**CURRICULUM VITAE**

**Martin Laurence Lee, PhD, CStat, CSci**

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DATE OF BIRTH: June 8, 1953

BIRTHPLACE: London, England (U.S. Citizen)

MARITAL STATUS: Married (two sons)

**EDUCATION** 1974 B.A., Mathematics, University of California at Los Angeles (Summa cum Laude)

 1975 M.S., Biostatistics, University of California at Los Angeles

 1979 Ph.D., Biostatistics, University of California at Los Angeles (minor in Biological Chemistry)

**EXPERIENCE**

2005 – 2019 Harbor Healthcare Systems

 CONSULTANT

 Provide statistical modeling of health outcomes data and develop novel approaches for assessing physician quality in terms of care of workplace injuries

2005 − 2012 Inspiration Biopharmaceuticals

 CONSULTANT

 Responsible for clinical trial and activities for a venture-capital supported biotech company involved in novel biological products for the treatment and care of individuals with hemophilia.

2001 − Present Prolacta Bioscience, Inc.

 VICE PRESIDENT, CLINICAL RESEARCH AND DEVELOPMENT/SENIOR VICE PRESIDENT, DATA ANALYTICS

 Responsible for all research and development, as well as regulatory activities for a venture-capital supported start-up intending to provide human breast milk for very low birth weight premature neonates.

2001 – Present Charles R. Drew University of Medicine and Science, Dept of Endocrinology

 PROFESSOR, INTERNAL MEDICINE

 Support group of medical researchers by providing statistical consultation and education.

2001 – 2007 Harbor-UCLA Medical Center, UCLA Vaccine Research Institute

 DIRECTOR, BIOSTATISTICS AND DATA MANAGEMENT

 Oversee group of biostatisticians and programmers working on vaccine research studies under government and commercial funding.

1998 – 2001 Baxter Healthcare Corporation, Hyland Immuno Division

 DIRECTOR, CLINICAL STRATEGY AND BIOSTATISTICS

 Responsible for biostatistics group in Los Angeles and Vienna facilities. Organize and oversee various new studies of existing products and strategize clinical research for new products.

1994 - Present Sepulveda VA Medical Center

 SENIOR HEALTH STATISTICIAN

 Consultant to a large group of physicians/researchers from Southern California VA Medical Centers with respect to research on health outcomes, quality of life and primary care.

1986 - Present International Quantitative Consultants, Inc.

 PRESIDENT

 Set up and manage consulting company to support clinical, statistical, and regulatory needs of various biologic, drug and device companies, particularly those in the biotechnology sector. In addition, serve as an EXPERT WITNESS for numerous healthcare fraud cases involving Medicare/Champas (for the U.S. Department of Justice), worker’s compensation (FBI), various state health insurance agencies (California, West Virginia, Florida, New York, etc.), as well as patent infringement and product liability cases. Work has included depositions and expert testimony in hearings and trials

1994 - 1996 VivoRx, Inc.

 VICE PRESIDENT, CLINICAL AND REGULATORY AFFAIRS

 Responsible for clinical and regulatory programs for a small, biotech company working on encapsulated islet cell transplantation for the treatment of type 1 diabetes.

1992 - 1996 MedClone, Inc.

 DIRECTOR, REGULATORY AND CLINICAL PROGRAMS

 Responsible for all regulatory, clinical and biostatistical programs for a venture capital-supported company working on the treatment of various autoimmune diseases using monoclonal antibody therapy.

1991 – present EXPERT WITNESS

 Serve as an expert statistical witness in numerous healthcare fraud cases for both the US Department of Justice, and numerous states Department of Justice. Testified in court (trials and administrative hearings) and provided depositions. Also, have worked on cases for the EPA and FTC as a statistical expert, along with product liability and patent infringement cases.

1990 - 1991 Trancel Corp.

 DIRECTOR, CLINICAL AFFAIRS

 Responsible for all pre-clinical and clinical programs for a venture capital supported company in the business of encapsulated cellular transplants.

1989 - 1990 Baxter Healthcare Corporation, Technology & Ventures Division

 VICE PRESIDENT, REGULATORY AFFAIRS/QUALITY ASSURANCE/CLINICAL PROGRAMS

 Responsible for all compliance activities for company manufacturing gastroenterologic and urologic devices. Responsible for preparation and submission of IDEs, PMAs, and 510(k)s, as well as foreign submissions. Also oversee quality assurance activities. Direct clinical research program worldwide. Supervise department of nine individuals.

