
Atlantic Causal Inference Conference 2011

Participation on Advisory Panels and Boards

Advisory Panel for the Alzheimer's Drug Discovery Foundation's 2019 advisory meeting on design/analysis of phase 2 trials for Alzheimer's Disease and Frontotemporal Dementia

EDITORIAL AND OTHER PEER REVIEW ACTIVITIES

Journal Peer Review Activities

Statistical Methods in Medical Research (2019-), Statistics in Medicine (2016-), Clinical Trials (2016), AIDS (2016-), Biometrics (2015-), Journal of the Royal Statistical Society Series B (2014-), Journal of the American Statistical Association (2014-), Annals of Statistics (2014-), Scandinavian Journal of Statistics (2015-), Biometrika (2009-), Statistical Communications in Infectious Diseases (2009-), International Journal of Biostatistics (2008-), IEEE/ACM Transactions on Networking (2004-), ACM Symposium on Theory of Computing (2004-).

Journal or Other Editorial Board Membership

Associate Editor: International Journal of Biostatistics	2009-present
Associate Editor: Journal of Causal Inference	2011-present
Associate Editor: Epidemiologic Methods	2011-2019

Proposal Reviews

NIH/NIAID Clinical Trial Special Emphasis Review Panel (2020)
NIH/NIMH Psychosocial Intervention Study Section (2020)
NIH/NIAID Investigator Initiated Clinical Trial Applications Review Panel (2021)

Review of Reports and Other Documents
Grant reviewer: Natural Sciences and Engineering Research Council of Canada (2011); Patient-Centered Outcomes Research Institute, 2019.

HONORS AND AWARDS

Honors
Fellow of the American Statistical Association, 2020.
Outstanding Teacher Recognition, Johns Hopkins Bloomberg School of Public Health:
(based on teaching evaluation score of at least 3.6 out of 4 points)
"Probability Theory I" (PhD level, measure-theoretic probability), 2014, 2015, 2016, 2018
"Statistical Inference IV" (PhD level, asymptotic statistics), 2015, 2018, 2019, 2020
"Essentials of Probability and Statistical Inference I: Probability" (Sc.M. level), 2011
"Essentials of Probability and Statistical Inference II: Statistical Inference" (Sc.M. level), 2011 and 2012

Awards
MIT Carroll Wilson Award: research grant for "study of an important societal problem with international dimensions" to assess communications technology needs of humanitarian aid organizations, 2002
Department of Defense 3-year Science and Engineering Graduate Fellowship, 1999
Fulbright Grant for Research in Paris, France, 1998
Phi Beta Kappa, 1997
Stanford Presidential Scholar, 1995, 1996

PUBLICATIONS

Journal Articles (peer reviewed) indicates a mentored student or post-doctoral fellow*

1. Benkeser, D., Diaz, I., Luedtke, A., Segal, J., Scharfstein, D., and **Rosenblum, M.** (2020) Improving Precision and Power in Randomized Trials for COVID-19 Treatments Using Covariate Adjustment, for Binary, Ordinal, or Time to Event Outcomes. *Biometrics.* This paper was selected to be a discussion paper. https://doi.org/10.1111/biom.13377

2. Canto, M.I., Trindade, A.J., Abrams, J., **Rosenblum, M.,** Dumot, J., Corbett, F.S., Diehl,D., Chak, A., Khara, H., McKinley, M. Shin, E.J., Waxman, I., Infantolino, A., Tofani, C., Samarasena, J., Chang, K., Wang, B., Goldblum, J., Voltaggio, L., Montgomery, E., Lightdale, C.J., Shaheen, N.J. (2020) Multifocal Cryoballoon Ablation for Eradication of Barrett's Esophagus-Related Neoplasia: A Prospective Multicenter Clinical Trial. *American Journal of Gastroenterology*. 115, 1879-1890. http://doi.org/10.14309/ajg.0000000000000822

3. **Rosenblum, M.**, *Fang, X., and Liu, H. (2020) Optimal, Two Stage, Adaptive Enrichment Designs for Randomized Trials Using Sparse Linear Programming. *Journal of the Royal Statistical Society, Series B.* 82, 749-772. http://doi.org/10.1111/rssb.12366

4. McGinty E.E., Stone E.M., Kennedy-Hendricks A., Bandara S., Murphy K.A., Stuart E.A., **Rosenblum M.**, Daumit G.L. (2020). Effects of Maryland's Affordable Care Act Medicaid Health Home Waiver on Quality of Cardiovascular Care among People with Serious Mental Illness. *Journal of General Internal Medicine.* https://doi.org/10.1007/s11606-020-05690-9

5. *Steingrimsson, J.A., Betz, J., *Qian, T., and **Rosenblum, M.** (2019) Optimized Adaptive Enrichment Designs for Three-Arm Trials: Learning which Subpopulations Benefit from Different Treatments. *Biostatistics.* https://doi.org/10.1093/biostatistics/kxz030

6. *Huang, E. J., Fang, E. X., Hanley, D. F., and **Rosenblum, M.** (2019) Constructing a Confidence Interval for the Fraction Who Benefit from Treatment, Using Randomized Trial Data. *Biometrics.* 75(4), 1228-1239. https://doi.org/10.1111/biom.13101

7. Wu, A.W., Weston, C.M., Chidinma, A.I., *Ruberman, C., Bone, L., Boonyasai, R., Hwang, S., Gentry, J., Purnell, L., Lu, Yanyan, Liang, S., and **Rosenblum, M.** (2019) The Baltimore Community-based Organizations Neighborhood Network: Enhancing Capacity Together (CONNECT) Cluster RCT. *American Journal of Preventive Medicine*. 57(2), e31-e41. https://doi.org/10.1016/j.amepre.2019.03.013

8. *Wang, B., Ogburn, E., and **Rosenblum, M.** (2019) Analysis of Covariance (ANCOVA) in Randomized Trials: More Precision and Valid Confidence Intervals, Without Model Assumptions. *Biometrics*. 75(4), 1391-1400. https://doi.org/10.1111/biom.13062

9. Hanley, D. F., Thompson, R. E., **Rosenblum, M.,** Yenokyan, G., Lane K., McBee, N., Mayo S. W., Bistran-Hall, A. J., Gandhi, D. Mould, W. A., Ullman, N., Ali, H., Carhuapoma, J. R. Kase, C. S., Lees, K. R., Dawson, J., Wilson, A., Betz, J. F., Sugar, E., Hao, Y., Avadhani, R., Caron, J.-L., Harrigan, M. R., Carlson, A. P., Bulters, D., LeDoux, D. E., Huang, J., Cobb, C., Gupta, G., Kitagawa, R., Chicoine, M. R., Patel, H., Dodd, R., Camarata, P. J., Wolfe, S., Stadnik, A., Money, P. L., Mitchell, P., Sarabia, R., Harnof, S., Barzo, P., Unterberg, A., Teitelbaum, J. S., Wang, W., Anderson, C. S., Mendelow, A. D., Gregson, B., Janis, S., Vespa, P., Ziai, W., Zuccarello, M., Awad, I. A., for the MISTIE III Investigators. (2019) Efficacy and safety of minimally invasive surgery with thrombolysis in intracerebral haemorrhage evacuation (MISTIE III): a randomised, controlled, open-label, blinded endpoint phase 3 trial. *The Lancet*. 393, 1021-1032. https://doi.org/10.1016/S0140-6736(19)30195-3

10. **Rosenblum, M.**, Miller, P., Reist, B., Stuart, E., Thieme, M., and Louis, T. (2019) Adaptive Design in Surveys and Clinical Trials: Similarities, Differences, and Opportunities for Cross-Fertilization. *Journal of the Royal Statistical Society, Series A (Statistics in Society)*. 182, 963-982. https://doi.org/10.1111/rssa.12438 Article selected for presentation at 2019 Royal Statistical Society International Conference.

11. *Dıaz, I., Colantuoni, E., Hanley, D. F., and **Rosenblum, M.** (2019) Improved Precision in the Analysis of Randomized Trials with Survival Outcomes, without Assuming Proportional Hazards. *Lifetime Data Analysis.* 25, 439–468. https://doi.org/10.1007/s10985-018-9428-5 with Erratum

12. Wu, A. W., Hwang, S., Weston, C. M., Ibe, C., Boonyasai, R. Bone, L., Basu, L., Lief, I. Gentry, J. Purnell, L., **Rosenblum, M.,** for the Baltimore CONNECT study team. (2018) Baltimore CONNECT: a randomized trial to build partnership between community organizations and a local health system. *Progress in Community Health Partnerships: Research, Education, and Action. Johns Hopkins University Press.* 12(3), 297-306. *Project MUSE*. https://doi.org/10.1353/cpr.2018.0054

13. Selim, M., Hanley, D., Broderick, J., Goldstein, J. N., Gregson, B. A., Falcione, G., Gonzales, N. R., Gurol, E., Kersten, J., Lewkowicz, H., Mendelow, A. D., Muehlschlegel, S., Neuman, R., Palesch, Y., **Rosenblum, M.,** Sheth, K. N., Singh, V., Ziai, W., Keep, R. F., Aronowski, J., Genstler, C., James, M. L., Ratan, R., Sansing, L., Youd, A., Xi, G., Zille, M., Anderson, C., Awad, I., Bastings, E., Bednar, M., Coon, A. L., Gottesman, R., Katz, B., Khan, S., Koenig, J., Koroshetz, W., Ling, S., Loftus, C., Lockhardt, J., Louis, T., Marler, J., Moy, C., Pena, C., Pollack, C., Omert, L., Shah, M., Shoamanesh, A., Singer, M., Steiner, T., Torbey, M., Tymianski, M., Wakhloo, A., Vespa, P., Zuccarello, M., Zheng, X. (2018) Basic and Translational Research in Intracerebral Hemorrhage. *Stroke.* 49(5), 1308-1314. https://doi.org/10.1161/STROKEAHA.117.019539

14. Selim, M., et al., (same author list as citation above). (2018). Unmet Needs and Challenges in Clinical Research of Intracerebral Hemorrhage. *Stroke,* 49(5), 1299-1307. https://doi.org/10.1161/STROKEAHA.117.019541

15. *Fisher, A., **Rosenblum, M.** & for the Alzheimer's Disease Neuroimaging Initiative (2018) Stochastic Optimization of Adaptive Enrichment Designs for Two Subpopulations, *Journal of Biopharmaceutical Statistics*, 28(5), 966-982. https://doi.org/10.1080/10543406.2018.1489401

16. *Qian, T., Colantuoni, E., Fisher, A., and **Rosenblum, M.** (2017) Sensitivity of Trial Performance to Delay Outcomes, Accrual Rates, and Prognostic Variables Based on a Simulated Randomized Trial with Adaptive Enrichment. *Contemporary Clinical Trials Communications.* 8, 39-48. https://doi.org/10.1016/j.conctc.2017.08.003

