

CURRICULUM VITAE

LAWRENCE HALE MOULTON

PART I

PERSONAL DATA

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EDUCATION

Ph.D. 1987 (defense 6/86), The Johns Hopkins University, Bloomberg School of Public Health Biostatistics.

M.S. 1978, University of Texas School of Public Health. Biometry.

B.A. 1976, State University of New York at Buffalo. Majors: Statistics and Mathematics

PROFESSIONAL EXPERIENCE

2003-Present Professor: Department of International Health, The Johns Hopkins University, Bloomberg School of Public Health. Joint appointment, Department of Biostatistics.

1996-2003 Associate Professor: Department of International Health, The Johns Hopkins University, Bloomberg School of Public Health. Joint appointment, Department of Biostatistics.

1997-Present Co-Director, Institute for Vaccine Safety, The Johns Hopkins University, Bloomberg School of Public Health.

1991-1996 Assistant Professor: Department of International Health, The Johns Hopkins University, Bloomberg School of Public Health. Joint appointment, Department of Biostatistics.

1986-1991 Assistant Professor: Department of Biostatistics, The University of Michigan, School of Public Health, Ann Arbor, Michigan.

- 1984-1985 Visiting Scientist: Unité 287 de l'Institut National de la Santé et de la Recherche Médicale, Institut Gustave-Roussy, France.
- 1983-1984 Biostatistician: Alcoholic Beverage Medical Research Foundation, The Johns Hopkins School of Medicine.
- 1982 Analyst/Programmer: Hypertension Prevention Trial Data Center, Department of Epidemiology, The Johns Hopkins University, Bloomberg School of Public Health.
- 1979-1980 Statistician and Adjunct Professor: Collège Polytechnique Universitaire and Faculté des Sciences Agronomiques, l'Université Nationale du Bénin, Bénin, West Africa (as a Peace Corps Volunteer).

PROFESSIONAL ACTIVITIES

Center Member:

Center for American Indian and Alaskan Native Health. Center statistician: collaborate on on design, implementation, analysis and publication of numerous studies.

Center for Clinical Trials

Hopkins Population Center

Institute for Vaccine Safety. Co-Director, and Quantitative Sciences Coordinator.

Association Member:

American Public Health Association

American Statistical Association

Biometric Society

Institute of Mathematical Statistics

International Society for Clinical Biostatistics

International Statistical Institute

Grant Review Activities: NIH and Other Agencies

NCI Study Section (Secondary Reviewer, 1993)

Natural Sciences and Engineering Research Council of Canada (Ad hoc Reviewer, 1995)

NIH Microbiology and Infectious Diseases Research Committee (Ad hoc Reviewer, 1996)

ZRG1 VACC 01 NIH Research Study Section, Member, November 1998

ZRG1 AARR-6(01) NIH Research Study Section, Ad Hoc Reviewer, March 1999

ZRG1 VACC 01 NIH Research Study Section, Member, November 1999

ZRG1 TMP(03) Special Study Section, Member, May 2000

ZRG1 VACC 01 NIH Research Study Section, Member, July 2000

ZRG1 VACC 04 NIH Research Study Section, Member, July 2000

Save the Children; December 2000

ZRG1 VACC 04 NIH Research Study Section, Ad Hoc Reviewer, August 2002
Bacteriology and Mycology Study Group External Consultative Group, NIH/NIAID; Member,
August 2002–present

NIAID. 2002-present. Bacteriology and Mycology Study Group External Consultative Group.
ZRG1 VACC-01 Q: HIV/AIDS Vaccines Ad Hoc Member, NIAID 2005
ZDK1 GRB-B/ NIDDK Ad Hoc Member, Dec 2005

NIAID ZAI1 LR-M (C1): Selection committee for the Statistical and Data Coordinating Center
for Clinical Research in Infectious Diseases; Chairperson.

Data and Safety Monitoring Board Membership

SmithKline Beecham. 1995-1996. A double-blind, randomized, dose-ranging, placebo
controlled study to assess the safety and efficacy of single IV doses of SB 209763 in infants and
young children hospitalized with RSV infection.

SmithKline Beecham. 1995-1996. Evaluation of the protective efficacy, safety and
immunogenicity of a recombinant DNA expressed protein vaccine for Lyme disease in healthy
subjects.

SmithKline Beecham. 1996. Respiratory Syncytial Virus International Advisory Board.

WHO/UNICEF, ADDR/AID. 1995-1995. WHO Treatment Effects Monitoring Committee:
Multicentre studies to evaluate the efficacy/safety of reduced osmolarity ORS solution in adult
patients with cholera and children with acute watery diarrhoea.

SmithKline Beecham; SBL. 1999-2002. Evaluation of an oral vaccine to prevent traveller's
diarrhea due to enterotoxigenic *E.coli*.

NIAID/DMID/STDB. 1999-2000. NIH Sexually Transmitted Diseases Branch DSMB: multiple
studies.

NIAID/DMID. 2000-present. Phase III Efficacy Trial of Azithromycin vs. Benzathine Penicillin
for the Treatment of Early Syphilis.

CDC. 2001-present. Anthrax Vaccine Adsorbed: Human Reactogenicity and Immunogenicity
Trial to Address Change in Route of Administration and Dose Reduction.

NIAID/DMID. 2003-present. A Phase II Randomized, Double-Blinded, Comparative Clinical
Trial for a Group B Streptococcus Serotype III-Tetanus Toxoid (GBS III-TT) Vaccine to Prevent
Vaginal Acquisition of GBS Type III.

NIAID 2004-present. NIAID DSMB for Intramural Programs: multiple studies.

JHU: 2005-present. DSMB for Mirzapur and Sylhet neonatal intervention trials.

NIAID 2006-present. Southeast Asia Influenza Clinical Research Network DSMB, meets

internationally.

JHU: 2007-present. Chairman: for vitamin A and neonatal sepsis trial, Shishu Hospital, Bangladesh.

Other Professional Activities

American Public Health Association

Statistics Section Representative to the Action Board of the American Public Health Association, 1991-1996. Member of Reference Committees on resolutions.

Elected Section Council Member (Councillor), Statistics Section, American Public Health Association, 2000-2003.

Chair, Officers' Nominations Committee, 2001.

Chair, Section Awards Committee, 2002, 2003.

Chair, Membership Committee, 2004.

Chair-Elect, and Program Chair, Statistics Section, American Public Health Association, 2004-2005.

Chair, Statistics Section, American Public Health Association, 2005-2006.

Non-Governmental Organizations

Carter Presidential Center. Analyzed and presented results on Haiti measles vaccine followup studies at the Consultation on Studies Involving High Titer Measles Vaccines Before Nine Months of Age, Atlanta, June, 1992.

Participant, International Vitamin A Consultative Group on Combining Vitamin A Distribution with EPI Contacts. Baltimore, July 1998.

Consultant to the Vietnam Veterans of America Foundation for development of landmine sampling methodology, and for prioritization of landmine clearance areas in Kosovo, 1998-2002.

Consultant to the Survey Action Center, Global Landmine Survey, regarding sampling, evaluation, and analysis issues, 2002-present.

Danish National Research Foundation, 2005.

Industry

GSK: Hib vaccine consult, 2003

sanofi-pasteur: several projects; short courses on group-randomized trials and longitudinal data analysis, 2005.

United States Government

Invited participant/presenter, Research Needs for the Design and Analysis of Surrogate Endpoints in Clinical Trials, an NIH Workshop, Bolger Center, Potomac, December 1998.