1979 - 1989 Baxter Healthcare Corporation, Hyland Division

 DIRECTOR, MEDICAL AFFAIRS

Responsible for worldwide direction of clinical research programs for company manufacturing blood proteins (biologics). Includes identification, design, implementation and finalization of clinical trials. Prepare IND and NDA/PLA submissions for FDA and maintain regulatory files. Also provide marketing research support to suggest new directions for existing products. Consult on technical Quality Assurance problems.

Supervise department of six individuals. Previous positions held included ASSOCIATE DIRECTOR, MEDICAL AFFAIRS; MANAGER, CLINICAL DEVELOPMENT; STAFF ASSOCIATE (Clinical Development); and BIOSTATISTICIAN.

1979 - Present University of California at Los Angeles, Fielding School of Public Health

 ADJUNCT PROFESSOR

 Teach courses in beginning biostatistics, clinical research, and experimental design to public health, medical, and nursing students. Courses include: Introduction to Biostatistics (required course for MPH in Public Health and elective for undergraduates in the biological sciences); Applied Biostatistics; Introduction to Pharmaceutical Statistics; and Introduction to Statistical Methods for Clinical Trials.

1973 - 1979 University of California at Los Angeles, University of Southern California, California State University at Northridge, California State University at Los Angeles

 Various statistical consulting positions held at UCLA School of Medicine and Dentistry and USC Shock Research Unit (Hollywood Presbyterian Medical Center). Teaching positions held at UCLA, Cal State Northridge and Cal State Los Angeles.

**PATENTS**

Methods for testing milk (E. Medo, M. Lee, D. Rechtman): U.S. Patent 7,943,315 (issued 5/17/11)

Human milk compositions and methods of making and using same (E. Medo, M. Lee, D. Rechtman and J. Fournell): U.S. Patent 8,545,920 B2 (issued 10/1/13)

**HONORS AND AWARDS**

Phi Beta Kappa, 1974

NIH Traineeship, 1974-75

Regents' Scholarship, 1973-74

Pi Mu Epsilon, National Mathematics Honor Fraternity

Delta Omega, National Public Health Honor Fraternity

Dean's List, eight times as an undergraduate

United States Public Health Service (USPHS) Trainee, 1974-75

Regent's Fellow, 1976-78

UCLA Alumni Association Scroll Award, 1979

Who's Who in the West, 1984-6

Baxter/Travenol Marketing Consistent Publication Award, 1986-88

Who's Who in Emerging Leaders in America, 1987

Who's Who in the World, 1990

Faculty of the Year, UCLA School of Public Health, 1992-93, 2001

Chartered Statistician, Royal Statistical Society, 1993

Best Contributed Paper Award, Honorable Mention, American Statistical Association, Biopharmaceutical Section, 2003

Chartered Scientist, The Science Council/Royal Statistical Society, 2009

Sentinel Award, Association of Certified Fraud Specialists, 2010

Certified Fraud Specialist, Association of Certified Fraud Specialists, 2010

Albert Nelson Marquis Lifetime Achievement Award from Marquis Who’s Who, 2018

Fellow, Institute of Biomedical Sciences, 2020

**PROFESSIONAL MEMBERSHIPS**

American Statistical Association

Biometrics Society

Institute of Biomedical Sciences, Fellow

International Society for Research on Human Milk and Lactation

International Society on Thrombosis and Hemostasis

Royal Statistical Society, Fellow

**TEXTBOOKS**

Lee ML and Strand V. (eds.) Intravenous Immunoglobulins in Clinical Practice, Marcel Dekker, Inc., 1997

Afifi A, Lee ML, Cobb G. An Electronic Companion to Biostatistics. Cogito Learning Media, 1998

**MEMBER, JOURNAL EDITORIAL BOARD**

Implementation Science, 2006-present

**PUBLICATIONS (peer-reviewed)**

 Lee ML. Inverse regression (letter), Technometrics, 21, 275, 1979.

 Lee ML, Kantrowitz JL, and Ellis J. An application of the negative binomial distribution to a problem in microbiologically clean area testing, J. Parenteral Science and Technology, 36, 237-246, 1983.

 Lee, ML, Maglalang EA, and Kingdon HS. An effect of predilution on potency assays of Factor VIII concentrates, Thrombosis Research, 30, 511-519, 1983.

 Heldebrant C, Kleszynski R, Short M, Aronson D, Brown L, Jacoby G, Lee ML, Thomas D, Barrowcliffe T, Howell I, Johnson RC. Assay of AHF concentrates and standards: failure to eliminate variability with a monographed assay, Thrombosis Research, 30, 337-346, 1983.