17. **Rosenblum, M.,** and Hanley, D.F. (2017) Adaptive Enrichment Designs for Stroke Clinical Trials. *Stroke*. 48(7), 2021–2025. https://doi.org/10.1161/STROKEAHA.116.015342

18. *Huang, E., Fang, E., Hanley, D., and **Rosenblum, M.,** (2017) Inequality in Treatment Benefits: Can We Determine If a New Treatment Benefits the Many or the Few? *Biostatistics*. 18(2), 308-324. https://doi.org/10.1093/biostatistics/kxw049

19. *Steingrimsson, J. A., Hanley, D. F., and **Rosenblum, M.** (2017) Improving Precision by Adjusting for Baseline Variables in Randomized Trials with Binary Outcomes, without Regression Model Assumptions. *Contemporary Clinical Trials*. 54, 18-24. http://dx.doi.org/10.1016/j.cct.2016.12.026

20. Hanley, D.F., Lane, K., McBee, N., Ziai, W, Tuhrim, S., Lees, K.R., Dawson, J., Gandhi, D., Ullman, N., Mould, W.A., Mayo, S.W., Mendelow, A.D., Gregson, B., Butcher, K., Vespa, P., Wright, D.W., Kase, C.S., Carhuapoma, J.R., Keyl, P.M., Diener-West, M., Betz, J.F., Thompson, C., Sugar, E.A., Yenokyan, G., Janis, S., John, S., Harnof, S., Lopez, G., Aldrich, E.F., Harrigan, M.R., Ansari, S., Jallo, J., Caron, J-L., LeDoux, D., Adeoye, O., Zuccarello, M., Adams, H.P., **Rosenblum, M.,** Thompson, R.E., Awad, I.A., for the CLEAR III Investigators. (2017) Thrombolytic removal of intraventricular haemorrhage in treatment of severe stroke: results of the randomised, multicentre, multiregion, placebo-controlled CLEAR III trial. *The Lancet.* 389(10069) 603-611. http://dx.doi.org/10.1016/S0140-6736(16)32410-2

21. Hanley, D. F., Thompson, R. E., Muschelli, J., **Rosenblum, M.,** McBee, N., Lane, K., Bistran-Hall, A. J., Mayo, S. W., Keyl, P., Gandhi, D., Morgan, T. C., Ullman, N., Mould, W. A., Carhuapoma, J. R., Kase, C., Ziai, W., Thompson, C. B., Yenokyan, G., Huang, E., Broaddus, W. C., Graham, R. S., Aldrich, E. F., Dodd, R., Wijman, C., Caron, J-L., Huang, J., Camarata, P., Mendelow, A. D., Gregson, B., Janis, S., Vespa, P., Martin, N., Awad, I., Zuccarello, M., for the MISTIE II Investigators. (2016) Safety and efficacy of minimally invasive surgery plus alteplase in intracerebral haemorrhage evacuation (MISTIE): a randomized, controlled, open-label, phase 2 trial. *Lancet Neurology.* 15(12), 1228-1237. http://dx.doi.org/10.1016/S1474-4422(16)30234-4

22. **Rosenblum, M.,** Thompson, R., *Luber, B., Hanley, D. (2016) Group Sequential Designs with Prospectively Planned Rules for Subpopulation Enrichment. *Statistics in Medicine*. 35(21), 3776-3791. https://doi.org/10.1002/sim.6957

23. **Rosenblum, M.,** Qian, T., Du, Y., and Qiu, H., Fisher, A. (2016) Multiple Testing Procedures for Adaptive Enrichment Designs: Combining Group Sequential and Reallocation Approaches. *Biostatistics*. 17(4), 650-662. https://doi.org/10.1093/biostatistics/kxw014

24. *Patil, P., Colantuoni, E., Leek, J. T., **Rosenblum, M.** (2016) Measuring the Contribution of Genomic Predictors to Improving Estimator Precision in Randomized trials. *Contemporary Clinical Trials Communications*. 3, 48-54. http://dx.doi.org/10.1016/j.conctc.2016.03.001

25. *Diaz, I., Colantuoni, E., **Rosenblum, M.** (2016) Enhanced Precision in the Analysis of Randomized Trials with Ordinal Outcomes. *Biometrics*. 72, 422-431. https://doi.org/10.1111/biom.12450

26. Webb, A., Ullman, N., Morgan, T., Muschelli, J., Kornbluth, J., Awad, I., Mayo, S., **Rosenblum, M.**, Ziai, W., Zuccarrello, M., Aldrich, F., John, S., Harnof, S., Lopez, G., Broaddus, W., Wijman, C., Vespa, P., Bullock, R., Haines, S., Cruz-Flores, S., Tuhrim, S., Hill, M., Narayan, R., Hanley, D., (2015) Accuracy of the ABC/2 score for intracerebral

hemorrhage: Systematic review and analysis of MISTIE, CLEAR-IVH, CLEAR III. *Stroke*. 46(9), 2470-6. https://doi.org/10.1161/STROKEAHA.114.007343

27. *Diaz, I. and **Rosenblum, M.** (2015) Targeted Maximum Likelihood Estimation Using Exponential Families. *International Journal of Biostatistics.* 11(2), 233-251. https://doi.org/10.1515/ijb-2014-0039

28. Colantuoni, E. and **Rosenblum, M.** (2015) Leveraging Prognostic Baseline Variables to Gain Precision in Randomized Trials. *Statistics in Medicine.* 34, 2602-2617. https://doi.org/10.1002/sim.6507 with Erratum

29. **Rosenblum, M**. (2015), Adaptive Randomized Trial Designs that Cannot be Dominated by Any Standard Design at the Same Total Sample Size. *Biometrika.* 102(1), 191-202. https://doi.org/10.1093/biomet/asu057

30. Bolton, P., Bass, J., Zangana, G.A.S., Kamal, T., Murray, S., Kaysen, D., Lejuez, C.W., Lindgren, K., Pagoto, S., Murray, L. Skavenski, S., Amin, N., Ahmed, A., **Rosenblum, M.** (2014) A randomized controlled trial of mental health interventions for survivors of systemic violence in Kurdistan, Northern Iraq. *BMC Psychiatry*. 14(360). https://doi.org/10.1186/s12888-014-0360-2

31. **Rosenblum, M.** (2014), Uniformly Most Powerful Tests for Simultaneously Detecting a Treatment Effect in the Overall Population and at Least One Subpopulation. *Journal of Statistical Planning and Inference*. 155, 107-116. https://doi.org/10.1016/j.jspi.2014.07.001

32. **Rosenblum, M.,** Liu, H., and Yen, E.-H. (2014), Optimal Tests of Treatment Effects for the Overall Population and Two Subpopulations in Randomized Trials, using Sparse Linear Programming, *Journal of the American Statistical Association, Theory and Methods Section*. 109(507), 1216-1228. https://doi.org/10.1080/01621459.2013.879063

33. *Rudolph, K., Diaz, I., **Rosenblum, M**., Stuart, E. A. (2014), Estimating population treatment effects from a survey sub-sample. *American Journal of Epidemiology,* 180(7), 737-748. https://doi.org/10.1093/aje/kwu197

34. **Rosenblum, M.** (2013), Confidence Intervals for the Selected Population in Randomized Trials that Adapt the Population Enrolled. *Biometrical Journal,* 55(3), 322-340. https://doi.org/10.1002/bimj.201200080
35. **Rosenblum, M**. and van der Laan, M. J. (2011), Optimizing Randomized Trial Designs to Distinguish which Subpopulations Benefit from Treatment. *Biometrika,* 98(4), 845–860. https://doi.org/10.1093/biomet/asr055

36. Rosenblum, M. and van der Laan, M. J. (2010), Targeted Maximum Likelihood Estimation of the Parameter of a Marginal Structural Model. *International Journal of Biostatistics,* 6(2). (with Erratum) https://doi.org/10.2202/1557-4679.1238

37. Rosenblum, M. and van der Laan, M. J. (2010), Simple, Efficient Estimators of Treatment Effects in Randomized Trials Using Generalized Linear Models to Leverage Baseline Variables. *International Journal of Biostatistics,* 6(1). https://doi.org/10.2202/1557-4679.1138

38. Shiboski S., **Rosenblum M.**, and Jewell N. P. (2010), The Impact of Secondary Condom Interventions on the Interpretation of Results from HIV Prevention Trials. *Statistical Communications in Infectious Diseases,* 2(1). https://doi.org/10.2202/1948-4690.1003

39. **Rosenblum M.**, Deeks S. G., van der Laan M. J., Bangsberg D. R. (2009), The Risk of Virologic Failure Decreases with Duration of HIV Suppression, at Greater than 50% Adherence to Antiretroviral Therapy. *PLoS ONE,* 4(9), e7196. https://doi.org/10.1371/journal.pone.0007196

40. **Rosenblum M** and van der Laan M. J. (2009), Using Regression Models to Analyze Randomized Trials: Asymptotically Valid Hypothesis Tests Despite Incorrectly Specified Models. *Biometrics*, 65, 937-945. https://doi.org/10.1111/j.1541-0420.2008.01177.x

41. **Rosenblum M.**, Jewell N. P., van der Laan M. J., Shiboski S., van der Straten A., Padian N. (2009), Analyzing Direct Effects in Randomized Trials with Secondary Interventions: An Application to HIV Prevention Trials. *Journal of the Royal Statistical Society. Series A,* 172, 443-465. https://doi.org/10.1111/j.1467-985X.2009.00585.x

42. **Rosenblum M.** and van der Laan, M. J. (2009), Confidence Intervals for the Population Mean Tailored to Small Sample Sizes, with Applications to Survey Sampling. *International Journal of Biostatistics*, 5(1). https://doi.org/10.2202/1557-4679.1118

43. Padian N., van der Straten A., Ramjee G., Chipato T., de Bruyn D., Blanchard K., Shiboski S., Montgomery E., Fancher H., Cheng H., **Rosenblum M.**, van der Laan M., Jewell N., McIntyre J., and the MIRA team (2007), Diaphragm and Lubricant Gel for Prevention of HIV Acquisition in Southern African Women: a Randomised Controlled Trial. *The Lancet*, 370(9583), 251-261. https://doi.org/10.1016/S0140-6736(07)60950-7

44. **Rosenblum M.**, Caramanis C., Goemans M. X., Tarokh V. (2006), Approximating Fluid Schedules in Crossbar Packet-Switches and Banyan Networks. *IEEE/ACM Transactions on Networking,* 14, 1374-1387.

45. Yim R., **Rosenblum M.**, and Tarokh V. (2005), Delay Bounds for Packetizing Time-Varying Fluid Policies with Speedup and Lookahead in Single Server Systems. *Proceedings of INFOCOM,* Miami, FL.

46. **Rosenblum M.**, Goemans M. X., and Tarokh V. (2004), Universal Bounds on Buffer Size for Packetizing Fluid Policies in Input Queued, Crossbar Switches. *Proceedings of INFOCOM*, Hong Kong.

