

**PETER D. GUARINO, M.P.H., Ph.D.**

Address: 1100 Fairview Ave. N, Seattle, WA 98109

Phone: 206.667.6761 Email: pguarino@scharp.org

**EDUCATION****Doctor of Philosophy, 2005**

University of London, London School of Hygiene and Tropical Medicine - Department of Epidemiology and Population Health, Medical Statistics Unit, London, United Kingdom

**Master of Public Health, 1998**

Yale University, School of Medicine - Department of Epidemiology and Public Health, Division of Epidemiology of Infectious Diseases, New Haven, CT USA

**Bachelor of Science in Public Health, 1993**

Southern Connecticut State University, New Haven, CT USA

**PROFESSIONAL EXPERIENCE****Statistical Center for HIV and AIDS Research and Prevention, Fred Hutchinson Cancer Research Center, Seattle, WA**

Director 2015–Present

**Friends Research Institute, Inc. Baltimore, MD**

Lead Biostatistician IRIS Statistical Center, Department of Veterans Affairs and Yale University 2001–2016

**Department of Veterans Affairs Cooperative Studies Program Coordinating Center, West Haven, CT**

Director 2012–2015

Acting Director 2010–2012

Senior Biostatistician 2005–2010

Biostatistician 1998–2005

**FACULTY AND TEACHING EXPERIENCE****Yale School of Public Health, New Haven, CT**

Assistant Clinical Professor of Biostatistics 2013–Present

**London School of Hygiene and Tropical Medicine, London, UK**External Assessor, *Clinical Trials Distance Learning Master's Program* 2008–2011**OTHER EXPERIENCE**

Board of Directors | Chair, VA Cooperative Studies Program Board of Directors 2010–2015

Member, Government Steering Committee: Joint DoD/VA Consortium to Alleviate PTSD 2013–2015

Member, Data and Safety Monitoring Board– *NAIMS* 2009–2015

Member, Society for Clinical Trials Education Committee 2013

Member, Data and Safety Monitoring Board– *NAIMS* 2006–2011Member, Data Monitoring Committee - *VA CSR&D sponsored medical/surgical studies* 2008–2011Consulting Editor, *Journal of Cardiac Failure*, San Francisco, CA 2001–2009

Member, NIH State-of-the-Science/Consensus Development Conference on Family History and Health. 2009

Member, Centers of Research Translation 2006

Consultant, *Irbesartan in Heart Failure with Preserved Systolic Function*. Bristol-Myers Squibb, Princeton, NJ 2001

**RESEARCH FUNDING**

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Current

UM1AI068635 (PI: P. Gilbert) 2006 -2020

NIH/NIAID, SDMC: HIV Vaccine Trials Network and the Statistical Center for HIV/AIDS Research & Prevention

Role: Director, Statistical Center for HIV / AIDS Research and Prevention

UM1AI068617 (PI: D. Donnell) 2006 -2020

NIH/NIAID, SDMC: HIV Prevention Trials Network and the Statistical Center for HIV/AIDS Research & Prevention

Role: Director, Statistical Center for HIV / AIDS Research and Prevention

UM1AI068615 (PI: E. Brown) 2006–2020

NIH/NIAID, SDMC: Microbicide Trials Network and the Statistical Center for HIV/AIDS Research & Prevention

Role: Director, Statistical Center for HIV / AIDS Research and Prevention

Past

Insulin Resistance Intervention after Stroke Trial (IRIS), Yale University, School of Medicine, New Haven, CT

Statistical Center Grant 2005–2016

VA Cooperative Studies Program Coordinating Center Core Grant, West Haven, CT 2010–2015

VA Cooperative Studies Program and the Department of Epidemiology and Public Health, New Haven, CT

Statistical Methodology Core Grant 2010–2015

Clinical Trials Experience

2014–2020 Planning and Executive Committees, CSP#592 – Efficacy and Safety of ICD Implantation in the Elderly.

2010–2024 Planning and Executive Committee, CSP#577 – Colonoscopy vs. Fecal Immunochemical Test in Reducing Mortality from Colorectal Cancer (CONFIRM).

2012–2015 Planning and Executive Committee, CSP#589 – Veterans Individual Placement and Support Towards Advancing Recovery (VIP-STAR).

2010–2015 Planning and Executive Committee, CSP#576 – VA Augmentation and Switching Treatments for Improving Depression Outcomes (VAST-D).

2010–2015 Executive Committee, CSP #565 – Combination Angiotensin Receptor Blocker and Angiotensin Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy.