 Lee ML. Statistical indiscretion, JAMA, 250, 2470, 1983.

 Gee LW, Harvey JMGH, Olson WP, and Lee ML. Sterility test systems for product recovery, J. Pharm. Sci., 74, 29-32, 1985.

 Ochs H, Fischer S, Virant F, Lee ML, Kingdon HS, Wedgwood R. Hepatitis and intravenous immunoglobulins, Lancet, i, 404-5, 1985.

 Gomperts ED, Fannon RB, Lee ML, Kingdon HS, Kantrowitz JL, Addiego JE, Carney J, Corrigan JJ, Hathaway W, Hilgartner MW, Katz J, Lovrien EW. Proplex vs. Proplex SX: A controlled double blind study of the effectiveness in treating acute hemarthroses in

hemophilia A patients with inhibitors to Factor VIII, Thrombosis Research, 42, 789-796, 1986.

 Ochs HD, Fischer SH, Virant FS, Lee ML, Mankarious S, Kingdon HS, and Wedgwood R. Non-A non-B hepatitis and intravenous immunoglobulins, Lancet, i, 323, 1986.

 Ochs HD, Fischer SH, Lee ML, Delson ES, Kingdon HS, Wedgwood RJ. Intravenous immunoglobulin home treatment for patients with primary immunodeficiency disease, Lancet, i, 610-611, 1986.

 Piszkiewicz D, Andrews J, Holst S, Kingdon H, Lee ML, Mankarious S, McDougal, JS, Slimak W, and Hooper J. Safety of immunoglobulin preparation containing antibody to LAV/HTLV-III, Prog. in Immunodeficiency Research and Therapy II, Elsevier Science Publishers B.V. (Biomedical Division), Amsterdam, 197-200, 1986.

 Ochs H, Lee ML, Fischer S, Delson E, Kingdon H, and Wedgwood R. Self-infusion of intravenous immunoglobulin by immunodeficient patients at home, J. Infectious Diseases, 156, 652-654, 1987.

 Lee ML, Kingdon HS, Hooper J, Courter SG, Holst SL, and Piszkiewicz D. Safety of an intravenous immunoglobulin preparation: Lack of seroconversion for human immunodeficiency virus antibodies, Clinical Therapeutics, 9, 300-303, 1987.

 Piszkiewicz D, Kingdon H, Lee ML, Hooper J. The incidence of HTLV-III/LAV seroconversion and non-A, non-B hepatitis in recipients of plasma products, Develop. Biol. Standard., 67, 327-331, 1987.

 Kantrowitz JL, Lee ML, McClure DA, Kingdon HS, and Thomas WR. Early experience with the use of anti-inhibitor coagulant complex to treat bleeding in hemophiliacs with inhibitors to Factor VIII, Clinical Therapeutics, 9, 405-419, 1987.

 Ochs HD, Lee ML, Fischer SH, Kingdon HS, and Wedgwood RJ. Efficacy of a new intact intravenous immunoglobulin preparation (Gammagard®) in primary immunodeficient patients, Clinical Therapeutics, 9, 512-522, 1987.

 Berkman SA, Lee ML, and Gale RP. Clinical uses of intravenous immunoglobulins, Seminars in Hematology, 25, 140-158, 1988.

 Mankarious S, Lee ML, Fischer S, Ochs HD, Wedgwood R. The half-lives of IgG subclasses and specific antibodies in patients with primary immunodeficiency who are

receiving intravenously administered immunoglobulins. J Lab Clin Med, 112, 634-640, 1988.

 Lee ML, Courter SG, Tait DA, and Kingdon HS. Long-term evaluation of intravenous immune globulin preparation with regard to non-A, non-B hepatitis safety. In: Zuckerman, A, ed., Viral Hepatitis and Liver Disease, New York: Alan R. Liss, 1988, pg 596-599.

 Co-operative Group for the Study of Immunoglobulin in Chronic Lymphocytic Leukemia. A randomized controlled clinical trial of intravenous immunoglobulin in chronic lymphocytic leukemia. New Engl. J. Med., 319, 901-907, 1988.

 Lee ML, Kantrowitz JL, and Taylor MG. Statistical evaluation of quality control tests. Pharmaceutical Technology, 12, 108-120, 1988.

 Griffiths H, Brennan V, Lea J, Bunch C, Lee ML, and Chapel H. Cross-over study of immunoglobulin replacement therapy in patients with low grade B-cell tumors, Blood, 73, 366-368, 1989.

 Berkman SA, Lee ML, and Gale RP. Clinical uses of intravenous immunoglobulins. Ann Int. Med., 112, 278-292, 1990.