Invited participant, and Chair, Working Group on Enhanced Surveillance and Scientific Response, National Vaccine Advisory Committee/Vaccine Safety and Communication Subcommittee, Washington, D.C., 1999-2000.

Consultant to the Health Resources and Services Administration, submitted expert report to U.S. Department of Justice regarding Rubella Omnibus filing, March 2000. Testified in court before the Special Master, February 2001.

Member, Anthrax Vaccine Expert Committee, Health Resources and Services Administration, 1999-present.

Advisor, FDA Vaccine and Related Products Advisory Committee Meeting on novel cell substrates. Rockville, May 2001. Special government employee to 7/2004.

Consultant to the Health Resources and Services Administration, submitted multiple expert reports to U.S. Department of Justice regarding vaccine safety, February 2002-present.

Consultant to the U.S. Department of Justice in vaccine litigation case, 2005.

Consultant to FDA, regarding Menactra safety, Oct 2005; short course on group-randomized trials, Nov 2005.

Advisor, FDA Vaccines and Related Biological Products Advisory Committee, regarding FluMist®; Gaithersburg, MD, May 2007.

United Nations

Presented methodology for the analysis of longitudinal data at, and participated in, the WHO workshop: Methodology to Measure Episodes of Childhood Pneumonia and other ALRI in Prospective Home Surveillance Studies-II, London, United Kingdom, June, 1993.

Presented a report on meningococcal B vaccine at the Eleventh PAHO Technical Advisory Group (TAG) Meeting on Vaccine Preventable Diseases, Washington, D.C., August, 1994.

Consultant to the Integrated Pest Management Programme of the Food and Agriculture Organization, Hanoi Medical College, Hanoi, Vietnam, October-November 1996.

Consultant to WHO/TDR for monitoring and analysis of single-injection leishmaniasis vaccine trials, Bam/Kerman/Isfahan/Tehran, Iran, February 1997.

Consultant to WHO/TDR for design and monitoring of multiple-injection leishmaniasis vaccine trials, Kerman/Isfahan/Tehran, Iran, September 1998.

Consultant to WHO/TDR for design and monitoring (including DSMB membership activities) of multiple-injection leishmaniasis vaccine trials, Tehran, Iran, May 1999.

Consultant to WHO/TDR for monitoring and analysis (including DSMB membership activities) of multiple-injection leishmaniasis vaccine trials, Tehran, Iran, June 2000.

Presenter/Temporary Advisor, Implications for assay parameters and methods of data analysis for the comparison of complement sources in the *Neisseria meningitidis* serogroup C serum bactericidal assays. WHO/HTP/V&B/VAD, Geneva, October 2000.

Member, WHO/TDR Product Development Team for Leishmaniasis Vaccines, 2000-present.

Temporary Advisor/Presenter, Geneva, December 2001; Geneva, October 2002.

Temporary Advisor/Presenter, Workshop on Child Survival and Routine Immunization. WHO/HTP/V&B/VAM, Geneva, October 2001.

Protocol reviewer, evaluation of field vaccine efficacy of a meningococcal trivalent vaccine, WHO/V&B, January 2003.

EDITORIAL ACTIVITIES

Referee For:

American Journal of Epidemiology
 American Journal of Public Health
 The American Statistician
 BMC Medical Research Methodology
 Biometrics
 Biostatistics
 Clinical Trials (Associate Editor)
 Communications in Statistics
 Controlled Clinical Trials
 International Journal of Epidemiology
 Journal of Agricultural, Biological, and Environmental Statistics
 Journal of Computational Statistics and Data Analysis
 Journal of Immunological Methods
 Journal of Multivariate Analysis
 Journal of Biopharmaceutical Statistics
 Journal of Immunological Methods
 Journal of Infectious Diseases
 Journal of the American Medical Association
 Journal of the American Statistical Association
 Mathematical Bioscience
 PLoS Neglected Tropical Diseases
 Statistica Sinica
 Statistics in Medicine
 Studies in Family Planning
 Technometrics

HONORS AND AWARDS

1984	Chateaubriand Scholarship for study in France
1987	Phi Beta Kappa
1987	Delta Omega, Alpha Chapter
1987	NCI/INSERM Bilateral Award for research in France
2003	Exceptional Public Service Award (Secretary of Defense; for work on the Anthrax Vaccine Expert Committee)

PUBLICATIONS

Peer Reviewed Journal Articles, Published or Accepted

1. Lê, M.G., **Moulton, L.H.**, Hill, C., Kramar, A.: Consumption of Dairy Produce and Alcohol in a Case-Control Study of Breast Cancer. Journal of the National Cancer Institute, Vol. 77, 633-636, 1986.
2. Attali, P., Ink, O., Pelletier, G., Vernier, C., Jean F., **Moulton, L.**, and Etienne, J.-E.: Dupuytren's contracture, alcohol consumption, and chronic liver disease. Archives of Internal Medicine, Vol. 147, 1065-1067, 1987.
3. Seixas, N.S., Robins, T.G., **Moulton, L.H.**: The Use of Geometric and Arithmetic Mean Exposures in Occupational Epidemiology. American Journal of Industrial Medicine, Vol. 14, 465-477, 1988.
4. Hujoel, P.P., **Moulton, L.H.**: Evaluation of Test Statistics in Split-Mouth Clinical Trials. Journal of Periodontal Research, Vol. 23, 378-380, 1988.
5. **Moulton, L.H.**, Zeger, S.L.: Analyzing Repeated Measures on Generalized Linear Models via the Bootstrap. Biometrics, Vol. 45, 381-394, 1989.
6. Connolly, M.A., Kimball, A.W., and **Moulton, L.H.**: Alcohol and Traffic Safety: A Sensitivity Analysis of Data from Composite Sources. Accident Analysis and Prevention, Vol. 21, 1-31, 1989.
7. Hujoel, P.P., **Moulton, L.H.**, Loesche, W.J.: Estimation of Sensitivity and Specificity of Site-Specific Diagnostic Tests. Journal of Periodontal Research, Vol. 25, 193-196, 1990.
8. Seixas, N.S., Robins, T.G., Rice, C.H., **Moulton, L.H.**: Assessment of Potential Biases in the Application of MSHA Respirable Coal Mine Dust Data to an Epidemiologic Study. American Industrial Hygiene Association Journal, Vol. 51, 534-540, 1990.
9. **Moulton, L.H.**, Zeger, S.L.: Bootstrapping Generalized Linear Models. Computational Statistics and Data Analysis, Vol. 11, 53-63, 1991.
10. Seixas, N.S., **Moulton, L.H.**, Robins, T.G., Rice, C.H., Attfield, M.D., Zellers, E.T.: Estimation of Cumulative Exposures for the National Study of Coal Workers' Pneumoconiosis. Applied Occupational and Environmental Hygiene, Vol. 6, 1032-1041, 1991.
11. **Moulton, L.H.**, Lê, M.G.: Latency and Time-Dependent Exposure in a Case-Control Study. Journal of Clinical Epidemiology, Vol. 44, 915-923, 1991.
12. Weissfeld, L.A., St. Laurent, R.T., **Moulton, L.H.** (random order): Confidence Intervals for the Comparison of Two Poisson Distributions. Communications in