47. Caramanis C., **Rosenblum M.**, Goemans M. X., Tarokh V. (2004), Scheduling Algorithms for Providing Flexible, Rate-Based, Quality of Service Guarantees for Packet-Switching in Banyan Networks. *Proceedings of the 38th Annual Conference on Information Sciences and Systems,* Princeton, NJ, 160-166.

48. **Rosenblum M.**, Yim R., Goemans M. X., Tarokh V. (2004), Worst-Case Delay Bounds for Packetizing Time-Varying Fluid Schedules for a Single Server in a Packet-Switched Network. *Proceedings of the 38th Annual Conference on Information Sciences and Systems,* Princeton, NJ, 1553-1559.

49. **Rosenblum, M.** (1994), A Derivation of the Law of Cosines Without Using the Pythagorean Theorem. *New England Mathematics Journal,* 27(1), 35-39.

Chapters

"Marginal Structural Models," and "Robust Analysis of RCTs Using Generalized Linear Models," in the book: van der Laan, M. J. and Rose, S. (2011) Targeted Learning, Causal Inference for Observational and Experimental Data. 1st Edition, Springer Series in Statistics.

Articles, Editorials and Other Publications Not Peer Reviewed

Commentaries:

1. *Wang, B., Ogburn, E., and **Rosenblum, M.** (2019) Rejoinder to "Robustness of ANCOVA in randomized trials with unequal randomization" by Jonathan W. Bartlett. *Biometrics*. https://doi.org/10.1111/biom.13182

2. **Rosenblum, M.**, *Wang B. (2019) The Critical Role of Statistical Analyses in Maximizing Power Gains from Covariate-Adaptive Trial Designs. *JAMA Network Open.* 2(4), e190789. doi:10.1001/jamanetworkopen.2019.0789

3. **Rosenblum, M.** (2016) Comment: Personalized Dose Finding Using Outcome Weighted Learning. *Journal of the American Statistical Association.* 111(516), 1541-1542. http://dx.doi.org/10.1080/01621459.2016.1243481

4. **Rosenblum, M.** and van der Laan, M. J. (2013), Rejoinder to "A Note on Using Regression Models to Analyze Randomized Trials: Asymptotically Valid Hypothesis Tests Despite Incorrectly Specified Models" *Biometrics*, 69, 290. https://doi.org/10.1111/j.1541-0420.2012.01799.x

5. Jewell, N.P., van der Straten, A., Montgomery, E.T., **Rosenblum, M.**, Padian, N., (2007) Diaphragms and Lubricant Gel for Prevention of HIV – Authors' reply. *The Lancet*, 370(9602), 1823-1824. https://doi.org/10.1016/S0140-6736(07)61766-8

Technical Reports/Working Papers:

1. *Wang, B., Susukida, R., Mojtabai, R., Masoumeh, A.-E.; and **Rosenblum, M.** Model-Robust Inference for Clinical Trials that Improve Precision by Stratified Randomization and Adjustment for Additional Baseline Variables. https://arxiv.org/abs/1910.13954

2. *Du, Y., Rosner, G. L., and **Rosenblum, M.** Phase II Adaptive Enrichment Design to Determine the Population to Enroll in Phase III Trials by Selecting Thresholds for Baseline Disease Severity. (Submitted October 31, 2018 to *Journal of Biopharmaceutical Statistics*) https://biostats.bepress.com/jhubiostat/paper290/

3. *Adams, R., Saria, S., and Rosenblum, M. The Impact of Time Series Length and Discretization on Longitudinal Causal Estimation Methods (Submitted November 16, 2020, to Biostatistics) https://arxiv.org/abs/2011.15099

4. *Qian, T., **Rosenblum, M.**, *Qiu, H. (2019) Improving Power in Group Sequential, Randomized Trials by Adjusting for Prognostic Baseline Variables and Short-term Outcomes. http://arxiv.org/abs/1910.05800

5. **Rosenblum, M.,** McDermott, A., and Colantuoni, E. (2018) Robust Estimation of the Average Treatment Effect in Alzheimer's Disease Clinical Trials. https://biostats.bepress.com/jhubiostat/paper291

6. **Rosenblum, M.** and Steingrimsson, J.A., (2016) Matching the Efficiency Gains of the Logistic Regression Estimator While Avoiding its Interpretability Problems, in Randomized Trials. https://biostats.bepress.com/jhubiostat/paper281

7. *Fisher, A. J., Jaffee, H., and **Rosenblum, M**., (2014) InterAdapt -- An Interactive Tool for Designing and Evaluating Randomized Trials with Adaptive Enrollment Criteria. https://biostats.bepress.com/jhubiostat/paper262/

8. **Rosenblum, M.** and van der Laan, M. J., (2010) Simple Examples of Estimating Causal Effects Using Targeted Maximum Likelihood Estimation. *U.C. Berkeley Division of Biostatistics Working Paper Series.* https://biostats.bepress.com/ucbbiostat/paper262

9. **Rosenblum, M.,** Jewell, N. P., van der Laan, M. J., Shiboski, S., van der Straten, A., Padian N., (2007) Detailed Version: Analyzing Direct Effects in Randomized Trials with Secondary Interventions: An Application to HIV Prevention Trials. *U.C. Berkeley Division of Biostatistics Working Paper Series.* https://biostats.bepress.com/ucbbiostat/paper225

PRACTICE ACTIVITIES

Practice-Related Reports

In response to a request from the U.S. FDA to the Johns Hopkins Center for Excellence in Regulatory Science and Innovation, I led the writing of a report titled "Improving Precision and

Power in Randomized Trials for COVID-19 Treatments Using Covariate Adjustment, for Ordinal or Time to Event Outcomes" (April, 2020). We simulated clinical trials based on data from hospitalized, COVID-19 positive patients; adjusting for baseline variables reduced the required sample size by an estimated 10-20%. We concluded that this statistical method could speed up many types of COVID-19 treatment trials. The subsequent FDA guidance for Industry for COVID-19 treatment trials (May, 2020) was informed by our report and echoed our main recommendation to use covariate adjustment to improve precision and power in COVID-19 treatment trials.

Presentations to Policymakers, Communities, and Other Stakeholders

I've taught short-courses (please see page 33) on my new statistical methods and software for optimizing randomized trial designs at the FDA, NIH, American Statistical Association Regulatory-Industry Workshop, Johns Hopkins Bloomberg School of Public Health and School of Medicine, the University of California Berkeley's Forum for Collaborative Research, the Belgian Statistical Society, and the University of Washington Summer Institute in Statistics for Clinical Research. I've also presented these at the Memorial Sloan Kettering Cancer Center and the Clinical Trials on Alzheimer's Disease Conference. My focus is on adaptive trial designs, which have potential to generate stronger evidence about who benefits from different treatments. The short-courses involved demonstrating the benefits and limitations of these adaptive designs in case studies involving stroke, Alzheimer's disease, cardiac resynchronization devices, and HIV treatment. Video recordings available here: http://rosenblum.jhu.edu

Software and Other Product Development

Through grants funded by the FDA and PCORI, I developed trial planning software for adaptive designs, available here: http://rosenblum.jhu.edu The software is free and open-source, and has a graphical user-interface that allows it to be used by a wide audience. The software is intended for clinical investigators (assisted by a statistician) who are planning a confirmatory trial where it's suspected that a subpopulation may benefit more than the overall population. The software optimizes the performance of adaptive designs and compares them to standard designs in terms of the sample size, duration, power, Type I error, estimator bias, and confidence intervals.

Other Practice Activities

Data Safety and Monitoring Board (DSMB) participation:

1. Phase 3 trial: STOP-C Study: a randomized trial to evaluate the impact of tailored HCV treatment adherence support on treatment outcomes in HIV/HCV coinfected and HCV mono-infected people who inject drugs in India" (PI: Mehta and Solomon, JHBSPH) 2020-2023.
2. Phase 3 clinical trial "TREAT 1.0: Treating Parents to Reduce NICU Transmission of *Staphylococcus aureus"* (PI: Milstone, Johns Hopkins School of Medicine) 2014-2018.
3. Phase 3 clinical trial called TREAT 2.0: Treating Parents to Reduce NICU Transmission of *Staphylococcus aureus* (PI: Milstone, Johns Hopkins School of Medicine) 2020-2022.
4. Mechanistic Associations between Intra-Myocardial Fat Deposition and Ventricular Tachycardia in Ischemic Cardiomyopathy (PI: Nazarian and Trayanova), 2018-present.

Innovative trial designs applied in research collaborations: A major focus on my research is developing innovative statistical methods for randomized trial design and analysis. I have implemented my new methods through collaborations with Johns Hopkins researchers, where I constructed novel experimental designs to address their research questions. These methods contributed to seven successful grant proposals by Johns Hopkins (JHU) clinical investigators (funded by NINDS, NICHD, NIA, NIAID, Gates Foundation, and PCORI) described below.

JHU Principal Investigator	**Title/Summary of Grants**	**Extramural Support (total funding)**	**My contribution**
Daniel Hanley, Professor of Neurological Surgery, Johns Hopkins School of Medicine (SOM)	1. 500 patient Phase 3 Trial: Clot Lysis, Evaluating Accelerated Resolution of Intraventricular Hemorrhage 2. 500 patient Phase 3 trial: Minimally Invasive Surgery Plus rt-PA for Intracerebral Hemorrhage Evacuation	National Institute of Neurological Disorders and Stroke (NINDS), with funding for each trial: **$21,573,567 and $13,349,659,** resp.	Implemented innovative adaptive trial design and new analysis method, leading to precision gains.
Albert Wu, Professor, JHBSPH	Community Engagement to Improve Quality of Care and Patient Outcomes (East Baltimore)	Funded by Patient Centered Outcomes Research Institute (PCORI) **$503,120**	Proposed, designed, and analyzed cluster randomized trial.
Craig W. Hendrix, Professor,SOM	Pharmacostatistical Modeling and Simulation of Randomized PrEP Trials	Funded by Gates Foundation. **$509,427**	Modeling to inform future trial designs
Craig W. Hendrix, Professor, SOM	Experimental design to test the impact of Depo-Provera on HIV susceptibility and pre-exposure prophylaxis.	National Institute for Children's Health and Human Development (NICHD)**$328,895**	Contributed to experimental design.
Larry Appel, Professor, SOM	Vitamin D Supplements to Prevent Falls in Older Adults: A Dose-Response Trial	National Institute on Aging (NIA). **$9,599,289**	Contributed to adaptive design to learn optimal Vitamin D dose
Marilyn Albert, Prof., SOM, and Michela Gallagher, Professor of Neurology	Phase II/III trial for Slowing Progression in Mild Cognitive Impairment	National Institute on Aging (NIA). **$985,241**	Developed trial design and wrote statistical analysis plan
Mark Marzinke, Professor, SOM	Improving PrEP Protection of Transgender Women through Mechanistic Pharmacokinetic Understanding	National Institute of Allergy and Infectious Diseases (NIAID)	Contributed to trial design; will analyze data