 Lee ML, Poon W-Y, Kingdon HS. A two-phase linear regression model for biological half-life data. J. Lab Clin. Med., 115, 745-748, 1990.

 Lee ML, and Kingdon HS. Response to "Assay discrepancies with highly purified Factor VIII concentrates," Thrombosis and Hemostasis, 20, 251-252, 1990.

 Gale RP, and Lee ML. Do different therapies of AML produce different outcomes? Leukemia Research, 14, 207-208, 1990.

 Barron KS, Murphy DJ, Silverman ED, Ruttenberg HD, Wright GB, Franklin W, Goldberg SJ, Higashino SM, Cox DG, and Lee ML. Treatment of Kawasaki Syndrome: A comparison of two dosage regimens of intravenous immune globulin. J. of Pediatrics, 117, 638-644, 1990.

 Dunn OJ, Clark VA, Lee M, and Chon Y. Applied Statistics: Analysis of Variance and Regression, 2nd ed., Answers to exercises. UCLA Department of Biostatistics, 1990.

29. Kingdon HS, Piszkiewicz D, Lee ML, Comter SG, Addiego JE. Hemofil M: Preclinical studies and clinical protocol design. Proceedings of the 6th International Symposium of Hemostasis and Thrombosis, 91-96, 1990.

30. Lee ML, and Lusher JM. The problem of therapeutic equivalence with paired qualitative data: An example from a clinical trial using hemophiliacs with an inhibitor to Factor VIII, Statistics in Medicine, 10, 433-441, 1991.

31. Lee ML, Mankarious S, Ochs H, Fischer S, and Wedgwood RJ. The pharmacokinetics of total IgG, IgG subclasses, and type specific antibodies in immunodeficient patients. Immunol. Investigations, 20, 193-198, 1991.

32. Chapel H, Griffiths H, Brennan V, Bunch C, Lea J, and Lee ML. Hypogammaglobulinemia in low grade B cell tumors: significance and therapy. Immunol. Investigations, 20, 187-191, 1991.

33. Chapel H, Griffiths H, and Lee M. IVIG indication in patients with low-grade B-cell tumors. In: Imbach, P. (Ed.), Immunotherapy with Intravenous Immunoglobulins. London: Academic Press, 165-172, 1991.

34. Morfini M, Lee ML, Messori A, and the Factor VIII/IX Scientific and Standardization Committee of the International Society for Thrombosis and Hemostasis. The design and analysis of half-life and recovery studies for Factor VIII and Factor IX. Thrombosis and Haemostasis, 66, 384-986, 1991.

35. Dicato M, Chapel H, Gamm H, Lee M, Ries F, Marichal S, Wirth C, Griffith H, Brennan V. Use of intravenous immunoglobulin in chronic lymphatic leukemia. A brief review. Cancer, 68, 1437-1439, 1991.

36. Hargreaves RM, Lea JR, Griffiths H, Faux J, Lee M, Chapel HM. Immunological response in myeloma. In: Chapel, H.M., Levinsky, R.J., Webster, A.D.B. (eds). Progress in Immune Deficiency III. London: Royal Society of Medicine Services, 138, 1991.

37. Chapel HM, Lee ML. Immunoglobulin replacement in patients with chronic lymphocytic leukemia (CLL): Kinetics of immunoglobulin metabolism. J. Clin. Immun., 12, 17-20, 1992.

38. Addiego JE, Gomperts E, Liu SL, Bailey P, Courter SG, Lee ML, Neslund GG, Kingdon HS, Griffith MJ. Treatment of hemophilia A with a highly purified Factor VIII concentrate prepared by anti-FVIIIc immunoaffinity chromatography. Thrombosis and Haemostasis, 67, 19-27, 1992.

39. van der Meche FGA, Schmitz PIM, and the Dutch Guillain-Barré Study Group. A randomized trial comparing intravenous immune globulin and plasma exchange in Guillain-Barré Syndrome. New Engl J Med., 326, 1123-1129, 1992.

40. Baker CJ, Melish MB, Hall RT, Casto DT, Vasan V, Givner LB, and the Multicenter Group for the Study of IVIG in Neonates. Intravenous immune globulin for the prevention of nosocomial infection in low birth weight neonates. New Engl J Med., 327, 213-219, 1992.

41. Cometta A, Baumgartner JD, Lee ML, Hanique G, Glauser MP, and the Intravenous Immunoglobulin Collaborative Study Group. Prophylactic intravenous administration of standard immune globulin as compared with core lipopolysaccharide immune globulin in patients at high risk of postsurgical infection. New Engl J Med., 327, 234-240, 1992.