- Statistics - Theory and Methods, Vol. 20, 3071-3081, 1991.
13. Foxman, B., **Moulton, L.H.**, Wolfe, R.A., Guire, K.E., Port, F.K, Hawthorne, V.M.: Geographic Variation in the Incidence of Treated End-Stage Renal Disease. The Journal of the American Society of Nephrology, Vol. 2, 1144-1152, 1991.
 14. Seixas, N.S., Robins, T.G., Attfield, M.D., **Moulton, L.H.**: Exposure-Response Relationships for Coal Mine Dust and Obstructive Lung Disease Following Enactment of the Federal Coal Mine Health and Safety Act of 1969. American Journal of Industrial Medicine, Vol. 21, 715-734, 1992.
 15. **Moulton, L.H.**, Port, F.K., Wolfe, R.A., Foxman, B., Guire, K.E.: Patterns of Low Incidence of Treated End-Stage Renal Disease Among the Elderly. American Journal of Kidney Diseases, Vol. 20, 55-62, 1992.
 16. Halsey, N.A., Coberly, J.S., Holt, E., Coreil, J., Kissinger, P., **Moulton, L.H.**, Brutus, J.-R., Boulos, R.: Sexual Behavior, Smoking and HIV-1 Infection in Haitian Women. Journal of the American Medical Association, Vol. 267, 2062-2066, 1992.
 17. **Moulton, L.H.**, Weissfeld, L.A., St. Laurent, R.T. (random order): Bartlett Correction Factors in Logistic Regression Models. Computational Statistics and Data Analysis, Vol. 15, 1-11, 1993.
 18. Seixas, N.S., Robins, T.G., Attfield, M.D., **Moulton, L.H.**: Longitudinal and Cross-Sectional Analyses of Coal Mine Dust Exposure and Pulmonary Function in New Miners. British Journal of Industrial Medicine, Vol. 50, 929-937, 1993.
 19. Holt, E.A., **Moulton, L.H.**, Siberry, G.K., Halsey, N.A. Differential Mortality by Measles Vaccine Titer and Sex. The Journal of Infectious Diseases, Vol. 168, 1087-1096, 1993.
 20. **Moulton, L.H.**, Foxman, B., Wolfe, R.A., Port, F.K. Potential Pitfalls in Interpreting Maps of Stabilized Rates. Epidemiology, Vol. 5, 297-301, 1994.
 21. Schechter, M., Harrison, L.H., Halsey, N.A., Trade, G., Santino, M., **Moulton, L.H.**, Quinn, T.C. Co-infection with Human T-Cell Lymphotropic Virus Type I and HIV in Brazil: Impact on Markers of HIV Disease Progression. Journal of the American Medical Association, Vol. 271, 353-357, 1994.
 22. Newcomer, W., Rivin, B., Reid, R., **Moulton, L.H.**, Wolff, M., Croll, J., Johnson, C., Brown, L., Nalin, D., Santosham, M. Immunogenicity, Safety, and Tolerability of Varying Doses and Regimens of Inactivated Hepatitis A (HAV) Vaccine in Navajo Children. The Pediatric Infectious Disease Journal, Vol. 13, 640-642, 1994.
 23. Manning, W.G., Blumberg, L., **Moulton, L.H.** The Demand for Alcohol: the Differential Response to Price. The Journal of Health Economics, Vol. 14, 123-148, 1995.

24. **Moulton, L.H.**, Holt, E.A., Job, J.S., Halsey, N.A. Percentile Regression Analysis of Correlated Antibody Responses. Statistics in Medicine, Vol. 14, 777-787, 1995.
25. **Moulton, L.H.**, Wolff, M.C., Brenneman, G., Santosham, M. Case-Cohort Analysis of Case-Coverage Studies of Vaccine Effectiveness. American Journal of Epidemiology, Vol. 142, 1000-1006, 1995.
26. **Moulton, L.H.**, Halsey, N.A. A Mixture Model with Detection Limits for Regression Analyses of Antibody Response to Vaccine. Biometrics, Vol. 51, 1570-1578, 1995.
27. Yoon, P.W., Black, R.E., **Moulton, L.H.**, Becker, S. The Effect of Not Breastfeeding on the Risk of Diarrheal and Respiratory Mortality in Children Under Two Years of Age in Cebu, The Philippines. American Journal of Epidemiology, Vol. 143, 1142-1148, 1996.
28. Dibley, M.J., Sadjimin, T., Kjolhede, C.L., **Moulton, L.H.** Vitamin A Supplementation Fails to Reduce Incidence of Acute Respiratory Illness and Diarrhea in Preschool-age Indonesian Children. Journal of Nutrition, Vol. 126, 434-442, 1996.
29. **Moulton, L.H.**, Halsey, N.A. A Mixed Gamma Model for Regression Analyses of Quantitative Assay Data. Vaccine, Vol. 14, 1154-1158, 1996.
30. Riley, A.P., Khan, N.U., **Moulton, L.H.** Predictors of First Birth Interval Length in Rural Bangladeshi Women. Population, Vol. 4-5, 883-896, 1996.
31. Robin, L.F., Lees, P.S.J., Winget, M., Steinhoff, M., **Moulton, L.H.**, Santosham, M., Correa, A. Wood-burning Stoves and Lower Respiratory Illnesses in Navajo Children Pediatric Infectious Disease Journal, Vol. 15, 859-865, 1996.
32. Yoon, P.W., Black, R.E., **Moulton, L.H.**, Becker, S. The Effect of Malnutrition on the Risk of Diarrhea and Respiratory Mortality in Children < 2 y of Age in Cebu, Philippines. American Journal of Clinical Nutrition, Vol. 65, 1070-1077, 1997.
33. Schechter, M., **Moulton, L.H.**, Harrison, L.H. HIV Viral Load and CD4⁺ Lymphocyte Counts in Subjects Coinfected with HTLV-I and HIV-1. Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology, Vol. 15, 308-311, 1997.
34. Santosham, M., **Moulton, L.H.**, Reid, R., Croll, J., Brenneman, G., Weatherholtz, R., Ward, R., Davidson, B., Forro, J., Zito, E., Mack, M., Camardo, J. Efficacy and Safety of High-Dose Rhesus-Human Reassortant Rotavirus Vaccine in Native American Populations. Journal of Pediatrics, Vol. 131, 632-638, 1997.
35. **Moulton, L.H.**, Dibley, M.J. Multivariate Time-to-Event Models for Studies of Recurrent Childhood Diseases. International Journal of Epidemiology, Vol. 26, 1334-1339, 1997.
36. Halsey, N.A., Coberly, J.S., Desormeaux, J., Losikoff, P., Atkinson, J., **Moulton, L.H.**, Contave, M., Johnson, M., Davis, H., Geiter, L., Johnson, E., Huebner, R., Boulos, R.,