PART II

TEACHING

Academic Advisees * indicates my role as co-advisor

Biostatistics PhD Students

Current:

Bingkai Wang — Biostatistics Ph.D. candidate — 2017-present

Graduated:

Yuchen Yang* — Ph.D. Biostatistics — 2020
Analyzing benefit-risk data in the presence of a primary endpoint and secondary measurements
Starting summer 2020 as Postdoc in Biostatistics at University of Pennsylvania

Emily Huang — Ph.D. Biostatistics — 2019
Statistical Methods for the Fraction Who Benefit Using a Randomized Trial
Current Position: Assistant Professor at Wake Forest University

Claire Ruberman — Ph.D. Biostatistics — 2018
Statistical Methods in the Analysis of Randomized Control Trials: Applications to Pre-Exposure Prophylaxis for HIV Prevention and a Community Engagement Intervention in East Baltimore
Current Position: FDA biostatistician

Yu Du — Ph.D. Biostatistics — 2018
Statistical Methods in Clinical Trial Design
Current Position: Clinical Trial Statistician for Diabetes Group at Eli Lilly

Tianchen Qian* — Ph.D. Biostatistics — 2017
Semiparametric Estimation in Observational Studies and Randomized Trials
Current Position: Assistant Professor, U.C. Irvine Department of Statistics

Biostatistics ScM Students

Current:

Melody Dehghan* — Biostatistics Sc.M. candidate — 2020-present

Graduated:

Brandon Luber — Sc.M. Biostatistics — 2012
Response-Adaptive Two-Stage Enrichment Design: A Simulation Study
Current Position: Senior Biostatistician at PRA Health Sciences

Po-Han Chen Sc.M. Biostatistics 2011
Leveraging Baseline Information to Improve Inference in Adaptive Randomized Experiments with Small Sample Size
Current Position: Statistician at Ethicon, Inc. (Medical Device Company)

MPH Advisees

Current:

Daniel Kim, MPH student 2020-present
Kenichiro Fujii MPH student 2020-present

Graduated:

Xue Jia MPH completed 2019 Now at Cleveland Clinic
Capstone: Comparing Several Covariate Adjustment Strategies in Randomized Trials with Binary Outcomes
Theresa Wadhwani MPH completed 2014 Now at Booz Allen Hamilton

Post-doctoral fellows:

Current:

Roy Adams, Computer Science postdoctoral researcher (co-advisor) 2019-present

Graduated:

Jon Steingrimsson, Biostatistics, 2015-2017
Current Position: Assistant Professor of Biostatistics, Brown School of Public Health

Ivan Diaz, Biostatistics 2013-2015
Current Position: Assistant Professor of Biostatistics, Dept. of Healthcare Policy & Research, Weill Cornell Medical College

Sherri Rose, NSF Postdoctoral Fellow in Biostatistics 2011-2013
Current Position: Associate Professor of Health Care Policy (Biostatistics) at Stanford University

Master's Thesis Reader

Su Jin Lim	Sc.M. Biostatistics	2018
Brandon Luber	Sc.M. Biostatistics	2012
Peter Rebeiro	Sc.M. Epidemiology	2012
Sobharani Rayapudi	Sc.M. Epidemiology	2011
Po-Han Chen	Sc.M. Biostatistics	2011
Maria Abraham	Sc.M. Biostatistics	2010

Preliminary Oral Exam Participation

Bohao Tang	Ph.D. candidate in Biostatistics	2020
Rohit Bhattacharya	Ph.D. candidate in Computer Science	2020
Huan Chen	Ph.D. candidate in Biostatistics	2020 (alternate)
Bonnie Smith	Ph.D. candidate in Biostatistics	2019 (alternate)
Qifang Bi	Ph.D. candidate in Epidemiology	2018
Bingkai Wang	Ph.D. candidate in Biostatistics	2018
Yuchen Yang	Ph.D. candidate in Biostatistics	2018

Prosenjit Kundu	Ph.D. candidate in Biostatistics	2018
Katharine Henry	Ph.D. candidate in Computer Science	2018
Joyce Qian	Ph.D. candidate in Epidemiology	2018
Sonal Parasrampuria	Ph.D. candidate in Health Policy and Management	2018 (alternate)
Lamar Hunt	Ph.D. candidate in Biostatistics	2017 (alternate)
Aozhou Wu	Ph.D. candidate in Epidemiology	2017 (alternate)
Yu Du	Ph.D. candidate in Biostatistics	2016
Claire Ruberman	Ph.D. candidate in Biostatistics	2016
Youjin Lee	Ph.D. candidate in Biostatistics	2016 (alternate)
Tara McAlexander	Ph.D. candidate in Environmental Health Sciences	2016 (alternate)
Nicole Fusco	Ph.D. candidate in Epidemiology	2016 (alternate)
Jim Aizire	Ph.D. candidate in Epidemiology	2016 (alternate)
Emily Huang	Ph.D. candidate in Biostatistics	2015
Tianchen Qian	Ph.D. candidate in Biostatistics	2015
Mariam Fofana	Ph.D. candidate in Epidemiology	2014
Tuo Zhao	Ph.D. candidate in Computer Science	2014
Prasad Patil	Ph.D. candidate in Biostatistics	2014
Derek Ng	Ph.D. candidate in Epidemiology	2013 (alternate)
Peter Rebeiro	Ph.D. candidate in Epidemiology	2013 (alternate)
Alison Turnbull	Ph.D. candidate in Epidemiology	2011 (alternate)
Shanshan Li	Ph.D. candidate in Biostatistics	2011 (alternate)
Samuel Galvagno	Ph.D. candidate, Graduate Training Program in Clin. Investigation	2010
Fang Tian	Ph.D. candidate in Epidemiology	2010
Robbin Stephens	Ph.D. candidate in Mental Health	2010
Nicholas Wada	Ph.D. candidate in Epidemiology	2010
George Wu	Ph.D. candidate in Biostatistics	2010
David Hanna	Ph.D. candidate in Epidemiology	2010 (alternate)

Doctoral Thesis Committee
(identical list as Final Oral Exam Participation below except for the following:)

Bonnie Smith	Ph.D. candidate in Biostatistics	2020-present

Final Oral Exam Participation

Yuchen Yang	Ph.D. Biostatistics	2020
Lamar Hunt	Ph.D. Biostatistics	2020 (alternate)
Harlan Pittell	Ph.D. Health Policy and Management	2020 (alternate)
Jonathan Levin	Ph.D. Health Policy and Management	2020 (alternate)
Claire Ruberman	Ph.D. Biostatistics	2018
Yu Du	Ph.D. Biostatistics	2018
Youjin Lee	Ph.D. Biostatistics	2018 (alternate)
Ryan Andrews	Ph.D. Mental Health	2018 (alternate)
Tianchen Qian	Ph.D. Biostatistics	2017
Emily Huang	Ph.D. Biostatistics	2017
Tuo Zhao	Ph.D. Computer Science	2016
Yi Lu	Ph.D. Biostatistics	2016
Prasad Patil	Ph.D. Biostatistics	2016

Aaron Fisher	Ph.D. Biostatistics	2016
Rebecca Campbell	Ph.D. International Health	2016
Parichoy Pal Choudhury	Ph.D. Biostatistics	2016 (alternate)
Maxwell Barffour	Ph.D. International Health	2014 (alternate)
Shilpa Viswanathan	Ph.D. Epidemiology	2014 (alternate)
Peter Rebeiro	Ph.D. Epidemiology	2014 (alternate)
Brandon Luber	Sc.M. Biostatistics	2012
Samuel Galvagno	Ph.D. Graduate Training Program in Clin. Investigation	2011 (alternate)
Adrienne Shapiro	Ph.D. Epidemiology	2011
Chuka Anude	Ph.D. Epidemiology	2011 (alternate)
Nick Reich	Ph.D. Biostatistics	2010 (alternate)

Classroom Instruction (my role is primary instructor unless indicated otherwise)

At Johns Hopkins Bloomberg School of Public Health: *Indicates teaching recognition

For each course below, the enrollment was at most 30 students.

2009-2010
Biostatistics 140.646: Essentials of Probability and Statistical Inference I: Probability
Biostatistics 140.655: Experimental and Non-experimental Designs for Estimating Causal Effects.
Biostatistics 140.850: Adaptive Designs in Clinical Trials

2010-2011
Biostatistics 140.646: Essentials of Probability and Statistical Inference I: Probability
Biostatistics 140.647: Essentials of Probability and Statistical Inference II: Statistical Inference
Biostatistics 140.655: Experimental and Non-experimental Designs for Estimating Causal Effects.
Biostatistics 140.850: Adaptive Designs in Clinical Trials

2011-2012
*Biostatistics 140.646: Essentials of Probability and Statistical Inference I: Probability
*Biostatistics 140.647: Essentials of Probability and Statistical Inference II: Statistical Inference

2012-2013
Biostatistics 140.646: Essentials of Probability and Statistical Inference I: Probability
*Biostatistics 140.647: Essentials of Probability and Statistical Inference II: Statistical Inference
Biostatistics 140.655: Experimental and Non-experimental Designs for Estimating Causal Effects.

2013-2014
Biostatistics 140.646: Essentials of Probability and Statistical Inference I: Probability
Biostatistics 140.647: Essentials of Probability and Statistical Inference II: Statistical Inference

Biostatistics 140.655: Experimental and Non-experimental Designs for Estimating Causal Effects.

2014-2019
*140.721: Probability Theory I. (Ph.D. level, Measure Theoretic Probability)

2014-2020
*140.734: Statistical Theory IV. (Ph.D. level, Asymptotic Statistics)

2019
Biostatistics 140.850: Adaptive Designs in Clinical Trials

Teaching at University of California, Berkeley, 2007-2008:
Statistics 20: Introduction to Probability and Statistics.
Statistics 131A: Statistical Inferences for Social and Life Scientists.

Other Teaching

Guest Lectures:
R3 Graduate Science Program, Causation Course, JHBSPH, 2019, 2020.
Center for American Indian Health, JHBSPH, "Adaptive Randomized Trial Designs", 2011

Instructor at Johns Hopkins Center for Talented Youth (CTY): Introduction to the Theoretical Foundations of Computer Science. Summer 1997.

RESEARCH GRANT PARTICIPATON

Ongoing Research Support
Burroughs Wellcome Fund (BWF) Innovation in Regulatory Science Award
PI: **Rosenblum, M.** 9/1/2017-8/31/2022 $500,000 direct costs
Statistical Methods and Automated Software Tool for Stress-Testing Adaptive Clinical Trial Designs
We will develop new methods and software to systematically probe trial designs to find and fix weaknesses before the trial is conducted. We will also develop new designs that are robust to violations of an investigator's initial assumptions. The potential impact is preventing some trial failures due to design flaws. The new methods, software, and trial designs could help clinical investigators who are designing trials, and regulators such as the FDA and EMA. Our software will be demonstrated in clinical applications using data from 3 trials in the areas of HIV prevention, cardiac resynchronization devices, and a cryogenic device for treating Barrett's esophagus. I lead the project team which includes an Assistant Professor, a PhD student, and a software developer.

