

Sally A. Hunsberger

5601 Fishers Lane, rm 4D13
Rockville, MD 20892-7630
voice: (240)-669-5257
email: sally.hunsberger@nih.gov

Education:

Ph.D., Biostatistics, Medical College of Virginia, VCU, Richmond, Virginia, December 1990.
Ph.D. dissertation "Semiparametric Regression in Likelihood Based Models."
B.A., Mathematics and Biology, Goshen College, Goshen, Indiana, May 1986.

Awards:

2006: Goshen College Champions of Character Award for those who have gone on to exemplify and demonstrate the core values of Goshen College.
1997: NIH Office of Equal Opportunity award for guiding the summer project of a stay in school student.
1994: NIH Merit Award for exceptional performance of statistical collaboration on clinical research programs in NHLBI.
1991: The Eastern North American Region Biometric Society Student Prize Award for best paper.
1986-1990: Medical College of Virginia, VCU, School of Graduate Studies Fellowship
1984, 1985: Academic All-American NAIA Tennis award

Professional Experience:

2013-present: Mathematical Statistician, Biometrics Research Branch, National Institute of Allergy and Infectious Diseases. Duties include: executive secretary for the Division of AIDS (DAIDS) prevention and therapeutic and the COVID-19 Vaccine DSMBs. Protocol review for the Laboratory of Clinical Immunology and Microbiology (LCIM) and Laboratory of Infectious Disease (LID). Statistical design and analysis for LCIM and LID studies. LCIM study designs are typically for rare diseases and LID typically performs challenge studies. Statistical partner for the La Red network which is a collaboration between NIH and Mexican ministry of health to study emerging infectious diseases.

2001-present: Member of Data Safety and Monitoring Committee for the Pediatric Heart Network, sponsored by the National Heart Lung and Blood Institute.

1999-2013: Mathematical Statistician, Biometrics Research Branch, National Cancer Institute. Duties included: Data Safety and Monitoring Committee member for the Children's Oncology Group(COG), National Surgical Adjuvant Breast and Bowel Project (NSABP), New Approaches to Neuroblastoma Treatment consortium (NANT) and, Pediatric Brain Tumor consortium (PBTC). Review Phase I, II and III cancer trial protocols. Develop Statistical procedures for Cancer research.

2006-2013: Member of the Data Safety and Monitoring Committee for the Gene and Cell therapy sponsored by the National Heart Lung and Blood Institute

1991-1999: Mathematical Statistician, Office of Biostatistics. National Heart, Lung and Blood Institute. Duties included: Consulting with intramural investigators at the NIH clinical center, performing statistical methodological research, participating in the design and analysis of large national multicentered clinical trials, and participating in DSMB discussions.

1998: One year sabbatical at St. Johns Medical college, Bangalore, India as a Biostatistics consultant.

1990: Medical College of Virginia, VCU. Instructor "Statistical Methods" course.

1986-1990: Medical College of Virginia, VCU, Graduate Research Assistant.

1987: Medical College of Virginia, VCU, Student Director Biostatistical Consulting Laboratory.

1985: Lovelace Biomedical and Environmental Research Institute, Summer Intern.

Professional Activities:

FDA Advisory committee member (beginning December 1, 2020) Antimicrobial Drugs Advisory Committee, temporary member for CEBER's Cellular Tissue and Gene Therapies Advisory Committee, October 12, 2017, Gastro Intestinal Drug advisory committee May 3, 2017 and October 17, 2017, Oncologic Drugs Advisory committee May 14, 2019 and the Bone, Reproductive and urologic Drugs Advisory committee October 29-30 2019. .

Program committee member for Eastern North American Region statistical (ENAR) meetings 2021.

Editorial board Journal of Clinical Oncology 2019-present.

Session Chair ENAR 2018.

Member American Statistical Association and Biometric Society Human Rights Committee member for the American Statistical Association (2009-2012).

Session Chair American Statistical Association meetings(2000).

Organized Invited Session spring ENAR meetings (1997).

Program chair for Biostatistics and Public Health for the Washington Statistical Society.(1993-1995).

Referee for *Biometrics*, *Controlled Clinical Trials*, *Epidemiology*, *Statistics in Medicine*, *Technometrics*, *Trials*, *Journal of the National Cancer Institute*, *Journal of Clinical Oncology*, *Journal of Acquired Immune Deficiency Syndrome* and Article for Book "Statistics for Quality: Dedicated to DON OWEN", editors: Subir Ghosh, William R. Schucany, and William B. Smith.