- Chaisson, R.E. Intermittent Preventive Therapy for Tuberculosis with Isoniazid or Rifampin and Pyrazinamide in Persons Infected with Human Immunodeficiency Virus. The Lancet, Vol. 351, 786-792, 1998.
37. Auerbach, B.S., Lake, A.M., Wilson, M.E., Willingham, F.F., Shematek, J., **Moulton, L.H.**, Deforest, A., Halsey, N.A. Dose-Response to a Two Component Acellular Pertussis Vaccine in Infants and Comparison with Whole-cell Vaccine. Biologicals, 1998, Vol. 26, 145-153.
38. Santoro-Lopes, G., Harrison, L.H., **Moulton, L.H.**, Lima, L.A.V., de Pinho, A.M.F., Hofer, C., Schechter, M. Gender and Survival After AIDS in Rio de Janeiro, Brazil. Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology, 1998, Vol. 19, 403-407.
39. **Moulton, L.H.**, Staat, M.A., Santosham, M., Ward, R.L. The Protective Effectiveness of Natural Rotavirus Infection in an American Indian Population. Journal of Infectious Diseases, Vol. 178, 1562-1566, 1998.
40. WHO/CHD Immunization-Linked Vitamin A Supplementation Study Group. Writing Committee: Arthur, P., Bahl, R., Bhan, M.K., Kirkwood, B.R., Martines, J., **Moulton, L.H.**, Penny, M.E., Ram, M., Underwood, B. Randomized Trial to Assess the Benefits and Safety of Linking Vitamin A Supplementation to Immunizations in Early Infancy. The Lancet, Vol. 352, 1257-1263, 1998.
41. Wolff, M.C., **Moulton, L.H.**, Newcomer W., Reid R., Santosham, M. A Case-Control Study of Risk Factors for *Haemophilus Influenzae* Type b Disease In Navajo Children. American Journal of Tropical Medicine & Hygiene, Vol 60, 263-266, 1999.
42. Halsey, N.A., **Moulton, L.H.**, O'Donovan, J.C., Walcher, J.R., Thoms, M.L., Margolis, H.S., Krause, D.S. Hepatitis B Vaccine Administered to Children and Adolescents at Yearly Intervals. Pediatrics, Vol 103:1243-1247, 1999.
43. Wawer, M.J., Sewankambo, N.K., Serwadda, D., Quinn, T.C., Paxton, L.A., Kiwanuka, N., Wabwire-Mangen, F., Li, C., Lutalo, T., Nalugoda, F., Gaydos, C.A., **Moulton, L.H.**, Meehan, M.O., Ahmed, S., Gray, R.H. Control of Sexually Transmitted Diseases for AIDS Prevention in Uganda: a Randomised Community Trial. The Lancet, Vol. 353, 525-535, 1999.
44. The Institute for Vaccine Safety Diabetes Workshop Panel. Childhood immunizations and type 1 diabetes: summary of an Institute for Vaccine Safety Workshop. Pediatric Infectious Disease Journal, Vol 18, 217-222, 1999.
45. Harrison, L.H., do Lago, R.F., Friedman, R.K., Rodrigues, J., Santos, E.M., de Melo, M.F., **Moulton, L.H.**, Schechter, M. Incident HIV Infection in a High-Risk, Homosexual, Male Cohort in Rio de Janeiro, Brazil. Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology, Vol. 21, 408-412, 1999.

46. Gray, R.H., Wawer, M.J., Sewankambo, N.K., Serwadda, D., Li, C., **Moulton, L.H.**, Lutalo, T., Wabwire-Mangen, F., Meehan, M.P., Ahmed, S., Paxton, L.A., Kiwanuka, N., Nalugoda, F., Korenromp, E.L., Quinn, T.C. and the Rakai Project Team. Relative risks and Population Attributable Fraction of Incident HIV Associated with Symptoms of Sexually Transmitted Diseases and Treatable Symptomatic Sexually Transmitted Disease in Rakai District, Uganda. AIDS, Vol. 13, 2113-2123, 1999.
47. Hadi, H., Stoltzfus, R.J., **Moulton, L.H.**, Dibley, M.J., West, K.P. Jr. Respiratory Infections Reduce the Growth Response to Vitamin A Supplementation in a Randomized Controlled Trial. International Journal of Epidemiology, Vol. 28, 874-881, 1999.
48. Hadi, H., Stoltzfus, R.J., Dibley, M.J., **Moulton, L.H.**, West, K.P. Jr., Kjolhede, C.L., Sadjimin, T. Vitamin A Supplementation Selectively Improves Linear Growth of Indonesian Preschool Children: Results from a Randomized Controlled Trial. American Journal of Clinical Nutrition, Vol. 71, 507-513, 2000.
49. **Moulton, L.H.**, Chung, S., Croll, J., Reid, R., Weatherholtz, R.C., Santosham, M. Estimation of the Indirect Effect of Hib Conjugate Vaccine in an American Indian Population. International Journal of Epidemiology, Vol. 29, 753-756, 2000.
50. Qureshi, H., Gessner, B.D., Leboulleux, D., Hasan, H., Alam, S.E., **Moulton, L.H.** The Incidence of Vaccine Preventable Influenza-like Illness Among Pakistani Pilgrims to the Haj Using Influenza Vaccine as a Probe. Vaccine, Vol.18, 2956-2962, 2000.
51. **Moulton, L.H.**, O'Brien, K.L., Kohberger, R., Chang, I., Reid, R., Weatherholtz, R., Hackell, J.G., Siber, G.R., Santosham, M. Design of a Group-Randomized *Streptococcus pneumoniae* Vaccine Trial. Controlled Clinical Trials, Vol. 22, 438-452, 2001.
52. Gray, R.H., Wabwire-Mangen, F., Kigozi, G., Sewankambo, N.K., Serwadda, D., **Moulton, L.H.**, Quinn, T.C., O'Brien, K.L., Meehan, M., Abramowsky, C., Robb, M., Wawer, M.J. Randomized Trial of Presumptive Sexually Transmitted Disease Therapy During Pregnancy in Rakai, Uganda. American Journal of Obstetrics and Gynecology, Vol. 185, 1209-1217, 2001.
53. Sever, J.L., Brenner, A.I., Gale, A.D., Lyle, J.M., **Moulton, L.H.**, West, D.J. (alphabetical order after first author). Safety of Anthrax Vaccine: A Review by the Anthrax Vaccine Expert Committee (AVEC) of Adverse Events Reported to the Vaccine Adverse Event Reporting System (VAERS). Pharmacoepidemiology and Drug Safety, Vol. 11, 1-14, 2002.
54. Checkley, W., Gilman, R.H., Black, R.E., Lescano, A.G., Cabrera, L., Taylor, D.N., **Moulton, L.H.** Effects of Nutritional Status on Diarrhea in Peruvian Children. Journal of Pediatrics, Vol. 140, 210-218, 2002.
55. Go, V.F., Quan, V.M., Chung, A., Zenilman, J.M., **Moulton, L.H.**, Celentano, D.D. Barriers to Reproductive Tract Infection (RTI) Care Among Vietnamese Women: Implications for RTI Control Programs. Sexually Transmitted Diseases, Vol. 29, 201-

- 206, 2002.
56. Benini, A.A., **Moulton, L.H.**, Conley, C.E. Landmines and Local Community Adaptation. Journal of Contingencies and Crisis Management, Vol. 10, 82-94, 2002.
 57. **Moulton, L.H.**, Curriero, F.C., Barroso, P.F. Mixture Models for Quantitative HIV RNA Data. Statistical Methods in Medical Research, Vol. 11, 1-9, 2002.
 58. Ball, R., Halsey, N., Braun, M.M., **Moulton, L.H.**, Gale, A.D., Rammohan, K., Wiznitzer, M., Johnson, R., Salive, M.E., and the VAERS Working Group. Development of Case Definitions for Acute Encephalopathy, Encephalitis, and Multiple Sclerosis Reports to the Vaccine Adverse Event Reporting System. Journal of Clinical Epidemiology, Vol. 55, 819-824, 2002.
 59. Bahl, R., Bhandari, N., Wahed, M.A., Kumar, G.T., Bhan, M.K., and the WHO/CHD Immunization-Linked Vitamin A Group. Vitamin A Supplementation of Women Postpartum and of Their Infants at Immunization Alters Breast Milk Retinol and Infant Vitamin A Status. The Journal of Nutrition, Vol.32, 3243-8, 2002.
 60. Furth, S.L., Hogg, R.J., Tarver, J., Moulton, L.H., Chan, C., Fivush, B.A. Varicella Vaccination in children with Chronic Renal Failure: A Report of the Southwest Pediatric Nephrology Study Group. Pediatric Nephrology, Vol. 18, 33-38, 2003.
 61. Garcia, H.H., Gilman, R.H., Gonzalez, A.E., Verastegui, M., Rodriguez, S., Gavidia, C., Tsang, V.C.W., Falcon, N., Lescano, A.G., **Moulton, L.H.**, Bernal, T., Tovar, M., and The Cysticercosis Working Group in Peru. Hyperendemic Human and Porcine *Taenia Solium* Infection in Peru. American Journal of Tropical Medicine & Hygiene, Vol. 68, 268-275, 2003.
 62. Kalter, D., Salgado, R., **Moulton, L.H.**, Nieto, P., Contreras, A., Egas, M.L., Black, R.E. Factors Constraining Adherence to Referral Advice for Severely Ill Children Managed by the Integrated Management of Childhood Illness Approach in Imbabura Province, Ecuador. Acta Paediatrica, Vol. 92, 103-110, 2003.
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Book Chapters