U01FD005942 (Alexander, C.) 09/15/16 – 08/31/23
FDA $990,566
Johns Hopkins Center of Excellence in Regulatory Science and Innovation
This is a partnership between the FDA and Johns Hopkins University that will produce innovative training and scientific exchange focused on strategically important areas of FDA regulation. I lead

a project titled **"Statistical methods to improve precision and reduce the required sample size in many phase 2 and 3 clinical trials, including COVID-19 trials, by covariate adjustment",** whose goal is to show how to appropriately adjust for prognostic baseline variables when outcomes are binary or time-to-event, in order to improve precision and power in randomized trials. The demonstrations consist of case studies, using completed trial data sets across the following 10 disease areas: stroke, Alzheimer's disease, heart failure, depression, schizophrenia, substance use disorder, autism, bipolar disorder, attention deficit hyperactivity disorder, anxiety disorder. The goal is to make these methods widely accessible and understandable to investigators across many disease areas, so that they can be implemented in future trials; dissemination will be through an online tutorial.

UL1TR003098 (Ford) 06/01/19 - 04/30/24
NIH/NCATS
Institutional Clinical and Translational Science Award
The purpose of this application is to enhance both the process and benefits of clinical and translational research by bringing together the diverse resources of the Johns Hopkins Medical Institutions (JHMI) and creating a new model for carrying out scientific research. Role: Co-Investigator in the Biostatistics Core.

R01AG048349 (Albert, Gallagher, Co-PIs) 09/15/15-05/31/20
NIH/NIA
Phase II/III trial for Slowing Progression in Mild Cognitive Impairment
A multi-center, randomized, placebo-controlled trial in amnestic mild cognitive impairment (aMCI). The trial will complement other trials using amyloid therapies in asymptomatic patients, thus adding a novel treatment approach in a symptomatic stage of disease. The proposed clinical trial will be the first Phase IIB study to target the condition of hyperactivity, which characterizes the clinical stage of aMCI. I optimized the primary analysis by selecting baseline covariates to adjust for, using previous trial data from the same population.

NSF 1418590 (S. Saria) (under no cost extension) 09/01/2014-08/31/19
Collaborative Research: Modeling Disease Trajectories in Patients with Complex, Multiphenotypic Conditions
The goal is to develop statistical and computational tools for characterizing disease progression in patients with complex, multiphenotypic conditions. Data contained in clinical registries are unstructured, from diverse sources and contain varying types of noise; therefore, these are challenging to use. We will demonstrate approaches for tackling these challenges. Our methods will be employed towards early prediction of risk for individual patients which can then be incorporated at the point of care or for clinical trial recruitment to make more informed choices regarding treatment plans. My role is to estimate the causal effect of dynamic treatment regimes based on electronic health record (EHR) data.

R01AI145675 (Marzinke) 07/01/19-06/30/24
NIH/NIAID
Improving PrEP Protection of Transgender Women through Mechanistic Pharmacokinetic Understanding

The specific aims of this project are, (i) Evaluate the two-way PK-PD interaction of Gender Affirming Hormone Therapy (GAHT) on TDF/FTC PrEP in Transgender Women (TGW), and (ii) to compare the likelihood of HIV protection during daily PrEP dosing and the IPERGAY (4 dose) PrEP regimen, both with and without GAHT. My role is to analyze the trial data.

U24TR001609 NIH/NCATS PI: Daniel Hanley 07/01/16-06/30/23
CTSA Network – Trial Innovation Centers (U24)
Johns Hopkins University and Tufts University (with Harvard Clinical Research Institute and MIT) are collaborating to improve the science of randomized clinical trials. The scientific purpose is to demonstrate that innovations in trial design, execution, and evaluation will get more treatments to more patients more quickly. My role is statistical consultant on adaptive trial designs, including a phase 2/3 Alzheimer's disease drug trial.

Completed Research Support:

U.S. Food and Drug Administration (FDA) 9/30/2014-12/31/2017
PI: **Rosenblum, M.** $399,568 direct costs
New Design and Analysis Tools for Randomized Trials, with Clinical Applications in Stroke, Cardiac Resynchronization Therapy, Alzheimer's Disease, and HIV Prevention.
We demonstrated the practical advantages and limitations of new adaptive trial designs across a variety of clinical settings including the following: new surgical interventions for stroke, new medical devices for cardiac resynchronization therapy, treatments to slow the progression of Alzheimer's disease, and pre-exposure prophylaxis for preventing HIV infection. For each application, we have established collaborations with clinical investigators at Johns Hopkins. These investigators identified clinically important questions about whether certain subpopulations (e.g., defined by age, sex, or disease severity) benefit from new treatments. We constructed new adaptive designs tailored to answer these questions and then conducted extensive simulation studies comparing them to standard designs. As PI, I led a team including a senior-level biostatistician, an Associate Scientist, a postdoc, and a Ph.D. student. I am responsible for all aspects of this project.

Patient-Centered Outcomes Research Institute (PCORI) 3/1/2014-2/28/2017
PI: **Rosenblum, M.** $727,311 direct costs
Innovative Randomized Trial Designs to Generate Stronger Evidence about Subpopulation Benefits and Harms.
The aim of this project is to develop new statistical methodology and an open-source, free software tool enabling investigators to construct new adaptive enrichment designs tailored to answer their specific research questions. It will automatically compare a wide variety of designs and recommend those with the best performance, tailored to the user's research goals, study population, and logistical constraints. This will be the first software package to provide this critical feature, which has the potential to make the advantages of adaptive designs much more widely available for use in practice. The resulting improved designs will efficiently generate crucial, subpopulation-specific information directly relevant to decisions of patients, clinicians, and regulators. As PI, my role is to lead a team including a senior-level biostatistician, postdoc, two Ph.D. students, and a software developer. I am responsible for all aspects of this project.

1RO1AI110371-01 (Hendrix, C.) 07/01/13 – 06/30/19

NIH/NIAID
Effect of Depo-Provera (MPA) on HIV susceptibility, immune activation, and PrEP PK
This study prospectively examines the impact of hormonal contraception, particularly injectable medroxyprogesterone acetate (MPA), on HIV acquisition and immune mediators. Using a cervical explant HIV challenge model, we assess the interactions among MPA, Pre-exposure Prophylaxis (TFV/FTC), immune mediators, and antiviral effect. My role is lead statistician for the study design and analysis.

U01NS080856 (Thompson, R) 09/15/13 – 07/31/19
NIH/NINDS
Minimally-Invasive Surgery Plus t-PA for Intracerebral Hemorrhage Evacuation (MISTIE) III
MISTIE III is an innovative, phase 3 neurosurgical trial that addresses multiple unmet needs of patients and the research community, striving for an effective treatment to save lives and improve recovery to independence after intracerebral hemorrhage (ICH). It aims to establish whether minimally invasive, catheter based, clot size reduction is associated with clinically significant functional benefits in the long term outcome of the ICH patient. My role was to lead development of the covariate adaptive randomized trial design, and to select/implement the method used in the primary analysis of this trial.

P50 AG005146 (Albert) 04/01/15-03/31/20
NIH/NIA, Johns Hopkins Alzheimer's Disease Research Center
To provide administrative, clinical, statistical, neuropathological and educational support for research concerning Alzheimer's disease and related disorders at Johns Hopkins University School of Medicine. I proposed a pilot project that was selected for funding by the Johns Hopkins Alzheimer's Disease Research Center. I evaluated the strengths and weaknesses of a new statistical method for improving power in Alzheimer's disease clinical trials.

4UL1TR001079-04 (Ford) 08/01/16-04/30/18
NIH/NCATS
Institute for Clinical and Translational Research
This project is focused, through collaboration among methodologists at four CTSA hubs, on enhancing network capacity by disseminating state-of-the-art methods and tools for the design and analysis of randomized clinical trials. My role was to develop open-source software for the primary analysis in phase 2 or 3 randomized trials, which leverages baseline covariates to improve the precision and power in trials with repeated measures outcomes.

Gates Foundation (Hendrix, C.) 4/11/14 – 4/10/16
Pharmacostatistical Modeling and Simulation of Randomized Clinical PrEP Trials
We propose development of a comprehensive model describing concentration-response relationships, adherence, and other influential variables in tenofovir-based pre-exposure prophylaxis (PrEP) to guide clinical management of PrEP in a variety of at risk populations globally and to guide clinical trial design for the next generation of PrEP agents. I led a team including a postdoc and Ph.D. student to develop a causal model to embed in clinical trial simulation software for planning future trials of pre-exposure prophylaxis (PrEP) for HIV prevention.

CD-12-11-4948 (Wu, A.) 07/01/13-06/30/16
PCORI Pilot Projects
Reverse Innovation & Community Engagement to Improve Quality of Care & Patient Outcomes.
The goals of this project are to improve the health of East Baltimore residents by enhancing communication and co-developing a community engagement partnership between Johns Hopkins hospitals and clinics, community based organizations (CBO's) and residents of the five surrounding zip codes. My role was to design the cluster randomized trial for this project, in which 22 CBO's are randomized to intervention or control, and to do the main data analysis at the end of the trial.

1P30AI094189 - 01A1 (Chaisson) 9/1/13 – 3/31/15
Johns Hopkins Center for AIDS Research (CFAR)
CFAR Scholar Grant for Faculty Development
The purpose of the overall grant is to establish a CFAR at Johns Hopkins, to support the recruitment and training of new investigators in HIV/AIDS, promote trans-disciplinary collaboration and to address the Baltimore HIV epidemic. My faculty development grant from CFAR was to estimate the minimum dosing frequency needed for high level (e.g. 90%) protection against HIV for three populations: heterosexual men, heterosexual women, and injection drug users. We applied targeted maximum likelihood estimation to this problem, to address time-dependent confounding.

HHSF223201000072C (Segal, J.) 09/20/10 – 09/19/13
U.S. FDA, Partnership in Applied Comparative Effectiveness Science (PACES)
The major goal of this project is to improve health outcomes by developing and disseminating evidence-based information and a patient-centered outcomes research (PCOR) scientific framework to patients, clinicians, and other decision makers, responding to their expressed needs, about which interventions are the most effective for patients under specific circumstances. I led a team of 4 Ph.D. students and a statistical programmer to develop open-source software that implements new adaptive designs.

3U01AI069918-04S1 (Gange, S.) 09/22/09 – 08/31/14
NIH/NIAID
North American AIDS Cohorts Collaboration on Research and Design (NA-ACCORD)
The purpose if this research is to determine the incidence of, risk factors for, and cause-specific mortality from major cardiovascular disease (myocardial infarction and stroke), chronic kidney disease, and non-AIDS-defining malignancies in HIV-infected persons in North America. My role was to apply newly developed causal inference methods to estimate the effect of different rules for when to start anti-retroviral therapy, using data from NA-ACCORD.