2002–2014 Planning and Executive Committee, CSP #546 – A Randomized, Clinical Trial of Vitamin E and Memantine in Alzheimer’s Disease.

2001–2015 Planning and Steering Committees: Insulin Resistance Intervention after Stroke Trial (IRIS), Yale University, School of Medicine, New Haven, CT

2006–2009 Executive Committee, CSP#453 – Homocysteinemia in Kidney and End Stage Renal Disease Study.

2005–2011 Planning and Executive Committees, CSP#558 – Robotic Assisted Upper Limb Neurorehabilitation in Stroke Patients

2004 - 2006 Planning Committee, CSP#552 – A Phase 3, Randomized, Double-Blind, Multicenter, Non-Inferiority Study in Vaccinia-Experienced Volunteers of Take Rate, Safety, Tolerability, and Immunogenicity of Three Concentrations: Undiluted, 1:10 Dilution, and 1:30 Dilution.

2001–2008 Planning and Trial Management Committees, CSP#512 – A Randomized, Controlled, Multicenter Trial to Assess the Optimal Management of Patients with HIV Infection for whom 1<sup>st</sup> and 2<sup>nd</sup>-line Highly Active Anti-Retroviral Therapy has Failed.

2001 Planning Committee, CSP#534 – Perioperative  $\beta$ -Adrenergic Receptor Blockade in Patients Undergoing Major Noncardiac Surgery.

1999 - 2000 Planning Committee, CSP#484 – Heart Failure in Patients with Preserved Systolic Function.

1998–2004 Planning and Executive Committees, CSP#470 – A Randomized, Multi-Center, Controlled Trial of Multi Modal Therapy in Veterans with Gulf War Illnesses.

## BIBLIOGRAPHY

### MANUSCRIPTS IN REFEREED JOURNALS

1. Kernan WN, Viscoli CM, Furie KL, Young LH, Inzucchi SE, Gorman M, **Guarino PD**, et al (2016) Pioglitazone after Ischemic Stroke or Transient Ischemic Attack. *N Engl J Med*, Feb 17, 2016, DOI: 10.1056/NEJMoa1506930
2. Gaziano JM, Concato J, Brophy M, Fiore L, Pyarajan S, Breeling J, Whitbourne S, Deen J, Shannon C, Humphries D, **Guarino P**, et al. (2016) Million Veteran Program: A mega-biobank to study genetic influences on health and disease. *J Clin Epidemiol*. 2016 Feb;70:214-23.
3. Leehey DJ, Zhang JH, Emanuele NV, Whaley-Connell A, Palevsky PM, Reilly RF, **Guarino P**, Fried LF; VA NEPHRON-D Study Group. (2015) BP and Renal Outcomes in Diabetic Kidney Disease: The Veterans Affairs Nephropathy in Diabetes Trial. *Clin J Am Soc Nephrol*. 2015 Dec 7;10(12):2159-69.
4. Wu X, **Guarino P**, Lo AC, Peduzzi P, Wininger M. (2015) Long-term Effectiveness of Intensive Therapy in Chronic Stroke. *Neurorehabil Neural Repair*. 2015 Oct 8.
5. Mohamed S, Johnson GR, Vertrees JE, **Guarino PD**, et al. (2015) The VA Augmentation and Switching Treatments for Improving Depression Outcomes (VAST-D) Study: Rationale and Design Considerations. *Psychiatry Research*. 229: 760-770
6. Dysken, MW, Sano, M, Asthana, S, Vertrees, JE, Pallaki, M,...**Guarino, PD**. (2014) Effect of Vitamin E and memantine on functional decline in Alzheimer's disease: The TEAM-AD VA Cooperative randomized trial. *JAMA*. 2014; 311(1):33-44.
7. Dysken, MW, **Guarino, PD**, Vertrees, J, Asthana, S, Sano, M, Llorente, M, et al. (2014). Vitamin E and memantine in Alzheimer's disease: Clinical trial methods and baseline data. *Alzheimer's & Dementia*, 10(1):36-44.
8. Zimering M, Zhang J, **Guarino P**, Emanuele N, McCullough P, Fried L. Investigators for the VA NEPHRON-D. (2014). Endothelial cell autoantibodies in predicting declining renal function, end-stage renal disease, or death in adult type 2 diabetic nephropathy. *Endocrinol.*, 5:128, 2014.
9. Fried, LF, Emanuele N, Zhang, JH, Brophy, M, Conner, TA... **Guarino, P**. (2013). Combined Angiotensin inhibition for treatment of diabetic nephropathy. *N Engl J Med*, 369(2), 1892-1903.
10. Vollset SE, Clarke R, Lewington S, Ebbing M, Halsey J, ... **Guarino P**. ... Peto R. B-Vitamin Treatment Trialists' Collaboration. (2013). Effects of folic acid supplementation on overall and site-specific cancer incidence during the randomised trials: meta-analyses of data on 50,000 individuals. *Lancet*. 381(9871):1029-36, 2013 Mar 23.
11. Zhang, J, Palevsky, P, Chertow, G, Hartigan, J, O'Connor, T, **Guarino, P**, Zhou, B. (2013). Piecewise analysis of patient survival after onset of acute kidney injury. *Clin J Am Soc Nephrol*, 8(10), 1679-1684.
12. Warren, S, Raisch, D, Campbell H, **Guarino, P**, Kaufman, J, et al.; Veterans Affairs Site Investigators. (2013). Medication adherence assessment in a clinical trial with centralized follow-up and direct-to-patient drug shipments. *Clin Trials*, 10(3), 441-8.
13. Rafeq Z, Roh JD, **Guarino P**, Kaufman J, Joseph, J. (2013). Adverse myocardial effects of B-vitamin therapy in subjects with chronic kidney disease and hyperhomocysteinemia. *Nutr Metab Cardiovasc Dis*. 23(9):836-42, 2013 Sep.