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Other Publications

Reports:

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Jefferys, J., Lee, T., **Moulton, L.**, Tonascia, J.: Hypertension Prevention Trial Clinic Data System Handbook (Vols. 1-4). National Technical Information Service (NTIS), U.S. Dept. of Commerce, Springfield, Virginia, 1984.

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Moulton, L.H., Wolfe, R.A., Guire, K.E.: Investigation of Statistical Methodology Utilized by the U.S. Renal Data System: The Use of Cox's Proportional Hazards Model for Observational Data. An Existing Data Study of the USRDS/Urban Institute, 1991.

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Moulton, L.H., Ross, A.: Protocol for the Sample Survey Component of the Level One Survey of the Global Landmine Survey. Prepared for the Vietnam Veterans of America Foundation, Washington, D.C., 1999.

Moulton, L.H.: Analysis of Kosovo District Data on Mine/UXO Incidents in 1999: District-Level Risk Factors. Prepared for the Vietnam Veterans of America Foundation, Washington, D.C., 2000.

Benini, A.A., Conley, C.E., Haeni, R.E., Messick, S., **Moulton, L.H.**, Wennerström, M. (alphabetical order): Decision Support for Mine Action. First report in the series— Navigating Post-Conflict Environments: Humanitarian Information Management. Vietnam Veterans of America Foundation/Information Management & Mine Action Programs, Washington, D.C., 2002.

Letters/Editorials:

Lê, M.G., Hill, C., Kramar, A., **Moulton, L.H.**: Possible Cohort Effects in Studies on Oral Contraceptive Use and Breast Cancer. British Journal of Cancer, Vol. 52, 805-806, 1985.

Moulton, L.H.: Centered, Not Centralized. The American Statistician, Vol. 40, 77, 1986.

Moulton, L.H.: Answer: Truncation, Etc. Terminology. Q/A Column of The Survey Statistician, 1991.

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MacIntyre CR, Kelly H, Jolley D, Butzkueven H, Salmon D, Halsey N, **Moulton LH**. Recombinant hepatitis B vaccine and the risk of multiple sclerosis: a prospective study. Neurology, Vol. 64, 1317, 2005.

Moulton, L.H. A Practical Look at Cluster-Randomized Trials. Clinical Trials, Vol. 2, 89, 2005. Editorial; also, edited this issue's set of articles on cluster-randomized trials stemming from a Medical Research Council conference.

CURRICULUM VITAE

LAWRENCE HALE MOULTON

PART II**TEACHING****Advisees**

Fernando Diaz, ScD Program, 1993-2001 (ABD, epidemiologist for Pfizer)
Hector Garcia, PhD Program, 1997-2002 (Professor of Neurology, U. Cayetano Heredia)
Andres Lescano, PhD Program, 1998-2007
Mirko Juan Zimic, PhD Program, 1999-2007
Yandong Qiang, PhD Program, 1999-2006
Monisha Jayakumar, PhD Program, 2005-present
Sofia Arriola, PhD Program, 2005-present
Saad bin Omer, PhD Program, 2003-2006
Wei-ju Chen, PhD Program, 2006-present

Guilherme Santoro-Lopes, Fogarty Fellow, 1996
Sandra Fuchs, Post-doctoral Fellow, 1996-7
William Pan, Post-doctoral Fellow, 2004-2005

James Borton, MPH Program, 1993-1994
Margaret MacDonald, MPH Program, 1993-1994
Judith Frank, MPH Program, 1994-1995
Claire Morin, MPH Program, 1994-1995
Michael Blum, MPH, 2004-2005 (not the advisor, just Capstone director)
Farideh Garmroudi, MPH Program 2005-2006 (and Capstone director)
Hasan Shihab, MPH Program 2005-2006 (not the advisor, just Capstone director)
Al Salem, MPH 2006-2007
Ali Lotfizadeh, MPH, 2007-

Summer Martin, MHS Program, 2000-2002
Tomoko Murayama, MHS Program, 2001-2003
Sheng-Shia Chung, MHS Program, 2002-2004
Stephanie Richard, MHS Program, 2002-2004
Terrell Carter, MHS Program, 2004-2006
Martha Montgomery, MHS Program, 2004-2005
Stephanie Irving, MHS Program, 2005-2007
Aimee Summers, MHS Program, 2005-2007
Mona Rahmani, MHS Program, 2005-2007
Brian Pike, MHS 2006-2007

Kirsten Vannice, MHS 2006-present

Preliminary Oral Participation

Yan Wang	June 1992	Population Dynamics
Steven Yoon	August 1992	International Health
Shu-Hui Chang	September 1992	Biostatistics
Yuchi Young	September 1992	Health Policy & Management
Paula Yoon	October 1992	International Health
Logan Brenzel	April 1993	International Health
Chris Forrest	July 1993	Health Policy & Management
Qi Mao	April 1994	Mathematical Sciences
Elizabeth Van Den Kerkhof	August 1994	Population Dynamics
Jing-Yee Kou	August 1994	Biostatistics
Hongzi Chen	September 1994	Biostatistics
Karina Kielmann	September 1995	International Health
Fernando Diaz	April 1996	International Health
Paulo Barroso	May 1996	International Health
Ying Qing Chen	August 1996	Biostatistics
Jane Jing Xu	September 1996	Biostatistics
Lisa Lee	December 1996	Population Dynamics
Hector Garcia	October 1997	International Health
Ricardo Rodrigues	October 1997	International Health
Wei-Ting Hwang	October 1997	Biostatistics
Robert Kelly	June 1998	Population Dynamics
Xianbin Li	April 1999	Biostatistics
Ming-Yu Fan	September 1999	Biostatistics
Chiung-Yu Huang	September 1999	Biostatistics
Laura Porter	October 1999	Population and Family Health Sciences
Natalie Blades	January 2000	Biostatistics
Emi Suzuki	February 2000	Population and Family Health Sciences
Manju Rani	March 2000	Population and Family Health Sciences
Asghar Nazeer	May 2000	Population and Family Health Sciences
Andres Lescano	August 2000	International Health
Shangqian Qi	March 2001	Epidemiology
Mirko Zimic	January 2002	International Health
Batya Elul	May 2002	Population and Family Health Sciences
Michelle Shardell	December 2002	Biostatistics
David Cohen	February 2003	Biostatistics
Mai Do	September 2003	Population and Family Health Sciences
Fan Li	October 2003	Biostatistics