P30MH086043 (Ialongo, N.) 07/01/09 – 02/28/14
NIH/NIMH
Center for Prevention & Early Intervention
The mission of the Center is to improve preventive and treatment interventions by bridging epidemiologic, intervention, and services research through the development of a research structure and research strategies capable of evaluating the effectiveness of evidence based interventions. My role is developing improved trial designs and analysis methods for cohort studies. I have applied

these methods in a statistical analysis of a randomized controlled trial of mental health interventions survivors of torture and related trauma in Kurdistan, Northern Iraq, led by Paul Bolton and Judith Bass (JHBSPH).

5 T32 MH-19105-19 (Kegeles, S.) 7/1/07-6/30/09
NIH/NIMH
Ruth L. Kirschstein National Research Service Award (NRSA), U.C. San Francisco
Role: Postdoctoral Trainee in AIDS Prevention Studies

R01 GM67233 (van der Laan, M.J.) 9/1/06-6/30/07
NIH/NIAID
Role: Postdoctoral Researcher

ACADEMIC SERVICE

Department of Biostatistics

2010-present Co-leader of Causal Inference Group, Department of Biostatistics, Johns Hopkins Bloomberg School of Public Health (JHBSPH)
2010-present Johns Hopkins Biostatistics Center: Consultant and Steering Committee Member
2020-present Inclusion, Diversity, Anti-Racism, and Equity (IDARE) Leader
2020-present Graduate Student Program Co-chair
2020-present Admissions Committee
2015 Planning Committee, Biostatistics Events for JHBSPH Centennial
2013 Planning Committee for Annual Retreat
2010-2011 Seminar Coordinator

Johns Hopkins Bloomberg School of Public Health:

2020-present Inclusion, Diversity, Anti-Racism, and Equity (IDARE) Strategic Plan Committee
2020-present Search Committee for Executive Vice Dean for Finance and Administration
2018-present Search Committee for Health Policy and Management Faculty Position
2016-present Conflict of Interest Committee
2016-present Technology Transfer Committee
2010-present Affiliate of the Johns Hopkins Center for Clinical Trials
2009-2014 Affiliate of the Johns Hopkins Center for Prevention and Early Intervention
2012-2013 Steering Committee, Prevention Core of Center for AIDS Research

Johns Hopkins University:

2013-2015 Co-chair, Johns Hopkins InHealth (Individualized Health) Methodology Steering Committee

PRESENTATIONS *both in-person and virtual

Scientific Meetings (all are oral presentations)

1. "Improving Precision and Power in Randomized Trials for COVID-19 Treatments Using Covariate Adjustment, for Binary, Ordinal, or Time to Event Outcomes", Lightning Talk at

the University of California, San Francisco-Stanford 2021 Innovations in Regulatory Science Summit (virtual), January 10, 2021.

2. "Improving Precision and Power in Randomized Trials for COVID-19 Treatments Using Covariate Adjustment, for Binary, Ordinal, or Time to Event Outcomes", 6th Seattle Symposium in Biostatistics (virtual), November 22, 2020.

3. "Improving Precision and Power in Randomized Trials for COVID-19 Treatments Using Covariate Adjustment, for Binary, Ordinal, or Time to Event Outcomes", Society for Clinical Trials Annual Meeting (virtual), September 30, 2020.

4. "Improving Precision and Power in Randomized Trials for COVID-19 Treatments Using Covariate Adjustment, for Binary, Ordinal, or Time to Event Outcomes", American Statistical Association (ASA) Biopharmaceutical Section Regulatory-Industry Statistics Workshop, Bethesda, MD, September 23, 2020.

5. "Machine Learning Versus Standard Methods for Covariate Adjustment: Performance Comparison Using Completed Randomized Trial Data Sets", International Biometric Society, Eastern North American Region (ENAR), Nashville, TN, March 24, 2020.

6. "Adaptive Enrichment Designs for Estimating Treatment Effects in the Overall Population and Subpopulations", Workshop on Subset Analysis in Clinical Studies, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), Bethesda, MD, March 11, 2020.

7. "Adaptive Design in Surveys and Clinical Trials: Similarities, Differences, and Opportunities for Cross-Fertilization", Causal Inference Program Opening Workshop, Statistical and Applied Mathematical Sciences Institute (SAMSI), Duke University, Durham, NC, December 11, 2019.

8. "Adaptive Design in Surveys and Clinical Trials: Similarities, Differences, and Opportunities for Cross-Fertilization", Royal Statistical Society, Belfast, Northern Ireland, September 3, 2019.

9. "Estimating the Protective Effect of Longitudinal Drug Concentration in Pre-Exposure Prophylaxis for HIV Prevention", International Biometric Society, Western North American Region (WNAR), Portland, OR, June 26, 2019.

10. "Methods for Adaptive Clinical Trials", Big Data & Innovative Trial Design for Global Nutrition Research Session at the American Society for Nutrition Annual Meeting, Baltimore, MD, June 8, 2019.

11. "Methods and Open-Source Software for Optimizing Adaptive Enrichment Designs", 12th Annual FDA/AdvaMed Medical Devices & Diagnostics Statistical Issues Conference, Washington, D.C., April 25, 2019.

12. "Randomized Trial Designs that Adapt Enrollment Criteria Based on Accruing Data: Optimality vs Flexibility Tradeoff", ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop, Washington, D.C., September 14, 2018.

13. "Randomized Trial Designs that Adapt Enrollment Criteria Based on Accruing Data: Optimality vs Flexibility Tradeoff", Joint Statistical Meetings (JSM), Vancouver, Canada, July 30, 2018.

14. "Estimating the Protective Effect of Longitudinal Drug Concentration in Pre-Exposure Prophylaxis for HIV Prevention", Workshop on Discovery of Causal Structure in High Dimensions, Centre de Recherches Mathematiques, Univ. Montreal, Canada, June 27, 2018.

15. "Case Studies of Precision Gains from Adjusting for Prognostic Baseline Variables in Randomized Trials", Translational Science, Washington, D.C., April 21, 2018.

16. "Adaptive Enrichment Trial Designs: Statistical Methods, Trial Optimization Software, and Case Studies", International Biometric Society, Eastern North American Region (ENAR), Atlanta, GA, March 26, 2018.

17. "An Optimized Adaptive Enrichment Design for Multi-Arm Trials", Joint Statistical Meetings (JSM), Baltimore, MD, July 30, 2017.

18. "Leveraging Prognostic Baseline Variables to Gain Precision in Randomized Trials", Association of Clinical and Translational Statisticians (ACTS) Annual Meeting, Baltimore, MD, July 29, 2017.

19. "Adaptive Randomized Trial Designs to Generate Stronger Evidence about Subpopulation Benefits and Harms", 6th World Intracranial Hemorrhage Conference, Baltimore, MD, May 3, 2017.

20. "Leveraging Prognostic Baseline Variables to Gain Precision in Randomized Trials", Translational Science, Washington, D.C., April 20, 2017.

21. "Adaptive Enrichment Trial Design to Learn which Subpopulations Benefit from Treatments, Based on Apoe4 Carrier Status," 9th Clinical Trials on Alzheimer's Disease (CTAD) Conference, San Diego, CA, December 8, 2016.

22. "Optimizing Adaptive Enrichment Designs, and Challenges in Using Data to Construct Realistic Simulations to Evaluate Design Performance," Second Seattle Symposium on Health Care Data Analytics, Seattle, WA, October 24, 2016.

23. Discussant: "Personalized Dose Finding Using Outcome Weighted Learning", Joint Statistical Meetings (JSM), Chicago, IL, August 2, 2016.

24. "New Developments of Bayesian Methods for Causal Inference", Discussant, Eastern North American Region (ENAR) International Biometric Society, Austin, TX, March 8, 2016.

25. "Optimal Two-Stage Adaptive Enrichment Designs, using Sparse Linear Programming", Duke-Industry Statistics Symposium, Duke University, Durham, NC, October 23, 2015.

26. "Optimal Tests of Treatment Effects for the Overall Population and Two Subpopulations in Randomized Trials, using Sparse Linear Programming", Keynote Speaker, 23rd Annual Meeting of Belgian Statistical Society, Antwerp, Belgium, October 16, 2015.

27. "Optimal Two-Stage Adaptive Enrichment Designs, using Sparse Linear Programming", American Statistical Association Biopharmaceutical FDA-Industry Workshop, Washington, D.C., September 17, 2015.

28. "Optimal Two-Stage Adaptive Enrichment Designs, using Sparse Linear Programming", International Chinese Statistical Association (ICSA) Applied Statistics Symposium and 13th Graybill Conference, Colorado State University, Fort Collins, CO, June 15, 2015.

29. "Optimal Two-Stage Adaptive Enrichment Designs, using Sparse Linear Programming", MacMillan-CSAP Workshop on Quantitative Research Methods, Yale University, New Haven, CT, March 26, 2015.

30. "Optimal Two-Stage Adaptive Enrichment Designs, using Sparse Linear Programming", Eastern North American Region (ENAR) International Biometric Society, Miami, FL, March 16, 2015.

31. "Optimal Two-Stage Adaptive Enrichment Designs, using Sparse Linear Programming", Innovative Methods Program for Advancing Clinical Trials (IMPACT) Symposium, jointly sponsored by University of North Carolina at Chapel Hill, Duke University and North Carolina State University, Cary, NC, November 20, 2014.

32. "Optimal Tests of Treatment Effects for the Overall Population and Two Subpopulations in Randomized Trials, using Sparse Linear Programming", Atlantic Causal Inference Conference, Brown University School of Public Health, Providence, RI, May 15, 2014.

33. "Optimal Tests of Treatment Effects for the Overall Population and Two Subpopulations in Randomized Trials, using Sparse Linear Programming", FDA/DIA Statistics Symposium, Bethesda, MD, April 8, 2014.

34. "Optimal Tests of Treatment Effects for the Overall Population and Two Subpopulations in Randomized Trials, using Sparse Linear Programming", Eastern North American Region (ENAR) International Biometric Society, Baltimore, MD, March 17, 2014.

35. "Confidence Intervals for the Population Mean, Tailored to Small Sample Sizes, with Applications to Survey Sampling" Alan Ross Symposium on Sampling, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, March 15, 2014.

36. "Optimal Tests of Treatment Effects for the Overall Population and Two Subpopulations in Randomized Trials, using Sparse Linear Programming," ICSA 2013 Applied Statistics Symposium/ISBS International Symposium on Biopharmaceutical Statistics Joint Meeting, Bethesda, MD, June 9, 2013.