42. Morfini M, Longo G, Messori A, Lee M, White G, Mannucci P, and the Recombinate Study Group. Pharmacokinetic properties of recombinant Factor VIII compared with a monoclonally purified concentrate (Hemofil® M). Thrombosis and Haemostasis, 68, 433-435, 1992.

43. Griffiths H, Lea J, Bunch C, Lee M, Chapel H. Predictors of infection in chronic lymphocytic leukaemia (CLL). J Clin Exp Immunol., 89, 374-377, 1992.

44. Soon-Shiong P, Feldman E, Nelson R, Komtebedde J, Smidsrod O, Skjak-Braek G, Espevik T, Heintz R, and Lee M. Successful reversal of spontaneous diabetes in dogs by intraperitoneal microencapsulated islets. Transplantation, 54, 769-774, 1992.

45. Lee ML, Gomperts ED, and Kingdon, HS. A note on the calculation of recovery for Factor VIII infusions, Thrombosis and Haemostasis, 69, 87, 1993.

46. Strand V, Lee ML, and the CD5 Plus RA Investigators Group. Differential patterns of response in patients with rheumatoid arthritis following administration of an anti-CD5 immunoconjugate. Clin Exp Rheumatol, 11 (Suppl 8), S161-S163, 1993.

47. Strand V, Lipsky PE, Cannon GW, Calabrese LH, Wiesenhutter C, Cohen SB, Olsen NJ, Lee ML, Lorenz TJ, Nelson B, and the CD5 Plus RA Investigators Group. Effects of administration of an anti-CD5 Plus immunoconjugate in rheumatoid arthritis: Results of two phase II studies. Arthritis and Rheumatism, 36, 620-630, 1993.

48. Bray GL, Gomperts ED, Gruppo R, Gordon EM, Manco-Johnson M, Shapiro A, Scheibel K, Courter S, Lee M, and the Recombinate Study Group. A multi-center study of recombinant Factor VIII (Recombinate®): Safety, efficacy and inhibitor risk in previously untreated patients with hemophilia A. Blood, 83, 2428-2435, 1994.

49. Lee ML, and Courter SG. Quality of life assessment versus clinical outcome measures: An example. Drug Information Journal, 28, 39-43, 1994.

1. Chapel HM, Lee M, Hargreaves R, Pamphilon DH, Prentice AG, and the UK Group for Immunoglobulin Replacement Therapy in Multiple Myeloma. Randomized trial of

intravenous immuoglobulin as prophylaxis against infection in plateau-phase multiple myeloma. Lancet, 343, 1059-1063, 1994.

51. Levy J, Youvan T, Lee M, and the Passive Hyperimmune Therapy Study Group. Passive hyperimmune plasma therapy in the treatment of acquired immunodeficiency syndrome: Results of a 12-month multicenter double blind controlled trial. Blood, 84, 2130-2135, 1994.

52. Chapel H and Lee M. The use of intravenous immune globulin in multiple myeloma. Clin Exp. Immunol, 97 (suppl 1), 21-24, 1994.

53. Thomas DP, Dasani H, Giangrande PLF, Lee CA, Hampton KK, Harman C, Lee ML. A cross-over pharmacokinetic study of prothrombin complex concentrate and a purified Factor IX concentrate. Brit. J. Hemat, 88, 1994.

54. Chapel H, Dicato M, Gamm H, Brennan V, Ries F, Bunch C, and Lee M. Immunoglobulin replacement in patients with chronic lymphocytic leukaemia: a comparison of two dose regimens. Brit J. Haematol, 88, 209-212,1994.

55. Busch MP, Operskalski EA, Mosley JW, Stevens CE, Schiff ER, Kleinman SH, Lee H, Lee M, Harris M, and the Transfusion Safety Study Group. Epidemologic background and long-term course of disease in human immunodeficiency virus type 1-infected blood donors identified before routine laboratory screening. Transfusion, 34, 858-864, 1994.

56. Gamm H, Huber CH, Chapel H, Lee M, Ries F, Dicato MA. Intravenous immune globulin in chronic lymphocytic leukaemia. Clin. Exp. Immunol, ­97­ (suppl 1), 17-20, 1994.

57. Hargreaves RM, Lea JR, Griffiths H, Faux JA, Holt JM, Reid C, Bunch C, Lee M, and Chapel HM. Immunological factors and risk of infection in plateau phase myeloma. J Clin Pathol, 48, 260-66, 1995.