14. Concato, J., **Guarino, P.** (2012). Randomised trial of radical prostatectomy versus watchful waiting finds reduced risk for death but uncertainty still reigns. Commentary. *N Engl J Med*, 17(2), 38-9.
15. Lo, AC, **Guarino, P** (2012). Robot therapy tipping point: Caveats for post hoc speculation. *Am J Phys Med Rehabil*, 91(11 Suppl 3), S298-300.
16. Lo, A, **Guarino PD**, Richards L, Haselkorn, J, Wittenberg, G, Federman, D, et al. (2010). "Robot-assisted therapy for long-term upper-limb impairment after stroke." *N Engl J Med*, 362(19), 1772-83.
17. Clarke, R, Halsey, J, Lewington, S, Lonn, E, Armitage, J, **Guarino, P**, Manson, J, et al. (2010). B-Vitamin Treatment Trialists' Collaboration. Effects of lowering homocysteine levels with B vitamins on cardiovascular disease, cancer, and cause-specific mortality: Meta-analysis of 8 randomized trials involving 37 485 individuals. *Arch Intern Med*. 170(18), 1622-1631. 2010 Oct 11.
18. Wagner, TH, Lo, AC, Peduzzi, P, Bravata, DM, Huang, GD, Krebs, HI...**Guarino P.** (2011). An Economic analysis of robot-assisted therapy for long-term upper-limb impairment after stroke. *Stroke*, 42(9), 2630-2.
19. Peduzzi, P, Kyriakides, T, O'Connor, TZ, **Guarino P**, Warren SR, Huang, GD. (2010). Methodological issues in comparative effectiveness research: Clinical trials. *Am J Med*, 123(12 Suppl 1), e8-15.
20. Berg, AO, Baird, M, Botkin, J, Driscoll, D, Fishman, PA, **Guarino, PD**, et al. (2009). National Institutes of Health state-of-the-science conference statement family history and improving health. *Ann Intern Med*. 26(1), 1-19. 2009 Aug 26.
21. Berg, AO, Baird, M, Botkin, J, Driscoll, D, Fishman, PA, **Guarino, PD**, et al. (2009). National Institutes of Health state-of-the-science conference statement family history and improving health. *Ann Intern Med*. 151(12), 872-7. 2009 Dec 15.
22. Lo, A, **Guarino, P**, Krebs, H, Volpe, B, Bever, C, Duncan, PW, et al. (2009) Multicenter randomized trial of robot-assisted rehabilitation for chronic stroke: Methods and entry characteristics for VA robotics. *Neurorehabil Neural Repair*, 2009 Oct. 23(8), 775-83.
23. Jamison, RL, Shih, MC, Humphries, DE, **Guarino, PD**, Kaufman, J, Goldfarb, DS, et al. (2009). The effect of the MTHFR C677T and A1298C Polymorphisms on survival in patients with advanced CKD and ESRD: A prospective study. *Am J Kidney Dis*, 53(5), 779-89.
24. Brady, C, Gaziano, M, Cxypoliski, R, **Guarino, PD**, et al. (2009). Homocysteine lowering and cognition in CKD: The Veterans Affairs homocysteine study. *Am J Kidney Dis*, 54(3), 440-9.
25. Jamison, R, Hartigan, P, Kaufman, J, Goldfarb, D, Warren, S, **Guarino, PD**, Gaziano, JM. (2007). Effect of Homocysteine lowering on mortality and vascular disease in advanced chronic kidney disease and end stage renal disease. *JAMA*, 298(10), 1163-70.
26. **Guarino, P**, Lamping, D, Elbourne, D, Carpenter, J, Peduzzi, P. (2006). A brief measure of perceived understanding of informed consent in a clinical trial was validated." *J Clin Epidemiol*, 59(6), 608-14. 2006 Jun.
27. **Guarino, P**, Elbourne, D, Carpenter, J, Peduzzi, P. (2006). Consumer involvement in consent document development: A multicenter cluster randomized trial to assess study participants' understanding. *Clin Trials*, 3(1), 19-30.

