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Michelle Secic, M.S.

PROFESSIONAL EXPERIENCE

Secic Statistical Consulting, Inc.: 1997-Present

President and Independent Consultant

- Collaborate with researchers from hospitals, pharmaceutical companies and medical device companies around the world on the statistical aspects of their research
- Write protocols, write statistical analysis plans, analyze data, and write reports for private use, submission to National Institute of Health (NIH), submission to Food and Drug Administration (FDA) or submission for publication in the medical literature; These tasks involve extensive use of SAS statistical software (ODS, macros, multiple PROCs, etc.); Experience with all phases of clinical trials
- Serve as voting member or independent statistical advisor for Data Safety and Monitoring Boards (DSMB), providing statistical expertise and tables/graphics for review by the boards
- Present webinars on current statistical topics (equivalence trials, patient reported outcomes, in vitro diagnostic statistics, etc.)

Cleveland Clinic Foundation: 1990-2001

Lead Biostatistician: 2000 to 2001

Manager of Research Section of the Transplant Center. Supervised other biostatisticians, statistical programmers, ORACLE programmers and transplant coordinators. Collaborated on medical research projects with researchers at the Cleveland Clinic Foundation.

Senior Biostatistician & Associate Team Leader: 1996 to 2000

Supervised others in our teamwork with Ophthalmology, Pediatrics and ENT. Coordinated and reviewed the work of biostatisticians, statistical programmers and database programmers. Collaborated on medical research projects with researchers at The Cleveland Clinic Foundation.

Biostatistician: 1991 to 1996

Collaborated on medical research projects with researchers in Ophthalmology, Pediatrics and ENT at The Cleveland Clinic Foundation.

Biostatistical Analyst: 1990 to 1991

Assisted biostatisticians in various duties related to the design and analysis of research studies.

The American College of Physicians Publishers:

Book Author: 2006 (2nd edition), 2002 (translation into Chinese), 1997 (1st edition)

Title: *How to Report Statistics in Medicine: Annotated Guidelines for Authors, Editors and Reviewers*

Published: The American College of Physicians, Philadelphia, PA, ISBN: 0943126444

Clinical Device Discussion Forum - www.clinicaldeviceforum.com

Advisory Board Statistician: 2002 to Present

Serve as the statistical expert for the online discussion forum. Active participant in the forum of over 900 members. Ensure all postings receive knowledgeable responses.

Clinical Design Group, Inc:

Senior Network Staff Associate: 1997 to Present

Provide off-site statistical consulting on clinical contracts for Clinical Design Group, Inc., Chicago, IL, via fax, e-mail, phone, and US mail. Statistical consulting includes statistical design of studies, protocol development, maintenance of databases, statistical analyses, presentations, and reports.

Williams & Wilkins Publishers: Journal of *Diseases of the Colon & Rectum*:

Formal Statistical Reviewer for Journal: 1997 to Present

Review manuscripts submitted to the journal of *Diseases of the Colon & Rectum* from a statistical standpoint. Provide formal written feedback to the editors and authors of the manuscripts.

American Statistical Association:

Presenter of Statistical Workshops: 1994 to 2001

Teaching scientific researchers, medical students, medical residents, journal editors and statisticians how to communicate statistical results with non-statisticians. The focus of the workshop is "How To Report Statistics in Medicine".

EDUCATION

Bowling Green State University, Bowling Green, Ohio

Master of Science in Applied Statistics, 1990

Bachelor of Arts in Statistics, 1989

Bachelor of Arts in Mathematics, 1989

PUBLICATIONS

Books:

Lang TA, Secic M. *How to Report Statistics in Medicine: Annotated Guidelines for Authors, Editors and Reviewers, 2nd Edition*. Philadelphia, PA. The American College of Physicians. August 2006.

Lang TA, Secic M. *How to Report Statistics in Medicine: Annotated Guidelines for Authors, Editors and Reviewers*. Philadelphia, PA. The American College of Physicians. March 1997.

Stark NJ. *Clinical Trials Design: Safety, Efficacy and Performance for Medical Devices*. Chicago, IL. Clinical Design Group, Inc. 2000. Acknowledgement.

Neter J, Kutner MH, Nachtsheim CJ, Wasserman W. *Instructor Solutions Manual to accompany Applied Linear Regression Models, 3rd Ed, and Applied Linear Statistical Models, 4th Ed*. Chicago, IL. Richard D. Irwin, a Times Mirror Higher Education Group, Inc. company. 1996. Acknowledgement.