Invited Presentations:

Patient-Centered Outcomes Research Institute, 2019: "Interim Analysis Discussion".

International Collaboration for Research Methods Development in Oncology workshop in India, 2018: "How to Handle Missing Data" and "Odds Ratios, Risk Ratios and Logistic Regression Methods".

International Collaboration for Research Methods Development in Oncology workshop in India, 2017: "How to Handle Missing Data".

US-Georgia writing Workshop, 2016: "What you need to know about statistics".

UHS-NIH Scientific Writing Workshop in Laos, 2015: "Overview of Study Designs" and "Writing the Results Section".

Goshen College, 2014: "Simple Approaches to Analyzing Self-Controlled Case Series (SCCS) Data".

ASCO International Clinical Trials workshop, Nepal, 2014: "Statistical Considerations in Clinical Trials".

Zhejiang International Symposium on the Progresses of Image Guided Radiation Therapy Conference, 2013: "Considerations of Clinical Trial Designs and Modern Image Guided Radiation Therapy".

Joint Statistical Meetings, August 2013: "Study Design Issues and Analysis Analysis of Error-prone Time to Event Data Using Progression Free Survival as an Example".

San Antonio Breast Cancer Symposium, December 2012. “When Should Studies be Randomized”.

Virginia Commonwealth University, December 2011. “A Finite Mixture Survival Model to Characterize Risk Groups of Neuroblastoma”.

Global Breast Cancer Conference, Seoul South Korea, October 2011. “Designs for Breast Cancer Studies in the Face of Changing Drug Development Issues” and “Seamless Phase II/III Designs for Breast Cancer Studies”.

Annual Meeting of Korean Cancer Association, Seoul South Korea, June 2007. “Study design considerations for clinical trials of targeted agents” and “Progression-Free Survival in Unblinded Randomized Trials: A Proposal”.

Joint Statistical Meetings, August 2006. “Testing Logistic Regression Coefficients with Clustered Data and Few Positive Outcomes”.

Speaker in Education Session at ASCO May 2005: “Ethical and Clinical Dilemmas Resulting from the Early Closure of Recent Clinical Trials in Breast Cancer”.

Discussant in Pediatric Oral Presentation session at ASCO May 2005.

Virginia Commonwealth University, Medical College of Virginia 1999: “A Test of Additivity in Semiparametric Regression using Kernel Smoothing.” .

National Cancer Institute 1996: “A Test of Additivity in Semiparametric Regression using Kernel Smoothing.”

Joint Statistical Meetings, Chicago 1996: “ Imputation Strategies for Missing Data in a School Based Multicenter Study of American Indian Children: The Pathways Study.”

Lecture Series sponsored by Division of Computer Research and Technology, National Institutes of Health 1993: “Designing Research Experiments an Iterative, Collaborative Process.”

Publications

Hunsberger, S., Ortega-Villa, A. M., Powers III, J. H., León, H. A. R., Sosa, S. C., Hernández, E. R., ... and de Blas, P. D. C. G. (2020). Patterns of signs, symptoms, and laboratory values associated with Zika, dengue, and undefined acute illnesses in a dengue endemic region: Secondary analysis of a prospective cohort study in southern Mexico. *International Journal of Infectious Diseases*, 98, 241-248.

Klumpp-Thomas, C., Kalish, H., Drew, M., Hunsberger, S., Snead, K., Fay, M. P., ... and Denson, J. P. (2020). Standardization of enzyme-linked immunosorbent assays for serosurveys of the SARS-CoV-2 pandemic using clinical and at-home blood sampling. *accepted Nature Communications*.

Dodd, L.E., Follmann, D., Wang, J., Koenig, F., Korn, L.L., Schoergenhofer, C., Proschan, M., Hunsberger, S., Bonnett, T., Makowski, M. and Belhadi, D., (2020). Endpoints for randomized controlled clinical trials for COVID-19 treatments. *Clinical Trials*, 17(5), pp.472-482.

Han, A., Czajkowski, L., Rosas, L. A., Cervantes-Medina, A., Xiao, Y., Gouzoulis, M., ... and Baus, H. A. (2020). Safety and Efficacy of CR6261 in an Influenza A H1N1 Healthy Human Challenge Model. *Clinical Infectious Diseases*.