28. Mori, D, Sogg, S, **Guarino, P**, Skinner, J, Williams, D, Barkhuizen, A, et al. (2006). Predictors of exercise compliance in individuals with Gulf War Veterans Illnesses: Department of Veterans Affairs cooperative study 470. *Mil Med*, 171(9), 917-23.
29. London, M, Itani, K, Perrino, A, **Guarino PD**, Schwartz, GG, Cunningham, F, et al. (2004). Perioperative beta blockade: A survey of physician attitudes in the Department of Veterans Affairs. *J Cardiothorac Vasc Anesth*, 18(1), 14-24.
30. Donta S, Clauw D, Engel, E, **Guarino, P**, Peduzzi, P, Williams, DA, et al. (2003). Cognitive behavioral therapy and aerobic exercise for Gulf War Veterans' illnesses: A randomized controlled trial. *JAMA*, 289(11), 1396-404.
31. Peduzzi, P, **Guarino, P**, Donta, S, Engel, E, Clauw, D, Fuessner, JR. (2002). Making informed consent meaningful: From theory to practice. *Control Clin Trials*, 23(2), 178-81.
32. Peduzzi, P, **Guarino, P**, Donta, S, Engel, E, Clauw, D, Fuessner, JR. (2002). Research on informed consent: Investigator-developed versus patient-developed consent documents: A VA Cooperative Study. *Control Clin Trials*, 23(2), 184-97.
33. Kyriakides, TC, **Guarino, P**. (2001). Timing of antiretroviral treatment initiation. *JAMA*, 285(13), 1702-3.
34. **Guarino, P**, Peduzzi, P, Donta, S, Engel, C, Clauw, DJ, Williams, DA, et al. (2001). A multicenter two by two factorial trial of cognitive behavioral therapy and aerobic exercise for Gulf War Veterans' illnesses: Design of a VA Cooperative Study (CSP #470). *Control Clin Trials*, 22(3), 310-32.

#### SELECTED PRESENTATIONS

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*Recruitment, retention and maintaining treatment adherence of older adults in clinical trials: Experience in VA Cooperative Studies of Alzheimer's disease and stroke rehabilitation.* The 32<sup>nd</sup> Annual Meeting of the Society of Clinical Trials. Vancouver, BC, Canada. 2011.

*Assessing capacity to give informed consent in outpatients with mild-to-moderate Alzheimer's disease.* The 28<sup>th</sup> Annual Meeting of the Society of Clinical Trials. Montreal, CA. 2007.

*Adaptive design of a robotic device trial in stroke patients.* The 27<sup>th</sup> Annual Meeting of the Society of Clinical Trials. Orlando, FL. 2006.

*Consumer involvement in consent document development: A multicenter cluster randomized trial to assess study participants' understanding.* The 27<sup>th</sup> Annual Meeting of the Society of Clinical Trials. Orlando, FL. 2006.

*Design of the VA Cooperative Study, A Randomized, Multicenter Controlled Trial of Multi Modal Therapy in Veterans with Gulf War Illnesses.* The 21<sup>st</sup> Annual meeting of the Society of Clinical Trials. Toronto, Canada. 2000.

*Four Years of Enhanced Laboratory Surveillance Demonstrates that Human Ehrlichia Infection is a Rapidly Emerging Infection in Connecticut.* The International Conference on Emerging Infectious Diseases, Atlanta, GA. 2000.