Neter J, Kutner MH, Nachtsheim CJ, Wasserman W. *Student Solutions Manual for use with Applied Linear Regression Models, 3rd Ed, and Applied Linear Statistical Models, 4th Ed*. Chicago, IL. Richard D. Irwin, a Times Mirror Higher Education Group, Inc. company. 1996. Acknowledgement.

Published Manuscripts:

Barrett DL, Secic M, Borowske D. The Gatekeeper Program: proactive identification and case management of at-risk older adults prevents nursing home placement, saving healthcare dollars program evaluation. *Home Healthc Nurse*. 2010 Mar;28(3):191-7.

Boltz M, Capezuti E, Kim H, Fairchild S, Secic M. Factor structure of the geriatric institutional assessment profile's professional issues scales. *Res Gerontol Nurs*. 2010 Apr;3(2):126-34.

Fuller M, Shermock K, Russo P, Secic M, Dirani R, Vallow S, Flanders S. Hospitalisation and resource utilisation in patients with schizophrenia following initiation of risperidone long-acting therapy in the Veterans Affairs Healthcare System. *J Med Econ*. 2009 Oct 12;12(4):317-24.

Bonny AE, Secic M, Cromer BA. A longitudinal comparison of body composition changes in adolescent girls receiving hormonal contraception. *J Adolesc Health*. 2009 Oct; 45(4):423-5.

- Jacobsen DW, Gatautis VJ, Green R, Robinson K, Savon SR, Secic M, Ji J, Otto JM, Taylor LM Jr. Total plasma homocysteine: the mediator/marker controversy continues. *Clin Chem*. 2009 Sep;55(9):1742-3.
- Boltz M, Capezuti E, Kim H, Fairchild S, Secic M. Test-Retest Reliability of the Geriatric Institutional Assessment Profile. *Clin Nurs Res*. 2009 18: 242-252.
- Skala K, Gervaz P, Buchs N, Inan I, Secic M, Mugnier-Konrad B, Morel P. Risk factors for mortality-morbidity after emergency-urgent colorectal surgery. *Int J Colorectal Dis*. 2009 Mar;24(3):311-6. Epub 2008 Oct 18.
- Boltz M, Capezuti E, Bowar-Ferres S, Norman R, Secic M, Kim H, Fairchild S, Mezey M, Fulmer T. Hospital nurses' perception of the geriatric nurse practice environment. *J Nurs Scholarsh*. 2008 40(3):282-9.
- Podichetty VK, Varley ES, Secic M. Role of patient-based health status outcome measurements in opioid management for low back pain. *J Opioid Manag*. 2008 May-Jun;4(3):153-62.
- Boltz M, Capezuti E, Bowar-Ferres S, Norman R, Secic M, Kim H, Fairchild S, Mezey M, Fulmer T. Changes in the Geriatric Care Environment Associated with NICHE (Nurses Improving Care for HealthSystem Elders). *Geriatr Nurs*. 2008 May-Jun;29(3):176-85.
- Capezuti E, Brush BL, Lane S, Rabinowitz HU, Secic M. Bed-exit alarm effectiveness. *Arch Gerontol Geriatr*. 2009 Jul-Aug; 49(1):27-31. Epub 2008 Jun 3.
- Buchs NC, Gervaz P, Secic M, Bucher P, Mugnier-Konrad B, Morel P. Incidence, consequences, and risk factors for anastomotic dehiscence after colorectal surgery: a prospective monocentric study. *Int J Colorectal Dis*. 2008 Mar;23(3):265-70.
- Capezuti E, Wagner L, Brush BL, Boltz M, Renz S, Secic M. Bed and toilet height as potential environmental risk factors. *Clin Nurs Res*. 2008 Feb; 17(1):50-66.
- Cromer BA, Bonny AE, Stager M, Lazebnik R, Rome E, Ziegler J, Camlin-Shingler K, Secic M. Bone mineral density in adolescent females using injectable or oral contraceptives: a 24-month prospective study. *Fertil Steril*. 2008 Jan 25. [Epub ahead of print]
- Kemmer N, Kaiser TE, Zacharias V, Secic M, Neff GW. Revisiting posttransplant survival for hepatitis C virus recipients. *Transplantation*. Oct 2007; 84(7):932-3.
- Mandel SE, Hanser SB, Secic M, Davis BA. Effects of music therapy on health-related outcomes in cardiac rehabilitation: a randomized controlled trial. *J Music Ther*. 2007;44(3):176-97.
- Kemmer N, Secic M, Zacharias V, Kaiser T, Neff GW. Long-term Analysis of Primary Nonfunction in Liver Transplant Recipients. *Transplant Proc*. 2007 Jun; 39(5): 1477-80.
- Kemmer N, Neff G, Secic M, Zacharias V, Kaiser T, Buell J. Ethnic Differences in Hepatocellular Carcinoma: Implications for Liver Transplantation. *Dig Dis Sci*. 2007 Jun; XXXXX
- Stager M, Harvey R, Secic M, Camlin-Shingler K, Cromer B. Self-reported physical activity and bone mineral density in urban adolescent girls. *J Pediatr Adolesc Gynecol*. 2006 Feb;19(1):17-22.
- Bonny AE, Ziegler J, Harvey R, Debanne SM, Secic M, Cromer BA. Weight Gain in Obese and Nonobese Adolescent Girls Initiating Depot Medroxyprogesterone, Oral Contraceptive Pills, or No Hormonal Contraceptive Method. *Arch Pediatr Adolesc Med*. 2006; 160:40-45.
- Bloomfield EL, Secic M, Porembka D. A correlation of catecholamine and vasoactive peptide release with hemodynamics in patients undergoing resection of arteriovenous malformations. *Neurocrit Care*. 2005; 3(2):127-131.
- Spindler KP, Warren TA, Callison JC, Secic M, Fleisch SB, Wright RW. Clinical outcome at a minimum of five years after reconstruction of the anterior cruciate ligament. *J Bone and Joint Surgery*. 2005 Aug;87(8):1673-1679.
- Rome E, Zeigler J, Secic M, Bonny A, Stager M, Lazebnik R, Cromer BA. Bone biochemical markers in adolescent girls using either depot medroxyprogesterone acetate or an oral contraceptive. *J Pediatr Adolesc Gynecol*. 2004 Dec;17(6):373-7.