Manning, J. E., Oliveira, F., Coutinho-Abreu, I. V., Herbert, S., Meneses, C., Kamhawi, S., ... and Cervantes-Medina, A. (2020). Safety and immunogenicity of a mosquito saliva peptide-based vaccine: a randomised, placebo-controlled, double-blind, phase 1 trial. *The Lancet*.

Zuñiga, J., Choreño-Parra, J. A., Jiménez-Alvarez, L., Cruz-Lagunas, A., Márquez, J. E., Ramírez-Martínez, G., ... and Cabello, C. (2020). A unique immune signature of serum cytokine and chemokine dynamics in patients with Zika virus infection from a tropical region in Southern Mexico. *International Journal of Infectious Diseases*.

Pleguezuelos, O., James, E., Fernandez, A., Lopes, V., Rosas, L. A., Cervantes-Medina, A., ... Hunsberger, S. (2020). Efficacy of FLU-v, a broad-spectrum influenza vaccine, in a randomized phase IIb human influenza challenge study. *NPJ vaccines*, 5(1), 1-9.

Ravell, J. C., Matsuda-Lennikov, M., Chauvin, S. D., Zou, J., Biancalana, M., Deeb, S. J., ... and Morawski, A. (2020). Defective glycosylation and multisystem abnormalities characterize the primary immunodeficiency XMEN disease. *The Journal of clinical investigation*, 130(1), 507-522.

Hong, G. H., Ortega-Villa, A. M., Hunsberger, S., Chetchotisakd, P., Anunnatsiri, S., Mootsikapun, P., ... and Holland, S. M. (2020). Natural history and evolution of anti-interferon-autoantibody-associated immunodeficiency syndrome in Thailand and the United States. *Clinical Infectious Diseases*, 71(1), 53-62.

Gouel-Cheron, A., Lumbard, K., Hunsberger, S., et. al. (2019). "Serial real-time RT-PCR and serology measurements substantially improve Zika and Dengue virus infection classification in a co-circulation area." *Antiviral research*, 172, 104638.

Kang, M., Grund, B., Hunsberger, S., Glidden, D., and Volberding, P. (2019). "Interim monitoring in a treatment strategy trial with a composite primary endpoint." *Contemporary clinical trials*, 86, 105846.

Noyola, D. E., Hunsberger, S., et.al (2019). "Comparison of rates of hospitalization between single and dual virus detection in a Mexican cohort of children and adults with influenza-like illness." *Open forum infectious diseases* (Vol. 6, No. 11, p. 424). US: Oxford University Press.

Hong, G. H., Ortega-Villa, A. M., Hunsberger, S., et. al. (2019). "Natural History and Evolution of Anti-Interferon-?? Autoantibody-Associated Immunodeficiency Syndrome in Thailand and the US." *Clinical infectious diseases: an official publication of the Infectious Diseases Society of America*.

Peterson, R. L... INSIGHT FLU-IVIG study group. (2019). "Comparison of an ordinal endpoint to time-to-event, longitudinal, and binary endpoints for use in evaluating treatments for severe influenza requiring hospitalization." *Contemporary Clinical Trials Communications*, 100401.

Ferré, E. M., et. al. (2019). "Lymphocyte-driven regional immunopathology in pneumonitis caused by impaired central immune tolerance." *Science translational medicine*, 11(495), page 5597.

Dropulic, L. K. et.al. (2019). "A Randomized, Double-Blind, Placebo-Controlled, Phase 1 Study of a Replication-Defective Herpes Simplex Virus 2 Vaccine, HSV529, in Adults With or Without HSV Infection." *The Journal of infectious diseases*.

Gamiño-Arroyo, A. E. et. al. (2019). "Efficacy and safety of nitazoxanide in addition to standard of care for the treatment of severe acute respiratory illness." *Clinical Infectious Diseases*, 69(11), pages 1903-1911.

Moser, J. A. et. al. (2019). "Underweight, overweight, and obesity as independent risk factors for hospitalization in adults and children from influenza and other respiratory viruses". *Influenza and other respiratory viruses*, 13(1), pages 3-9.

Ortiz-Hernández, A. et. al. (2019). “Differential risk of hospitalization among single virus infections causing influenza-like illnesses”. *Influenza and Other Respiratory viruses*, pages 36-43.

Hunsberger, Sally, and Matthew J. Memoli (2018). “Efficacy analysis in healthy-volunteer influenza challenge trials: intention to treat.” *Antimicrobial agents and chemotherapy*

Marciano, Beatriz E., et al. (2018). “X-linked carriers of chronic granulomatous disease: Illness, lyonization, and stability.” *Journal of Allergy and Clinical Immunology* pages 365-371.