58. Abzug MJ, Keyserling HL, Lee ML, Levin MJ, Rothbart HA. Neonatal enterovirus infection: Virology, serology, and effects of intravenous immune globulin. Clin Inf Dis, 20, 1201-6, 1995.

59. Harada N, Chiu V, Fowler E, Lee M, Reuben DB. Physical therapy to improve functioning of older people in residential care facilities. Phys Ther, 75, 830-839, 1995.

60. Lee ML, Chapel H, Bennan V, Gamm H, Dicato M, Courter SG. Quality of life assessments and clinical outcome measures in patients with B-cell lymphoproliferative disease receiving intravenous immunoglobulin. In: Proceedings: Early Decision in DMARD Development IV. Biologic Agents in Autoimmune Disease. Atlanta, Ga: Arthritis Foundation, 1995.

61. Strand V, Lee M. Intravenous immunoglobulin (IVIG) in the treatment of autoimmune disease. In: Strand V, Simon L, Scott R (eds.), Emerging Therapies in Autoimmune Disease. New York: Marcel Dekker, 1996, 235-256.

62. Gifford DR, Mittman BS, Fink A, Lanto AB, Lee ML, Vickrey BG. Can a specialty society educate its members to think differently about clinical decisions? Results of a randomized trial. J Gen Intern Med, 11: 664-672, 1996

63. Lee ML. Quality of life and cost-effectiveness issues of IVIG in chronic lymphocytic leukemia: A re-evaluation. In: Kazatchkine MD, Morell A (eds). Intravenous Immunoglobulin Research and Therapy. New York: Parthenon Publishing Group, 1996, 350-351.

64. Bain PG, Motomura M, Newsom-Davis J, Misbah SA, Chapel HM, Lee ML, Vincent A, Lang B. Effects of intravenous immunoglobulin on muscle weakness and calcium-channel autoantibodies in the Lambert-Eaton Syndrome. Neurology, 1997.

65. McGill V, Kowal-Vern A, Lee M, Greenhalgh D, Gomperts E, Bray G, Gamelli R. Use of fibrin sealant in thermal injury. J Burn Care Rehabil, 18: 429-34, 1997.

66. Atkinson JB, Gomperts ED, Kang R, Lee M, Arensman RM, Bartlett RH, Rais-Bharami K,, Breaux CW, Cornish JD, Haase GM, Roden J, Zwischenberger JB. Prospective, randomized evaluation of the efficacy of fibrin sealant as a topical hemostatic agent at the cannulation site in neonates undergoing extracorporeal membrane oxygenation. Am J Surg, 173: 479-484, 1997.

67. White GC, Courter S, Bray GL, Lee M, Gomperts ED and the Recombinate Previously Treated Patient Study Group. A multicenter study of recombinant factor VIII (Recombinate™) in previously treated patients with hemophilia A. Thrombosis and Haemostasis, 77: 660-7, 1997.

68. Lee ML, Gale RP, Yap PL. Use of intravenous immunoglobulin to prevent or treat infections in persons with immune deficiency. Ann Rev Med, 48: 93-102, 1997.

69. Lee ML, Strand V. Pharmacoeconomics of intravenous immunoglobulin. In: Lee ML, Strand V (eds.), Intravenous Immunogloblins in Clinical Practice. New York: Marcel Dekker, 1997, 19-22.

70. Lee ML. Alternative methods for the administration of intravenous immunoglobulins. In: Lee ML, Strand V (eds.), Intravenous Immunoglobulins in Clinical Practice. New York: Marcel Dekker, 1997, 107-111.

71. Lee ML. Intravenous immunoglobulin and other autoimmune diseases. In: Lee ML, Strand V (eds.), Intravenous Immunoglobulins in Clinical Practice. New York: Marcel Dekker, 1997, 447-449.

72. Lee ML, Courter SG. Quality of life assessment versus clinical outcome measures. Adv in Thenatology, 8: 39-43, 1997

73. Sorenson PS, Wanscher B, Jensen CV, Schrieber K, Blinkenberg M, Ravnborg M, Kirsmerer H, Laaren VA, Lee ML. Intravenous immune globulin G reduces MRI activity in relapsing multiple sclerosis. Neurology, 50: 1273-1281, 1998.