Rongheng Lin	December 2003	Biostatistics
Adaline Muyeed	January 2004	Population and Family Health Sciences
Haijiang Wang	February 2004	Population and Family Health Sciences
Wanchung Hu	February 2004	International Health
Elizabeth Johnson	December 2004	Biostatistics
Xiaojun You	December 2004	Biostatistics
John McGready	January 2005	Biostatistics
Ann Miller	March 2005	Epidemiology
Sanny Chen	January 2006	International Health
Shivam Gupta	May 2006	Epidemiology
Xianbin Li	August 2006	Biostatistics
Christina Schumacher	September 2006	Epidemiology
Chongzhi Di	December 2006	Biostatistics
Keri Althoff	December 2006	Epidemiology

Final Oral Participation

(5 Ph.D. defenses at University of Michigan, 1987-1991)

Joanne Katz, Sc.D.	May 1992	International Health
Jiangang Liao, Ph.D.	March 1993	Biostatistics
Yan Wang, Dr.P.H.	October 1993	Population Dynamics
Paula Yoon, Sc.D.	November 1993	International Health
Laurence Magder, Ph.D.	March 1994	Biostatistics
Yutaka Yasui, Ph.D.	April 1994	Biostatistics
John Hanfelt, Ph.D.	August 1994	Biostatistics
Kai-Li Liaw, Ph.D.	October 1994	Epidemiology
Saul Morris, Ph.D.	January 1995	

(University of London, School of Hygiene and Tropical Medicine)

Sunil Sazawal, Ph.D.	May 1995	International Health
Patrick Heagerty, Ph.D.	August 1995	Biostatistics
Hongzi Chen, Ph.D.	March 1997	Biostatistics
Min-Chi Chen, Ph.D.	September 1997	Biostatistics
Elizabeth Van Den Kerkhoff, Dr.P.H.	February 1998	Population Dynamics
Lisa Lee, Ph.D.	March 1998	Population Dynamics
Wenzheng Huang, Ph.D.	August 1998	Biostatistics
Ying Qing Chen, Ph.D.	March 1999	Biostatistics
Jane Xu, Ph.D.	August 1999	Biostatistics
Yen-Feng Chiu, Ph.D.	October 1999	Biostatistics
Renee Rees, Ph.D.	June 2000	Biostatistics
Robert Kelly, Ph.D.	December 2000	Population and Family Health Sciences
Xianbin Li, Ph.D.	March 2001	Biostatistics
Asghar Nazeer, Dr.P.H.	March 2001	Population and Family Health Sciences
Hector Garcia, Ph.D.	December 2001	Advisor; International Health
Ming-Yu Fan, Ph.D.	March 2002	Biostatistics

Chiung-Yu Huang, Ph.D.	March 2002	Biostatistics
Peyvand Khalegian, Dr.P.H.	October 2002	International Health
Paul Freeman, Dr.P.H.	November 2002	International Health
Wesley Eddings, Ph.D.	October 2003	Biostatistics
Frederick Makumbi, Ph.D.	November 2003	Population and Family Health Sciences
Hans Steinsland, Ph.D.	December 2003	
(University of Bergen, Department of Microbiology and Immunology)		
Mai Phuong Do, Dr.P.H.	October 2004	Population and Family Health Sciences
Michelle Shardell, Ph.D.	November 2004	Biostatistics
Irina Zablotska	December 2004	Population and Family Health Sciences
Carolyn Mohan, Dr.P.H.	March 2005	Population and Family Health Sciences
Marta Marsh, Ph.D.	March 2005	Epidemiology
Aamir Khan, Ph.D.	August 2005	International Health
Fan Li, Ph.D.	March 2006	Biostatistics
Rudolf Titanji, Ph.D.	March 2006	International Health
Claudine Shinoff, Ph.D.	March 2006	Epidemiology
Ann Miller, Ph.D.	November 2006	Epidemiology
Saad bin Omer, Ph.D.	December 2006	International Health
Sanny Chen	March 2007	International Health
Xiaojun You	April 2007	Biostatistics
Wan-chung Hu	July 2007	International Health
Andres Lescano	June 2007	International Health
Alison Gump	September 2007	Epidemiology
Mirko Zimic	October 2007	International Health

Sc.M Reader

Christofer Price	March 1995	Biostatistics
Shing Mirn Lee	April 1998	Biostatistics
Liping Li	April 1998	Biostatistics
Ting-Li Su	September 1998	Biostatistics
Cissy Mutuluza	December 1998	International Health
Bryan Lau	September 1999	Epidemiology
Lauren Cain	April 2005	Epidemiology
Brendan Klick	August 2005	Epidemiology
Blake Charvat	May 2007	Biostatistics

Classroom Instruction

l'Université Nationale du Bénin (1980):

Théorie et Pratique du Sondage (1 semestre)

Introduction aux Méthodes Statistiques (1 semestre)

The University of Michigan (1986-1991):

Statistical Methods in Environmental Epidemiology (5 semesters)
 Analysis of Variance (2 semesters)
 Statistical Methods for Epidemiologic Studies (5 semesters)
 Demographic Methods (2 semesters)

University of Hanoi Medical College:

Biostatistics: A Basic Course (2 wk, 6 hr/day, 1996)

The Johns Hopkins University:

International Health Graduate Seminar, 1 credit each term

(Ave. 16 enrolled per term, 4 terms 1991-1992, 4 terms 1992-1993, 4 terms 1993-1994, 4 terms 1994-1995, 4 terms 1995-1996, 2 terms 1997, 2 Terms 1998, 2 terms 1999, 2 terms 2000, 2 terms 2001, 2 terms 2002, 2 terms 2003)

Center for Clinical Trials short course lecture, 1998: Restricted Randomization and Stratification

Sample size section of BSPH distance education course: *Clinical Vaccine Trials: Planning and Implementation*; 2000-present

Group-Randomized Trials–special studies course, 1 term 2000, 1 credit, with Anthony & Valente

DPC Doctoral Research Seminar (8 enrolled, 1 term 2003, 3 terms 2004; 6 enrolled, 4 terms 2004-2005; 4 enrolled, 4 terms 2005-2006; 5 enrolled, 2 terms 2006)

RESEARCH GRANT PARTICIPATION

Tuberculosis and HIV Infection, ended 9/92, CDC.

Role: Principal Statistician, 36% FY 91-92 effort.

Clinical trial for tuberculosis prevention among HIV-infected Haitians.

HIV and HTLV-1 Cohort Studies of Haitian Women and Infants, ended 5/92, NIAID.

Role: Principal Statistician, 26% FY 91-92 effort.

Investigation of factors relating to prevalence and transmission of HIV and HTLV-1.

REACH Measles Vaccine Study Follow-Up, ended 12/91, John Snow.

Role: Principal Statistician, 12% FY 91-92 effort.

Investigation of the effect of high-titer measles vaccine on mortality in Haitian children.

Morbidity and Vitamin A Study, ended 12/92, AID.

Role: Statistical Consultant/Principal Statistician, 20% FY 92-93 effort.

Evaluation of the benefit of vitamin A supplementation in terms of morbidity outcomes in a randomized trial in Central Java.

Rotavirus Vaccine Efficacy in Gila River, Apache and Navajo Children, ended 1/94, Wyeth-Ayerst.

Role: Principal Statistician, 10% FY 92-93 effort.

Investigation of safety, immunogenicity and efficacy of two RRVs.

Low Birth Weight, Malnutrition and Non-Breastfeeding as Risk Factors for Diarrhea and Pneumonia Mortality, ended 8/93, WHO.

Role: Statistical Consultant, 5% FY 92-93 effort.

Investigation of main and interactive effects of LBW, PCM, and not breastfeeding on pneumonia and diarrhea mortality in the Philippines.

TB/HIV Demonstration Project-Trial Preventive Therapy Efficacy Study, ended 9/94, CDC.