Dropulic, L. et. al. (2017). “A replication-defective herpes simplex virus (HSV)-2 vaccine, HSV529, is safe and well-tolerated in adults with or without HSV infection and induces significant HSV-2-Specific antibody responses in HSV seronegative individuals.” *Open forum infectious diseases* (Vol. 4, No. suppl 1, pp. S415-S416). US: Oxford University Press.

Peterson, R. L., Vock, D. M., Powers, J. H., Emery, S., Cruz, E. F., Hunsberger, S., ... IN-SIGHT FLU-IVIG Study Group. (2017). “Analysis of an ordinal endpoint for use in evaluating treatments for severe influenza requiring hospitalization”. *Clinical Trials*, 14(3), pages 264-276.

Hunsberger, S. and Proschan, M. A. (2017). “Simple approaches to analyzing self-controlled case series (SCCS) data.” *Statistics in Biopharmaceutical Research*, 9(1), pages 65-72.

Hunsberger, S, and Proschan, MA (2016). “Simple approaches to analyzing self-controlled case series (SCCS) Data.” *Statistics in Biopharmaceutical Research*

Godfrey, C., Tauscher G, Hunsberger, S, Austin, M, Scott, L, Schouten, J, Leutkemeyer, A, Benson, C, Coombs, R, and Swindells, S (2016). “A survey of tuberculosis infection control practices at the NIH/NIAID/DAIDS-supported clinical trial sites in low and middle income countries” *BMC Infectious Diseases* 1.

Colombo R, Fiorentino, Dodd, L, Hunsberger S, Haney, C, Barrett, K, Nabha, L, Davey, R and Olivier K (2016). “A phase 1 randomized, double-blind, placebo-controlled, crossover trial of DAS181 (Fludase®) in adult subjects with well-controlled asthma.” *BMC Infectious Diseases* 16.1 (2016): 1.

Ferre, Elise MN, et al. (2016). “Redefined clinical features and diagnostic criteria in autoimmune polyendocrinopathy-candidiasis-ectodermal dystrophy.” *JCI Insight* 1.13.

Paulin-Prado, P, Nishimura, K, Freimanis-Harce L, Hunsberger S, et al (2016). “Clinical characteristics of asthmatic patients with influenza-like illness and risk of severe exacerbations in Mexico.” *Annals of Allergy, Asthma & Immunology* 116.5 (2016): 402-407.

LoRusso PM et al. (2015). “Pilot trial of selecting molecularly guided therapy for patients iwth non-V600 BRAF mutant metastatic melanoma experience of the SU2C/MRA melanoma dream team.” *Molecular Cancer Therapeutics* 1962–1971.

McShane, L and Hunsberger S (2015) “An Overview of phase II clinical trial designs with biomarkers” book chapter in *Design and Analysis of Clinical Trials for Predictive Medicine* 71–87. Shigeyuki Matsui, Marc Buyse and Richard Simon. (Editors) Chapman and Hall/CRC.

Hunsberger, S, Albert, PS and Thoma, M (2014). “Approaches to retrospective sampling for longitudinal transition regression model.” *Statistics and its interface* 7.1 (2014): 75.

Schwandt A, Harris PJ, Hunsberger S, Deleporte A, Smith GL, Vulih D, Anderson BD and Ivy SP (2014). “The role of age on dose-limiting toxicities in phase I dose-escalation trials.” *Clinical Cancer Research* 4768–4775.