37. "Estimating the Minimum Dosing Frequency of Pre-Exposure Prophylaxis Needed to Provide a High Level of Protection Against HIV Infection," Johns Hopkins University Center for AIDS Research Annual Meeting, Baltimore, MD, June 7, 2013

38. "Optimal Clinical Trial Designs for Estimating Treatment Effects in HIV Subpopulations," Partnership in Applied Comparative Effectiveness Science (PACES), FDA, White Oak, MD, December 7, 2012.

39. "Estimation and Confidence Intervals in Randomized Trials That Adapt Enrollment Criteria," Joint Statistical Meetings (JSM) Social Statistics Section, San Diego, CA, August 1, 2012.

40. "Consonant Multiple Testing Procedures for Subpopulation Treatment Effects in Randomized Trials," Western North American Region (WNAR)/Institute of Mathematical Statistics (IMS) and Graybill Conference, Fort Collins, CO, June 18, 2012.

41. "Determining which Subpopulations Benefit from a Vaccine, Using Adaptive Designs", Eastern North American Region (ENAR) International Biometric Society, Washington, D.C., April 3, 2012.

42. "Brief Overview of Adaptive Designs" The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Conference on Reducing the Impact of Chronic Kidney Disease, Opportunities for Randomized Clinical Trials, Bethesda, MD, July 19, 2011.

43. Invited Discussant: "Causal Inference and its Applications in Drug Development," International Chinese Statistical Association (ICSA) 20th Applied Statistics Symposium, New York City, NY, June 28, 2011.

44. "Optimizing Randomized Trial Designs to Distinguish which Subpopulations Benefit from Treatment," Recent Advances in Statistics and Causal Analysis. INSERM, Bordeaux, France, June 8, 2011.

45. "Targeted Maximum Likelihood Estimation for Dynamic Treatment Regimes", Eastern North American Region (ENAR) International Biometric Society, Miami, March 21, 2011.

46. "Practical Implications of Adaptive Design," Emerging Issues in Clinical Trials for New Anti-retroviral (ARV) Development, Forum for Collaborative HIV Research, Washington D.C., September 30, 2010.

47. "Adaptive Randomized Trial Designs for PrEP: Trials that Adapt the Population Sampled based on Interim Data," PrEP Trial Design Optimization Workshop, The Bill and Melinda Gates Foundation. Seattle, WA. June 2, 2010.

48. "Adaptive Designs for Observational Studies: Changing the Population Sampled Based on Interim Data," Atlantic Causal Inference Conference, New York University (NYU), New York. May 21, 2010.

49. "Optimizing Group Sequential Designs that Allow with Changes to Population Sampled Based on Interim Data" The 57th Session of the International Statistical Institute, Durban, South Africa, August 21, 2009.

50. "Targeted Maximum Likelihood Estimation of the Parameter of a Marginal Structural Model," Causal Inference in Statistics and the Quantitative Sciences Workshop. Banff, Canada, March 7, 2009.

51. "Estimating the Effects of New HIV Intervention Methods using Causal Inference Techniques—the MIRA trial." 7th World Congress on Probability and Statistics, Singapore. July 16, 2008.

52. "Intention-to-Treat Analyses of 2-Armed Randomized Controlled Trials: Can We Improve on the Gold Standard?" Panelist. Society for Epidemiological Research (SER), Chicago, Illinois. June 26, 2008.

53. "Multihop, Long-Distance 802.11 Networks." Technology and Infrastructure for Emerging Regions Workshop. University of California, Berkeley. October 29, 2005.

54. "Universal Bounds on Buffer Size for Packetizing Fluid Policies in Input Queued, Crossbar Switches." INFOCOM, Hong Kong. 2004.

55. "Worst-Case Delay Bounds for Packetizing Time-Varying Fluid Schedules for a Single Server in a Packet-Switched Network." 38th Annual Conference on Information Sciences and Systems, Princeton, NJ. 2004.

Invited Seminars

1. "Improving Precision and Power in Randomized Trials for COVID-19 Treatments Using Covariate Adjustment, for Binary, Ordinal, or Time to Event Outcomes", University of Michigan Statistics Department Seminar (virtual), October 16, 2020.

2. "Optimal Two-Stage Adaptive Enrichment Designs, using Sparse Linear Programming", University of California, Berkeley, Biostatistics Department Seminar, Berkeley, CA, July 15, 2019.

3. "Optimal Two-Stage Adaptive Enrichment Designs, using Sparse Linear Programming", Department of Biostatistics, Boston University School of Public Health, Boston, MA, February 5, 2019.

4. "Optimal Two-Stage Adaptive Enrichment Designs, using Sparse Linear Programming", Department of Biostatistics, Harvard School of Public Health, Boston, MA, January 30, 2019.
5. "Adaptive Enrichment Trial Designs: Statistical Methods, Trial Optimization Software, and Case Studies", Math and Statistics Department Seminar, University of Maryland, Baltimore County, Baltimore, MD, September 21, 2018

6. "Leveraging Prognostic Baseline Variables to Gain Precision in Randomized Trials", Victorian Centre for Biostatistics, Department of Epidemiology and Preventive Medicine, School of Public Health and Preventive Medicine, Monash University, Melbourne, Australia, January 12, 2017.

7. "Improving Precision by Adjusting for Prognostic Baseline Variables in Randomized Trials with Binary Outcomes, without Regression Model Assumptions", Department of Statistics, University of Colombo, Sri Lanka, January 17, 2017.

8. "Leveraging Prognostic Baseline Variables to Gain Precision in Randomized Trials," Joint Seminar hosted by Department of Veterans Affairs Hines Cooperative Studies Program (responsible for large multicenter clinical trials) and Department of Epidemiology and Biostatistics, University of Illinois at Chicago, IL, August 5, 2016.

9. "Optimal Tests of Treatment Effects for the Overall Population and Two Subpopulations in Randomized Trials, using Sparse Linear Programming", Seminar Department of Stochastic Modeling (MODAL'X), University of Paris West Nanterre La Defense, France, May 30, 2016.

10. "Innovative RCT Designs: Identifying Patients who Benefit from New Treatments", Biostatistics, Epidemiology, and Data Management (BEAD) Core Seminar, Johns Hopkins Bayview Medical Center, Baltimore, MD, April 20, 2016.

11. "Optimal Two-Stage Adaptive Enrichment Designs, using Sparse Linear Programming", Department of Biostatistics and Computational Biology Colloquium, University of Rochester Medical Center, Rochester, NY, December 3, 2015.

12. "Introduction to Causal Inference Methods for Observational Studies", Math and Statistics Department, Dalhousie University, Halifax, Nova Scotia, Canada, November 2, 2015.

13. "Adaptive Enrichment Designs for Delayed Endpoints, and Prototype Software Tool for Design", FDA Statistical Association (FDASA) Seminar, U.S. Food and Drug Administration, White Oak, MD, October 26, 2015.

14. "Optimal Two-Stage Adaptive Enrichment Designs, using Sparse Linear Programming", Department of Statistics, Informatics, and Applications, University of Florence, Italy, July 27, 2015.

15. "Introduction to Adaptive Designs", Math and Statistics Department, Dalhousie University, Halifax, Nova Scotia, Canada, June 4, 2015.

16. "Optimal Two-Stage Adaptive Enrichment Designs, using Sparse Linear Programming", Math and Statistics Department Seminar, American University, Washington, D.C., April 21, 2015.

17. "Optimal Two-Stage Adaptive Enrichment Designs, using Sparse Linear Programming", Math and Statistics Department Seminar, University of Maryland, Baltimore County, Baltimore, MD, April 10, 2015.

18. "Optimal Two-Stage Adaptive Enrichment Designs, using Sparse Linear Programming", Epidemiology and Biostatistics Department Seminar, Memorial Sloan Kettering Cancer Center, New York City, NY, April 8, 2015.

19. "Optimal Two-Stage Adaptive Enrichment Designs, using Sparse Linear Programming." Math and Statistics Department Seminar, Dalhousie University, Halifax, Nova Scotia, Canada, March 2, 2015.

20. "Optimal Two-Stage Adaptive Enrichment Designs, using Sparse Linear Programming", Biostatistics Department Seminar, University of Washington, Seattle, WA, January 22, 2015.

21. "Optimal Tests of Treatment Effects for the Overall Population and Two Subpopulations in Randomized Trials, using Sparse Linear Programming", Harvard University, Biostatistics Department Seminar, Boston, MA, September 25, 2014.

22. "Optimal Tests of Treatment Effects for the Overall Population and Two Subpopulations in Randomized Trials, using Sparse Linear Programming", Columbia University, Biostatistics Department Seminar, New York City, NY, September 11, 2014.

23. "Optimal Tests of Treatment Effects for the Overall Population and Two Subpopulations in Randomized Trials, using Sparse Linear Programming", University of California, San Francisco, Epidemiology and Biostatistics Department Seminar, San Francisco, CA, August 28, 2014.

24. "Optimal Tests of Treatment Effects for the Overall Population and Two Subpopulations in Randomized Trials, using Sparse Linear Programming", University of California, Berkeley, Biostatistics Department Seminar, Berkeley, CA, August 27, 2014.

25. "Leveraging Prognostic Baseline Variables to Gain Precision in Randomized Trials," Math and Statistics Department Seminar, Dalhousie University, Halifax, Nova Scotia, Canada, August 20, 2014.

26. "Optimal Tests of Treatment Effects for the Overall Population and Two Subpopulations in Randomized Trials, using Sparse Linear Programming", Stanford Statistics Department Seminar, Stanford, CA, June 3, 2014.

27. "Optimal Tests of Treatment Effects for the Overall Population and Two Subpopulations in Randomized Trials, using Sparse Linear Programming", Math and Statistics Department Seminar, Dalhousie University, Halifax, Nova Scotia, Canada, April 3, 2014.

28. "Optimal Tests of Treatment Effects for the Overall Population and Two Subpopulations in Randomized Trials, using Sparse Linear Programming", Biostatistics Department Seminar, University of Minnesota, Minneapolis, MN, March 23, 2014.

29. "Optimal Tests of Treatment Effects for the Overall Population and Two Subpopulations in Randomized Trials, using Sparse Linear Programming", Indian Statistical Institute, Kolkata, India, January 21, 2014.

30. "Statistical Challenges in the Design and Analysis of Randomized Trials for Learning which Populations Benefit from Different Treatments" Center for Clinical Trials Seminar, Johns Hopkins University, Baltimore, MD, December 4, 2013.

31. "Some Statistical Ideas for Speeding Translation of Genomic Biomarkers to the Clinic," (Joint talk with Dr. Jeff Leek), Research Program in Quantitative Sciences Seminar, Division of Oncology Biostatistics/Bioinformatics, Kimmel Cancer Center, Johns Hopkins School of Medicine, Baltimore, MD, December 19, 2013.

32. "Optimal Tests of Treatment Effects for the Overall Population and Two Subpopulations in Randomized Trials, using Sparse Linear Programming", Biostatistics Research Branch Seminar Series, NIH/NIAID, Bethesda, MD, November 5, 2013.