Bakris GL, Weir MR, Secic M, Campbell B, Weis-McNulty A. Differential effects of calcium antagonist subclasses on markers of nephropathy progression. *Kidney International*. 2004 June;65(6):1991-2002.

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Fuller MA, Shermock KM, Secic M, Grogg A. A comparative study of the development of diabetes in patients taking risperidone and olanzapine. *Pharmacotherapy*. 2003 Sept;23(8):1037-1043.

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Oikonomakis I, Wexner SD, Gervaz P, You SY, Secic M, Giamundo P. Sefrafilm(R): A Retrospective Preliminary Evaluation of the Impact on Short-Term Oncologic Outcome in Colorectal Cancer. *Dis Colon Rectum*. 2002 Oct;45(10):1376-80.

Prina LD, Rancatore E, Secic M, Weber RE. Comparison of Stone Size and Response to Analgesic Treatment in Predicting Outcome of Patients with Renal Colic. *Eur J Emerg Med*. 2002 Jun;9(2):135-9.

Fuller MA, Shermock KM, Secic M, Laich JS, Durkin MB. Service Use and Costs Among VA Patients with Schizophrenia Taking Risperidone or Olanzapine. *Psychiatric Services*. July 2002;53(7):855-860.

Yamani MH, Haji SA, Starling RC, Tuzcu EM, Ratliff NB, Cook DJ, Abdo A, Crowe T, Secic M, McCarthy P, Young JB. Myocardial Ischemic-Fibrotic Injury After Human Heart Transplantation Is Associated With Increased Progression of Vasculopathy, Decreased Cellular Rejection and Poor Long-Term Outcome. *Journal of the American College of Cardiology*. March 2002;39:6,970-977.

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Gervaz P, Bouzourene H, Cerottini JP, Chaubert P, Benhattar J, Secic M, Sexner S, Givel JC, Belin B. Dukes B Colorectal Cancer: Distinct Genetic Categories and Clinical Outcome Based on Proximal or Distal Tumor Location. *Diseases of The Colon and Rectum*. March 2001, 44(3):364-372.

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Goodkin DE, Kinkel RP, Weinstock-Guttman B, VanderBrug Medendorp S, Secic M, Gogol D, Perryman JE, Uccelli MM, Neilley L. A Phase II Study of IV Methylprednisolone in Secondary-Progressive Multiple Sclerosis. *Neurology*, 1998, 51:1,239-245.

Hirakawa K, Stulberg BN, Wilde AH, Bauer TW, Secic M. Results of 2-stage Reimplantation for Infected Total Knee Arthroplasty. *Journal of Arthroplasty*, 1998. 13: 1, 22-8.

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Kottke-Marchant K, Green R, Jacobsen DW, Gupta A, Savon SR, Secic M, Robinson K. High Plasma Homocysteine: A Risk Factor for Arterial and Venous Thrombosis in Patients with Normal Coagulation Profiles. *Clin Appl Thrombosis/Hemostasis*, 1997. 3(4):239-244.