- Griffith, D, Adjemian, J, Brown-Elliott, Philley J, Prevots, R, Hunsberger S, Gaston C, Olivier K and Wallace R (2014) “The value of semi-quantitative mycobacterial cultures for predicting culture conversion during MAC lung disease therapy” *European Respiratory Journal* 246.
- DeMichele, A, Berry, D., Zujewski, J, Hunsberger S, et. al. (2013). “Developing Safety Criteria for Introducing New Agents into Neoadjuvant Trials.” *Clinical Cancer Research* 2817–2823.
- Hunsberger, S (2012). “Phase II/III Designs” Chapter 12 in *Handbook of Statistics in Clinical Oncology, Third Edition*, Crowley J and Hoering A. (editors) CRC Press.
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- Gupta, Sachin, Hunsberger, S. Boerner, Scott; et al (2012). “Meta-Analysis of the relationship between dose and benefit in phase I targeted agent trials.” *Journal of the National Cancer Institute* 104(24):1860–1866.
- Fay, MP and Hunsberger S (2012). “Practical issues on using weighted logrank tests with interval censored events in clinical trials” Chapter 13 in *Interval Censored Time-to-Event Data: Methods and Applications*, Chen, DG, Sun, J and Peace KE (editors) Chapman and Hall/CRC.
- Wang, M, Dignam, J, Zhang, QE, DeGroot, JF, Mehta, MP, Hunsberger S (2012). “Integrated Phase II/III clinical trials in oncology; A case study.” *Clinical Trials* 9(6):741–747.
- LoRusso, PM, Boerner, S, Hunsberger S (2011). “Clinical Development of vascular disrupting agents: What lessons can we learn from ASA404?” *Journal of clinical Oncology* 29(22): 2952–2955.
- Smith, M., Devidas M., Wheatley, K, Lock RB and Hunsberger, S (2011). “Strategies for new agent development and clinical trial considerations” Chapter 8 in *Childhood Leukemia*, Reaman, GH and Smith FO (editors) Springer-Verlag.
- Hunsberger, S, Albert, PS and Dodd, L (2010). “Analysis of progression-free survival data using a discrete time survival model that incorporates measurements with and without diagnostic error.” *Clinical Trials* 7(6): 634–642.
- Hunsberger, S, Zhao, Y, and Simon R (2010). “A comparison of phase II study strategies.” *Clinical Cancer Research* 15(19): 5950–5955.
- Hunsberger, S, Albert, PS and London, WB (2009). “A finite mixture survival model to characterize risk groups of neuroblastoma.” *Statistics in Medicine*, 28(8): 1301–1314
- McShane, LM, Hunsberger, S and Adjei, AA (2009). “Effective Incorporation of Biomarkers into Phase II Trials.” *Clinical Cancer Research*, 15 (6),1898–1905
- Ballard-Barbash R, Hunsberger, S, Alciati MH et al. (2009). “Physical activity, weight control and breast cancer risk and survival: clinical trial rationale and design considerations. ” *Journal of the National Cancer Institute* 101(9): 630–643.
- Korn, EL, Hunsberger, S, Freidlin, B, Smith MA, and Abrams JS (2008). “Comments on ‘Maintaining confidentiality of interim data to enhance trial integrity and credibility’ by TR Fleming et al.” *Clinical Trials* 5(4): 364–365.
- Hunsberger, S, Freidlin, B and Smith, MA (2008). “Complexities in interpretation of osteosarcoma clinical trial results.” *Journal of Clinical Oncology* 26(18):3103–3104.

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Proschan MA, Hunsberger SA (2006). "Combining treatment selection and definitive testing." *Biometrical Journal* 48 (4): 690–692 AUG.

Korn EL, Hunsberger S, Freidlin B, Smith MA, and Abrams JS(2005). "Preliminary data release for randomized clinical trials of noninferiority: a new proposal." *Journal of Clinical Oncology* , 23 (24): 5831–5836.

Albert, P.S. and Hunsberger, S (2005). "On analyzing circadian rhythm data using non-linear mixed models with harmonic terms." *Biometrics*, 61 (4): 1115–1120.

Korn EL, Rubinstein LV, Hunsberger SA, Pluda JM, Eisenhauer E and Arbusk SG (2005). "Clinical trial design for cytostatic agents and agents directed at novel molecular targets." In *Strategies for Discovery and Clinical Testing of Novel Anticancer Agents* (eds., A.A. Adjei and J. Buolamwini), Elsevier, 6: 003 Suppl.

Rubinstein LV, Korn EL, Freidlin B, Hunsberger SA, Ivy SP, and Smith MA (2005). "Randomized phase 2 design issues and a proposal for phase 2 screening trials." *Journal of Clinical Oncology*, 23 (28): 7199–7206.

Hunsberger S, Rubinstein LV, Dancey J, and Korn EL (2005). "Dose Escalation Trial Designs Based on a Molecularly Targeted Endpoint." *Statistics in Medicine*, 24:2171–2181 .

Albert PS, Hunsberger SA, Hu N (2004). "Identifying multiple change points in heterogeneous binary data with an application to molecular genetics." *Biostatistics* 5(4):515–529.

Lader E, Egan D, Hunsberger S, Garg R, Czajkowski S, McSherry F (2003). "The effect of digoxin on the quality of life in patients with heart failure." *Journal of Cardiac Failure* 9 (1): 4–12.