1. Kerr EA, Hays R, Mitchinson A, Lee M, Siu AL. The influence of gatekeeping and utilization review to control access to specialists on patient satisfaction with care. Medical Care Research and Review, 55: 59-77, 1998.
2. Chernof BA, Sherman SE, Lanto AB, Lee ML, Yano EM, Rubenstein I.V. Health habit counseling amidst competing demands: effects of patient health habits and visit characteristics. Med Care 37: 738-47, 1999.
3. Dresselhaus TR, Luck J, Wright BC, Spragg RG, Lee ML, Bozzette SA. Analyzing the time and value of house staff inpatient work. J Gen Intern Med 13: 534-40, 1998.
4. Greenhalgh DG, Gamelli RL, Lee ML, Delavari M, Lynch JB, Hansbrough JF, Achauer BM, Miller SF, MacPhee M, Bray GL. A multicenter trial to evaluate the safety and potential efficacy of pooled human fibrin sealant for the treatment of burn wounds. J. Trauma: Injury, Infection and Critical Care, 46: 433-440, 1999.
5. Rodell MB, Lee ML. Determination of reasons for cessation of participation in serial plasmapheresis programs. Transfusion, 39: 900-903, 1999.
6. Smith BL, Lee M, Leader S, Wertlake P. Economic impact of automated primary screening for cervical cancer. J Reprod Med, 44: 518-528, 1999.
7. Waytes AT, Igel H, Zerlanth G, Wappler N, Lee M, Schwarz O. A safer plasma supply from renumerated donors, “The Immuno/Community Bio-Resources Experiment”. In: Brown F, Vyas G (eds): Advances in Transfusion Safety. Dev. Bio. Basel: Karger, 37-51, 1999.
8. Spertini F, Leimgruber A, Morel B, Khazaeli MB, Yamamoto K, Dayer JM, Weisbart RH, Lee ML. Idiotypic vaccination with a murine anti-ds DNA antibody: Phase I study in patients with non-active systemic lupus erythematosus with nephritis. J Rheumatology, 26: 2602-8, 1999.
9. Shekelle PG, Kravitz RL, Beart J, Marger M, Wang M, Lee M. Are nonspecific guidelines potentially harmful? A randomized comparison of the effect of nonspecific or specific guidelines on physician decision-making. Health Services Research, 34: 1429-1448, 2000.
10. Goodkin DE, Shulman M, Winkelhake J, Waubant E, Andersson PB, Stewart T, Nelson S, Fischbein N, Coyle PK, Frohman E, Jacobs L, Holcenberg J, Lee M, Mocci S. A phase I trial of solubilized DR 2: MBP 84-102 (AG284) in multiple sclerosis. Neurology, 54: 1414-1420, 2000.
11. Peabody JW, Luck J, Glassman P, Dresselhaus TR, Lee M. Comparison of vignettes, standardized patients and chart abstraction: A prospective validation study of 3 methods for measuring quality. J Amer Med Assoc, 283: 1715-1722, 2000.
12. Lee ML, Tomsu K, Von Eschen KB. Duration of survival for disseminated malignant melanoma: results of a meta-analysis. Melanoma Res, 10: 81-92, 2000.
13. Saliba D, Kington R, Buchanan J, Bell R, Wang M, Lee M, Herbst M, Lee D, Sur D, Rubenstein L. Appropriateness of the decision to transfer nursing facility residents to the hospital. J Am Geriatr Soc, 48: 154-163, 2000.
14. Parham GP, Andrews NR, Lee ML. Comparison of immediate and deferred colposcopy in a cervical screening program. Obstet Gynecol, 95: 340-4, 2000.
15. Dresselhaus TR, Peabody JW, Lee M, Wang M, Luck J. Measuring compliance with preventive care guidelines: a comparison of standardized patients, clinical vignettes and the medical record. J Gen Int Med, 15: 782-8, 2000.
16. St. Clair EW, Cohen SB, Lee ML, Fleischmann RM, Lee SH, Moreland LW, Olsen NJ, Pratt PW, Yocum DE, Heck L, Winkelhake J, Holcenberg JS, Shulman MJ. Treatment of rheumatoid arthritis with a DR4/1 peptide. J Rheumatol, 27: 1855-63, 2000.
17. Luck J, Peabody JW, Dresslhaus TR, Lee M, Glassman P. How well does chart abstraction measure quality? A prospective comparison of standardized patients with the medical record. Am J Med, 108: 642-649, 2000.
18. Kramer BJ, Damron-Rodriguez J, Lee M, Wang M. Medical house staff performance on the facts of aging quiz: a comparison of test formats. Geron Geriatrics Educ. 21: 41-51, 2001.
19. Ramey DW, Lee M, Messer NT. A review of the Western veterinary literature on equine acupuncture. J Eq Vet Sci 21: 56-60, 2001.
20. Lee M, Morfini M, Schulman S, Ingerslev J, and the Factor VIII/Factor IX Scientific and Standardization Committee of the International Society for Thrombosis and Haemostasis. The design and analysis of pharmacokinetic studies of coagulation factors. Website of the International Society for Thrombosis and Haemostasis ([www.isth.org](http://www.isth.org)), 2002.
21. Lee ML, Yano EM, Wang M, Simon BF, Rubenstein LV. What patient population does visit-based sampling in primary care settings represent? Medical Care, 40: 761-770, 2002.
22. Sorensen PS, Fazekas F, Lee M. Intravenous immunoglobulin G for the treatment of relapsing-remitting multiple sclerosis: a meta-analysis. Eur J Neuro, 9: 557-563, 2002.
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24. Cradock-O’Leary J, Young AS, Yano EM, Wang M, Lee ML. Use of general medical services by VA patients with psychiatric disorders. Psychiatr Serv, 53: 874-878, 2002.
25. Hambleton J, Wages D, Radu-Radulescu L, Adams, M, MacKenzie M, Shafer S, Lee M, Smyers J, Wiesehahn G, Corash L. Pharmacokinetic study of FFP photochemically treated with amotosalen (S-59) and UV light compared to FFP in healthy volunteers anticoagulated with warfarin. Transfusion, 42: 1302-1307, 2002.
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20. Lee ML. The design and analysis of pharmacokinetic studies of coagulation factors. World Federation of Hemophilia Meeting, Vancouver, Canada, 2006.
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35. Huynh AK, Rose DE, Lee ML, Rubenstein LV, Stockdale SE. Evaluation of patient-assessed provider communication in Veterans Assessment and Improvement Laboratory (VAIL) QII using non-randomized stepped wedge design. Oral presentation at the 2017 HSR&D/QUERI National Conference, Crystal City, VA, July 2017.