33. "Statistical Challenges in Individualized Health", Johns Hopkins Institute for Computational Medicine, Baltimore, MD, October 30, 2013.

34. "Optimal Tests of Treatment Effects for the Overall Population and Two Subpopulations in Randomized Trials, using Sparse Linear Programming", Department of Biostatistics Seminar, University of North Carolina, Chapel Hill, October 23, 2013.

35. "Optimal Tests of Treatment Effects for the Overall Population and Two Subpopulations in Randomized Trials, using Sparse Linear Programming", Department of Biostatistics Seminar, University of Pennsylvania, Philadelphia, September 24, 2013.

36. "Optimal Clinical Trial Designs for Estimating Treatment Effects in Subpopulations," Welch Center for Prevention, Epidemiology and Clinical Research, Johns Hopkins University, Baltimore, MD, October 3, 2012.

37. "Optimal Confidence Intervals and Multiple Testing Procedures for Enrichment Clinical Trial Designs," Center for Devices and Radiological Health (CDRH), FDA, White Oak, MD, August 29, 2012.

38. "Improved Statistical Methods for Randomized Trials and Observational Studies," Center for Medical Technology Policy, Baltimore, MD, June 12, 2012.

39. "Targeted Maximum Likelihood Estimation for Dynamic Treatment Regimes," Workshop on Personalized Medicine, Harvard School of Public Health, Cambridge, MA, May 15, 2012.

40. "Optimal Confidence Intervals for Enrichment Clinical Trial Designs", Harvard University Biostatistics Department Causal Inference Seminar, May 2, 2012

41. "Confidence Intervals in Group Sequential Designs that Allow Changes to the Population Sampled Based on Interim Data," Brown University Center for Statistical Science, Providence, RI, March 26, 2012.

42. "Confidence Intervals in Group Sequential Designs that Allow Changes to the Population Sampled Based on Interim Data," Cornell University, Department of Statistical Science, February 22, 2012.

43. "Confidence Intervals in Group Sequential Designs that Allow Changes to the Population Sampled Based on Interim Data," Vanderbilt University, Department of Biostatistics, February 8, 2012.

44. "Confidence Intervals in Group Sequential Designs that Allow Changes to the Population Sampled Based on Interim Data," National Cancer Institute (NCI), Rockville, MD, November 14, 2011.

45. "Optimal Tests of Treatment Effects for the Overall Population and Two Subpopulations in Randomized Trials, using Sparse Linear Programming," Causal Inference Symposium, Dept. of Biostatistics, University of Pennsylvania, May 6, 2013.

46. "Targeted Maximum Likelihood Estimation for Dynamic Treatment Regimes," Causal Inference Seminar, Harvard School of Public Health, Cambridge, MA, May 2, 2011.

47. "Optimizing Randomized Trial Designs to Distinguish which Subpopulations Benefit from Treatment," Math/Statistics Department Seminar, U.S. Naval Academy, Annapolis, MD, April 27, 2011.

48. "Optimizing Randomized Trial Designs to Distinguish which Subpopulations Benefit from Treatment," Statistics Department Seminar, George Mason University, April 8, 2011.

49. "Randomized Trial Designs that Allow Preplanned Adaptations," The Department of Surgery Research Seminar, Johns Hopkins School of Medicine, November 18, 2010.

50. "Optimizing Randomized Trial Designs to Distinguish which Subpopulations Benefit from Treatment", McGill University Department of Epidemiology, Biostatistics & Occupational Health, Biostatistics Seminar, Montreal, Quebec, November 2, 2010.

51. "Optimizing Group Sequential Designs that Allow with Changes to Population Sampled Based on Interim Data," FDA, White Oak, MD, May 6, 2010.

52. "Optimizing Group Sequential Designs that Allow with Changes to Population Sampled Based on Interim Data," Seminar in Applied Math Department (MAP5) University of Paris Descartes, Paris, France, March 26, 2010.

53. "Targeted Maximum Likelihood Estimation Applied to Marginal Structural Models", Causal Inference Seminar, Johns Hopkins Bloomberg School of Public Health, Johns Hopkins University, November 17, 2009.

54. "Estimating Direct Effects of New HIV Prevention Methods. Focus: the MIRA Trial." Department of Epidemiology Seminar, Johns Hopkins Bloomberg School of Public Health, Johns Hopkins University, November 16, 2009.

55. "Optimizing Group Sequential Designs that Allow with Changes to Population Sampled Based on Interim Data", Seminar of Applied Math and Statistics Department, Johns Hopkins University, October 1, 2009.

56. "Adaptive Designs in Group Sequential Trials with Changes to Population Sampled", Center for AIDS Prevention Studies, University of California, San Francisco, CA, May 22, 2009.

57. "Using Regression Models to Analyze Randomized Trials: Asymptotically Valid Hypothesis Tests Despite Incorrectly Specified Models." University of Maryland School of Public Health, Department of Epidemiology and Biostatistics Seminar, College Park, MD. February 25, 2009.

58. "Using Regression Models to Analyze Randomized Trials: Asymptotically Valid Hypothesis Tests Despite Incorrectly Specified Models." Biostatistics Research Branch Seminar, NIAID (NIH), Bethesda, MD. February 24, 2009.

59. "Using Regression Models to Analyze Randomized Trials: Asymptotically Valid Hypothesis Tests Despite Incorrectly Specified Models." Harvard School of Public Health, Department of Biostatistics Seminar, Cambridge, MA. February 17, 2009.

60. "Using Regression Models to Analyze Randomized Trials: Asymptotically Valid Hypothesis Tests Despite Incorrectly Specified Models." Columbia School of Public Health, Department of Biostatistics Seminar, New York, NY. February 13, 2009.

61. "Using Regression Models to Analyze Randomized Trials: Asymptotically Valid Hypothesis Tests Despite Incorrectly Specified Models." Johns Hopkins Bloomberg School of Public Health, Department of Biostatistics Seminar, Baltimore, MD. February 11, 2009.

62. "Using Regression Models to Analyze Randomized Trials: Asymptotically Valid Hypothesis Tests Despite Incorrectly Specified Models." University of Pennsylvania Department of Statistics Seminar, Philadelphia, PA. February 4, 2009.

63. "Using Regression Models to Analyze Randomized Trials: Asymptotically Valid Hypothesis Tests Despite Incorrectly Specified Models." Boston University Department of Mathematics and Statistics Seminar, Boston, MA. January 29, 2009.

64. "Using Regression Models to Analyze Randomized Trials: Asymptotically Valid Hypothesis Tests Despite Incorrectly Specified Models." Department of Biostatistics Seminar, University of Michigan, Ann Arbor, MI. January 22, 2009.

65. "Using Regression Models to Analyze Randomized Trials: Asymptotically Valid Hypothesis Tests Despite Incorrectly Specified Models." University of California, Davis, Department of Statistics Seminar, Davis, CA. May 1, 2008.

66. "Using Regression Models to Analyze Randomized Trials: Asymptotically Valid Hypothesis Tests Despite Incorrectly Specified Models", University of California, Berkeley, Statistics Colloquium, Berkeley, California. February 26, 2008.

67. "Estimating Direct Effects of New HIV Prevention Methods. Focus: the MIRA Trial." Fred Hutchinson Cancer Research Center, Seattle, Washington. January 13, 2008.

68. "Estimating the Effect of Latex Diaphragms in Preventing HIV among Women: Statistical Issues in Methods for Improving Reproductive Health in Africa." University of California Berkeley School of Public Health Research Symposium, Berkeley, California, March 8, 2007.

Short Courses

1. "Adaptive Enrichment Trial Designs: Statistical Methods, Trial Optimization Software, and Case Studies", Instructor of half-day course, 6th Seattle Symposium in Biostatistics, November 15, 2020.

2. "Adaptive Enrichment Trial Designs: Statistical Methods, Trial Optimization Software, and Case Studies", Instructor of half-day course, ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop, September 12, 2018. (79 participants)

3. "Adaptive Enrichment Trial Designs: Statistical Methods, Trial Optimization Software, and Case Studies", Instructor of Webinar for the Biopharmaceutical Section of the American Statistical Association, May 15, 2017. (131 participants)

4. "Adaptive Enrichment Trial Designs: Statistical Methods, Trial Optimization Software, and Four Case Studies", Instructor of half-day course, U.S. Food and Drug Administration (FDA), Silver Spring, MD, November 20, 2017. Course materials and video recording available at http://rosenblum.jhu.edu

5. "Adaptive Enrichment Designs for Confirmatory Randomized Trials: Statistical Methods and Software Tools", Instructor of half-day course, Institute for Clinical and Translational Research, Johns Hopkins University, August 30, 2017. (127 registered participants)

6. "Adaptive Enrichment Designs for Confirmatory Randomized Trials: Statistical Methods and Software Tools", Instructor of half-day course, University of California Berkeley's Forum for Collaborative Research in Washington, D.C., June 13, 2017.

7. "Doubly Robust Estimators, with Focus on Targeted Maximum Likelihood Estimation", Causal Inference Methods for PCOR using Observational Data, National Institutes of Health, Bethesda, MD, February 27-28, 2017.

8. "Adaptive Enrichment Designs for Confirmatory Randomized Trials: Methods and Software," Instructor of 1 day course, Graduate Summer Institute for Epidemiology and Biostatistics, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, June 21, 2016.

9. "Adaptive Enrichment Designs: Methods and Software," Instructor of 2.5 hour workshop, 23rd Annual Meeting of Belgian Statistical Society, Antwerp, Belgium, October 16, 2015.

10. "Adaptive Enrichment Designs: Methods and Software," Instructor of 1-day course, Summer Institute in Statistics for Clinical Research (SISCR). University of Washington, Seattle, WA, June 27, 2014; July 2, 2015; July 28, 2016.

11. "New Statistical Methods for Adaptive Randomized Trial Designs," Instructor of half-day course at the U.S. FDA, White Oak, MD, June 26, 2013.

ADDITIONAL INFORMATION

A major focus of my research is developing improved statistical methods for the design and analysis of randomized trials. My research questions are motivated by challenges that arose when I designed trials of new surgical interventions for stroke, a drug for preventing Alzheimer's disease, a cryogenic device for treating Barrett's esophagus, and a community health intervention in Baltimore. Specific research goals include (i) developing new adaptive designs for determining which subpopulations benefit from different treatments (precision medicine), (ii) creating open-source software that tailors adaptive designs to have optimal performance in the scenarios input by the clinical investigator, (iii) stress-testing trial designs, i.e., systematically evaluating how robust they are to violations of assumptions made during trial planning, and (iv) using machine learning to optimize precision gains from adjusting for prognostic baseline variables. I also conduct research in causal inference for dynamic treatment regimes, with applications in HIV prevention, HIV treatment, and estimating the health impact of a machine-learning based, early-alert system for sepsis (where the last application is based on electronic health record data).

Keywords

Clinical trials, causal inference, regulatory science