Proschan MA, Liu Q, Hunsberger S (2003). "Proschan MA, Liu Q, Hunsberger S." *Controlled Clinical Trials* 24 (1): 4–15.

Dorgan JF, Hunsberger SA. et al. (2003). "Diet and sex hormones in girls: Findings from a randomized controlled clinical trial." *Journal of the National Cancer Institute* 95 (2): 132–141.

Hunsberger S, Albert PS, Follmann DA, Suh E (2002). "Parametric and semiparametric approaches to testing for seasonal trend in serial count data." *Biostatistics* 3 (2):289–298.

Thompson B, Jacob RG, Frederick M, Geller NV, Hunsberger S (2002). "Innovative designs in behavioural trials." *Statistics in Medicine* 21 (19): 2981–2989.

Philbin EF, Hunsberger S, Garg R, Lader E, Thadani U, McSherry F, Silver MA (2002). "Usefulness of clinical information to distinguish patients with normal from those with low ejection fractions in heart failure." *American Journal of Cardiology* 89 (10): 1218.

Vaz M, Hunsberger S, Diffey B. (2002) "Prediction equations for handgrip strength in healthy Indian male and female subjects encompassing a wide age range." *Annals of Human Biology* 29 (2): 131–141

Hunsberger, S., and Follmann D.(2001) "A Test of Additivity in Semiparametric Regression using Kernel Smoothing." *Statistics in Medicine* 20:1–19.

Moss J, Avila NA, Barnes PM, Litzenberger RA, Bechtel J, Brooks PG, Hedin CJ, Hunsberger S, Kristof AS. (2001). "Prevalence and clinical characteristics of lymphangiomyomatosis (LAM) in patients with tuberous sclerosis complex." *American Journal of Respiratory and Critical Care Medicine* 164 (4): 669–671.

Proschan MA, McMahon RP, Shih JH, Hunsberger SA, Geller NL, Knatterud G, Wittes J. (2001). "Sensitivity analysis using an imputation method for missing binary data in clinical trials." *Journal of Statistical Planning and Inference* 96 (1): 155–165 Sp. Iss. SI.

Hunsberger, S., Davis, C.E., Murray, D., and Fabsitz, R. (2001). "Imputation Strategies for Missing Data in a School Based Multicenter Study of American Indian Children: The Pathways Study." *Statistics in Medicine* 20:305–316.

Obarzanek, E., Kimm S.Y., Barton, B.A., Van Horn, L., Kwiterovich, P.O., Simons-Morton, D.G., Hunsberger, S., Lasser, N.L., Robson, A.M., Franklin, F.A., Lauer, R.M., Stevens, V.J., Friedman, L.A., Dorgan, J.F., and Greenlick, M.R. (2001). "Long-Term Safety and Efficacy of a Cholesterol-Lowering Diet in Children: Seven-Year Results of the Dietary Intervention Study in Children(DISC)." *Pediatrics* 107:256–264.

Lohman, T.G., Caballero, B., Himes, J.H., Davis, C.E., Stewart, D., Houtkooper, L., Going, S.B., Hunsberger, S.A., Weber, J.L., Reid, R., and Stephenson, L (2000). "Estimation of Body Fat From Anthropometry and Bioelectrical Impedance in Native American Children." *International Journal of Obesity* 24:1–7.

Mathew, J., Hunsberger, S., Fleg, J., McSherry, F., Williford, W., and Yusuf, S (2000). "Incidence, Predictive Factors and Prognostic Significance of Supraventricular Tachyarrhythmias in Congestive Heart Failure". *Chest* 118:914-922.

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The Writing Group for the PEPI Trial (1996). "Effects of Hormone Therapy on Bone Mineral Density in the Spine and Hip: Results from the Postmenopausal Estrogen/Progestin Intervention (PEPI) Trial." *Journal of the American Medical Association*, 6:276(17):1430–1442

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Proschan, M.A. and Hunsberger, S. (1995). "Extending Studies Based on Conditional Power." *Biometrics*, 51:1315–1324.

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The Writing Group for the PEPI Trial (1995). "Effects of Estrogen or Estrogen/Progestin Regimens on Heart Disease Risk Factors in Postmenopausal Women." *The Journal of the American Medical Association*, 273:199–206.

Hunsberger, S.A. (1994). "Semiparametric Regression in Likelihood Based Models." *Journal of the American Statistical Association*, 89:1354–1365.

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