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**OTHER PUBLICATIONS**

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**INVITED PAPERS**

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4. Lee ML. Clinical directions in intravenous immunoglobulin use, Oklahoma Society of Hospital Pharmacists Winter Meeting, Oklahoma City, 1987.
5. Lee ML. Hyland monoclonal factor VIII trial-preliminary result, U.C. Irvine Medical Center Hemophilia Symposium, Irvine, 1988.
6. Lee ML. A two-phase linear regression model for biological half-life data, Department of Statistics Seminar, Chinese University of Hong Kong, Shatin, Hong Kong, 1989.
7. Lee ML. Statistical validity of quality control tests, 1st International Conference on Pharmaceutical Quality Control, New Brunswick, New Jersey, 1990.
8. Lee ML. Pharmacokinetics of IgG subclasses, 3rd Symposium of Immune Deficiencies, Warsaw, Poland, 1990.
9. Lee ML. Assays of recombinant factor VIII products, Factor VIII Standardization Meeting, National Institute for Biological Standards and Control, London, 1990.
10. Lee ML. Pharmacokinetic methods for factor VIII. International Society for Thrombosis and Hemostasis Meeting, Barcelona, 1990.
11. Lee ML. Cost effectiveness, quality of life measures, and clinical trials. Regulatory Affairs Professional Society Annual Meeting, Washington, D.C., 1992.
12. Lee ML. Outcomes and new standards for product innovation - functional changes to meet demands. Conference on Capitalizing on Health Care Reform, Chicago, 1993.
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18. Lee ML. The combination of quality of life and survival data to evaluate therapies for stage 4 malignant melanoma. Symposium on Pharmaceuticals in the Palliative Care of Diseases of Differing Etiologies: Pharmaceutical Financial Opportunities, New York, 1998.
19. Lee ML. Accounting for patient clustering in health services research and policy literature. RAND workshop: Using Hierarchical Models and Structural Equations to Study Health Care Quality: Accounting for the Organizational Context, RAND Corporation, Santa Monica, CA, 1998.
20. Lee ML. The design and analysis of pharmacokinetic studies of coagulation factors. Grand Rounds, Aflac Cancer Center and Blood Disorders Service, Childrens’ Healthcare of Atlanta, 2006.
21. Lee ML. Current research with human milk. Focus on Human Milk Conference,

 Maastricht, The Netherlands, 2008.

**DISSERTATION TITLE**

Some nearest neighbor estimators for the inverse regression problem with application to instrument calibration and radioimmunoassay

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**OTHER RELEVANT ACADEMIC PROGRAMS**

Accounting Concepts for Non-Financial Managers - California State University at Los Angeles, 1983

Introduction to Human Anatomy and Physiology - University of California at Los Angeles, Extension, 1984

MBA Program, California Coast University