Alexander F, Wyllie R, Jirousek K, Secic M, Porvasnik S. Delayed Gastric Emptying Affects Outcome of Nissen Fundoplication in Neurologically Impaired Children. *Surgery*, 1997. 122(4):690-698.

Hirakawa K, Bauer TW, Hashimoto Y, Stulberg BN, Wilde AH, Secic M. Effect of Femoral Head Diameter on Tissue Concentration of Wear Debris. *Journal of Biomedical Materials Research*, 1997. 36:529-535.

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Gupta A, Kottke-Marchant K, Secic M, Jacobsen DW, Green R, Robinson K. Elevated Plasma Homocysteine: A Common Reversible Risk Factor for Thromboembolism in Men and Women. *Journal of the American College of Cardiology*, 1996. 27(2):273A-274A.

O'Hagan AR, Ellsworth R, Secic M, Rothner AD, Brouhard BH. Renal Manifestations of Tuberous Sclerosis Complex. *Clinical Pediatrics*, 1996. 35(10):483-490.

Hanna JP, Frank JI, Furlan AJ, Sila CA, Secic M. Prediction of Worsening Consciousness From Edema After Hemispheric Infarction. *Journal of Stroke and Cerebrovascular Diseases*, 1996. 6(1):25-29.

Lavertu P, Guay ME, Meeker SS, Kmiecick JR, Secic M, Wanamaker JR, Eliachar I, Wood BG. Secondary Tracheoesophageal Puncture: Factors Predictive of Voice Quality and Prosthesis Use. *Head and Neck*, 1996. 393-398.

Weinstock-Guttman B, Secic M, Kinkel RP. A composite outcome measure to monitor clinical response to M.S. treatment protocols. *Journal of Neuroimmunology*, 1996. (971):56-63.

Hirakawa K, Bauer TW, Stulberg BN, Wilde AH, Secic M. Characterization and Comparison of Wear Debris From Failed Total Hip Implants of Different Types. *Journal of Bone and Joint Surgery*, 1996. 78-A(8):1235-1243.

Lonzer MD, Imrie R, Roger D, Worley D, Licata A, Secic M. Effects of Heredity, Age, Weight, Puberty, Activity and Calcium Intake on Bone Mineral Density in Children. *Clinical Pediatrics*, 1996. April:185-189.

Lowder CY, Secic M, Butler CP, Dodds EM, Recillas-Gispert C. CD8+ T lymphocytes and cytomegalovirus retinitis in patients with the acquired immunodeficiency syndrome - Reply. *American Journal of Ophthalmology*, 1996. 121(4):455-456.

Bloomfield EL, Porembka DT, Ebrahim ZY, Grimes-Rice M, Secic M, Little JR, Lockrem JD. Analysis of Catecholamine and Vasoactive Peptide Release in Intracranial Arterial Venous Malformations. *Journal of Neurosurgical Anesthesiology*, 1996. April;8(2).

Secic M. Discussion of the Comparison of GLM and MIXED Procedures for a Repeated Measures Design: One Within and One Between Subjects Factor. *Mid-West SAS User's Group Proceedings*, 1995 October.

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Jacobsen DW, Gatautis VJ, Green R, Robinson K, Savon SR, Secic M, Ji J, Otto J, Taylor LM Jr. Rapid HPLC Determination of Total Homocysteine and Other Thiols in Serum and Plasma: Sex Differences and Correlations with Cobalamin and Folate Levels in Normal Subjects. *Clinical Chemistry*, 1994. 40:873-881.

Broughan TA, Valenzuela R, Escorcía E, Secic M, Vogt DP. Mouse Antibody-coated Lymphocytes During OKT-3 Therapy in Liver Transplantation. *Clinical Transplantation*, 1994. 8:488-491.

Vanek EP, Carey W, Secic M, Jackman D, Fleshler B. Value of Needs Assessment Surveys. *Journal of Continuing Education in the Health Professions*, 1994. 14(4):224-231.

Gupta MK, McBride N, Secic M, Sheeler L, Kohse L, Licata A, Hoogwerf B. TSH Receptor Antibodies in Graves' Ophthalmopathy: High Association and Predictive Role of Thyroid Stimulating but not TSH Binding Inhibitory Antibodies. *Endocrine Journal*, 1994. 2:305-310.

Wood DA, Hughes GB, Secic M, Good TL. Objective Measurement of Normal Facial Movement with Video Microscaling. *The American Journal of Otology*, 1994. 15(1):61-65.