Role: Principal Statistician, 13% effort.

Study compares compliance, adverse reactions, antimicrobial resistance, and efficacy of two TB prophylactic regimens among HIV-infected Haitians.

Statistical Methodology for Vaccine Evaluation, ended 11/98, NIAID FIRST Award.

Role: Principal Investigator, 50% effort.

Development of methodology for planning and evaluating clinical and observational vaccine studies.

Long Term Efficacy of BCG Vaccine Among American Indians and Alaska Natives, ended 9/95, DHHS/PHS.

Role: Principal Statistician, 30% effort.

To determine long term protective value of BCG vaccine and examine cancer incidence and mortality in a 56-year follow-up of 3000 participants in a clinical trial initiated in 1936.

Pneumococcal Vaccine in HIV Positive Adults, ended 5/94, Praxis Biologicals.

Role: Principal Statistician, 14% effort.

To compare immunogenicity and safety of the licensed 23-valent Pnu-Immune vaccine to a pentavalent CRM197 investigational vaccine.

Long-Term Follow-up After High Titer Measles Vaccine, ended 8/95, NIAID.

Role: Principal Statistician, 5% effort.

To 1) obtain blood specimens on 400 participants in the high titer measles vaccine trial and to store sera and PBMCs for subsequent studies and 2) determine if there was a persistent difference of mortality as of 1993 in the study subjects.

Efficacy of TB Chemoprophylaxis in PPD(-) HIV(+) Adults, ended 1/99, NIAID.

Role: Principal Statistician, 5% effort.

To determine the efficacy of six months of daily isoniazid (INH) or three months of daily rifampin (RIF) in preventing tuberculosis (TB) in HIV seropositive, chest radiograph (CXR) negative, tuberculin skin test (PPD) negative adults residing in an area highly endemic for TB.

Preparatory AIDS Vaccine Evaluation Study in Rio de Janeiro (Subcontract for Preparatory AIDS Vaccine Evaluate Studies & Non-Vaccine Preventive Intervention Trials), ended 10/97, FHI.

Role: Principal Statistician, 10%

To determine the HIV seroincidence in a cohort of 2,000 homosexual or bisexual men aged 18 to 35 in Rio de Janeiro, Brazil, a WHO HIV vaccine evaluation site.

Reduction of HIV Transmission and Viable Home Care for People with AIDS and HIV Infection: "The Community Home Care Project", ended 9/96, before full initiation, Government of Kenya (World Bank).

Role: Statistical Consultant, 4% effort.

To reduce HIV transmission in Kenya through control of other sexually transmitted diseases (STD), to control tuberculosis by preventing disease in high risk individuals, and to provide integrated home care to people with HIV and AIDS.

Efficacy of HIVIG Administered to Infants for Prevention of Maternal-Infant HIV Transmission (Subcontract for Preparatory AIDS Vaccine Evaluate Studies & Non-Vaccine Preventive Intervention Trials), ended 9/97, before full initiation, FHI.

Role: Principal Statistician, 5% effort.

To determine if one dose of hyperimmune HIV intravenous immune globulin (HIVIG) administered to infants born to HIV seropositive women will effectively reduce the risk of maternal-infant HIV transmission (MIT).

Planning Grant for the Conjugate Pneumococcal Vaccine Efficacy Trial, ended 9/95, Connaught.

Role: Principal Statistician, 10% effort.

To set up logistics and obtain the necessary approvals from various community groups for the Octavalent Pneumococcal Vaccine Efficacy Trial.

Long Term Efficacy and Effectiveness of PedvaxHIB Among Navajo Children Following an Efficacy Trial, ended 8/95, Merck.

Role: Principal Statistician, 10% effort.

To evaluate the effectiveness of PedvaxHIB in the entire Navajo population.

Vitamin A Collaborating Studies Center, ended 12/97, USAID.

Role: Principal Investigator and Statistician for the Data Management Center of the Multicentre Trial on Immunization-Linked Vitamin A Supplementation, 10% effort.

Effects of vitamin A supplementation in conjunction with routine immunizations in a randomized trial of 9500 infants in three countries.

The Effect of Albendazole on Cysticercosis Associated Epilepsy, ended 8/01, FDA/SmithKline Beecham.

Role: Principal Statistician, 8% effort.

To examine, via a double blind randomized study, the effects of albendazole therapy on the severity and duration of epilepsy in Peruvian patients with epilepsy secondary to neurocysticercosis.

Safety, Reactogenicity and Efficacy of the Octavalent Mixture of Pneumococcal types 3, 4, 6B, 9V, 14, 18C, 19F and 23F Conjugate Vaccines (PncD and PncT) in Infants, ended 8/96, Pasteur-Mérieux.

Role: Principal Statistician, 10% effort for planning.

To evaluate the vaccine efficacy of an octavalent preparation for invasive Spn disease in a controlled double blind trial.

A Randomized, Community Trial of STD Control for AIDS Prevention, Rakai District, Uganda, ended 4/99, NIH, Rockefeller, World Bank.

Role: Principal Statistician for last year of project, 25% effort.

To evaluate the effect on intensive STD control efforts on reduction of HIV incidence in a set of high HIV prevalence communities.

Standardized Definitions and Data Collection for Encephalitis, Encephalopathy, and Multiple Sclerosis in VAERS Reports, ended 7/99, FDA.

Role: Principal Statistician, 5% effort.

To improve the classification of selected severe neurologic disorders reported to VAERS.

A Double-Masked, Controlled Study of the Efficacy and Effectiveness of a Pneumococcal Vaccine Containing Seven Serotypes, ended 12/00, Wyeth-Lederle Vaccines and Pediatrics.

Role: Principal Statistician, 20% effort.

To demonstrate that the Pnc-7 vaccine is effective in preventing invasive vaccine-type pneumococcal disease occurring in infants and toddlers.

Family Health and Child Survival Cooperative Agreement (Strep Pneumo), ended 12/00, USAID. Role: Principal Statistician, 5% effort.

To integrate child survival and reproductive health and family planning activities to improve child survival.

Family Health and Child Survival Cooperative Agreement: IMCI Referral Study, ended 12/31/00, USAID.

Role: Principal Statistician, 4% effort.

Family Health and Child Survival Cooperative Agreement: Surveillance for Bacterial Infection in India (GRASP), ended 12/31/02, USAID.

Role: Principal Statistician, 10% effort.

To integrate child survival and reproductive health and family planning activities to improve child survival.

Merck/VAERS Database Comparison, ended 12/31/02, Merck.

Role: Principal Investigator, 15% effort.

To research and summarize data in the FDA's VAERS and Merck's WAES data systems with respect to events involving MMRII and VARIVAX vaccines.

Family Health and Child Survival Cooperative Agreement (Bacterial Meningitis), ended 12/31/02, USAID.

Role: Principal Statistician, 10% effort.

To integrate child survival and reproductive health and family planning activities to improve child survival.

Refining Clinical Criteria for Presumptive Drug Therapy of Suspected Streptococcal Pharyngitis: An Approach to Reducing Unnecessary Use of Antibiotics, ended 12/31/02, USAID.

Role: Principal Statistician, 10% effort.

To evaluate the modified guideline in order to reduce the unnecessary use of antibiotics which will allow more accurate use of presumptive antibiotic therapy.

Epidemiology and Effect of Prevnar, ended 12/31/02, Wyeth-Ayerst Pharmaceuticals.

Role: Principal Statistician, 10% effort.

To study the epidemiology and effect of Prevnar on pneumococcal disease among Navajo adults.

Nevirapine Use to Prevent Maternal-Infant HIV Transmission, ends 8/31/03, NIH/NIAID.

Role: Principal Statistician, 5% effort.

To compare the rates of HIV infection in infants born to HIV seropositive women in a trial incorporating NVP and early weaning interventions.

Novel TB Prevention Regimens for HIV-Infected Adults, ends 5/31/06, NIH/NIAID.

Role: Principal Statistician, 5% effort.

To determine the effectiveness of two novel treatments on the risk of TB in a population of HIV-infected adults receiving clinical care and follow up in Soweto, South Africa.

Zimbabwe Vitamin A for Mothers and Babies Project, ended 9/30/03, CIDA/USAID.

Role: Principal Statistician, 10% effort.

To evaluate effects of maternal and infant vitamin A supplementation on infant mortality and HIV transmission.

Statistical Methods in AIDS Research, ended 5/31/03, NIH/NICHD.

Role: Co-Investigator, 25% effort.

To develop and apply statistical methods in AIDS research to improve scientific inferences from longitudinal studies of HIV disease.

An Integrated Approach for the Control of Taenia Solium Cysticercosis (Peru), ends 8/31/04.

Role: Principal Statistician, 5% effort.

To develop a field-applicable serodiagnostic test and to better understand the transmission and infection dynamics for T. solium.

Technical Assistance Agreement: Lombok II (HIB Project), end 12/31/03.

Role: Principal Statistician, 20% effort.

To use Hib vaccine as a probe in a community-randomized trial to estimate the burden of vaccine-preventable pneumonias and other outcomes.

HIV-IG for Prevention of Vertical Transmission, ends 3/31/04, NIH/NIAID.

Role: Principal Statistician, 10% effort.

To develop a HIVIG product from Ugandan plasma for use in a phase I/II and phase III trial in Uganda to prevent HIV-1 vertical transmission.

Effect of Zinc and Iron on Mortality in Children- Zanzibar, ended 6/30/03, USAID.

Role: Statistician, 5% effort.

To provide critical information on the usefulness of improving zinc and iron status to enhance child survival in Zanzibar.

Safety and Efficacy of Pentavalent Human-bovine Reassortant Rotavirus Vaccine in Healthy Infants, ends 6/30/04, Merck Research Laboratories.

Role: Principal Statistician for American Indian component, 9% effort.

To evaluate the efficacy of a 3-dose regimen of the pentavalent human-bovine reassortant rotavirus vaccine against rotavirus disease caused by Serotypes G1, G2, G3, and G4 occurring more than 14 days following the third dose; and to assess the safety of the pentavalent human-bovine rotavirus vaccine with respect to intussusception within 42 days of any dose of vaccine/placebo.

Clinical Immunization Safety Assessment, ends 9/29/2006, CDC.

Role: Statistician, 5% effort.

To participate in the CDC coordinated network of centers to better define vaccine-associated adverse events, determine causal relationships with vaccines, identify risk factors, and improve the safety of immunization programs.

Implementation of Mandatory Immunization Laws, ends 4/30/2004, CDC.

Role: Principal Statistician, 15% effort.

To determine if variability in local implementation and enforcement of non-medical exemptions, and the knowledge, attitudes, and beliefs of school nurses/administrators are associated with the frequency of exemptions; determine the reasons why parents refuse to vaccinate their children; and explore issues surrounding privacy/confidentiality and costs associated with immunization registries.

New Paradigms for Reducing HIV-Related Tuberculosis, ends 8/31/04, Gates Foundation.

Role: Director, Biostatistics Core; Member, Executive Committee. 20% effort.

CREATE (Consortium to Respond Effectively to the AIDS/TB Epidemic), ends 2011, Gates Foundation.

Role: Director, Biostatistics Core; Member, Executive Committee. 50% effort.

This program project will conduct community randomized trials to control TB in HIV endemic areas. Magnitude of projects: almost \$45 million over 7 years.

A Phase 3 Study of MEDI-524 (Numax™), an Enhanced Potency Humanized Respiratory Syncytial Virus (RSV) Monoclonal Antibody, for the Prevention of RSV Disease Among Navajo and White Mountain Apache Infants, MedImmune.

Role: Principal Statistician, 10% effort.

Consultant, Pneumo-ADIP

Consultant, Bangladesh GRT health services project (Becker)

ACADEMIC SERVICE

Department

Computer Committee, 1992-1998, 2001–present

Pediatric Vaccine Monitoring Committee, 1993-1998

Behavioral Scientist Search Committee, 1999

Working Group on Academic Programs, Chair, 2000

Strategic Planning Committee, 2001

Faculty Budget Advisory Committee, 2002-present

Coordinator, Johns Hopkins Peace Corps Masters International Program, 2003-present

Strategic Directions Subcommittee, Chair, 2006

School

MPH Admissions Committee Member, 1991-1996

Ad Hoc Reviewer, 1997-1999

Strategic Planning Education/Academic Subcommittee, 1992-1993

Faculty Senator, 1995-1997; 1998-2000; 2002-2004, 2005-2007

Committee to Review the Department of Population Dynamics, 1997-1998

Committee on Affirmative Action, 1998-2001

Ad Hoc Promotions Committee Member, 1999-2000; 2002; 2003; 2004; (2007 for the School of Medicine) (referee several times for promotions elsewhere: University of Washington, University of London, Case Western Reserve University, University of Virginia)

Ad Hoc Subcommittee on Faculty Equity and Mentoring, 2000

Web Presence Committee, 2000

Committee on Human Research, New Applications Committee, 2002–2005

School Committee on Appointments and Promotions, 2005-2008

Faculty Research Initiatives Fund, 2005-2007

Committee to Review the Department of Biostatistics, 2007-2008

PRESENTATIONS

Scientific Meetings--Contributed Presentations

Moulton, L.H.: Bootstrapping Generalized Linear Models. Abstracts First European Biometric Conference, Budapest, Hungary, 1985.

Moulton, L.H.: Robustness Considerations in Bootstrapping Generalized Linear Models. Contributed Papers Centenary Session of the International Statistical Institute, Amsterdam, The Netherlands, 1985.

Moulton, L.H.: Bootstrapping Generalized Linear Models. The 2nd International Conference on Generalized Linear Models, Lancaster, United Kingdom, 1985.

Moulton, L.H.: Bootstrap and Robust Analyses of Matched Case-Control Studies. The ASA Joint Statistical Meetings, San Francisco, 1987.

Moulton, L.H., Lê, M.G.: Issues in Modelling Time-Dependent Exposure Data in Case-Control Studies. The ASA Joint Statistical Meetings, New Orleans, 1988.

Moulton, L.H., and Lê, M.G.: Time-Dependent Covariates in Retrospective Epidemiologic Studies. The 47th Session of the International Statistical Institute, Paris, 1989.

Moulton, L.H., St. Laurent, R.T., Weissfeld, L.A.: Bartlett Factors in Binomial Regression Analyses. The Biometric Society ENAR Spring Meeting, Houston, 1991.

Moulton, L.H., Port F.K., Wolfe, R.A., Foxman, B., Guire, K.E.: Patterns of Low Incidence of Treated End-Stage Renal Disease Among the Elderly. The APHA Annual Meeting, Atlanta, 1991.

Moulton, L.H., Wolfe, R.A., Port, F.K., Foxman, B.: An Appraisal of NCI Mapping Techniques with Application to End-Stage Renal Disease. The APHA Annual Meeting, Atlanta, 1991.

Moulton, L.H.: Use and Interpretation of Percentile Regression With Application to Measles Vaccine Safety Data. The ASA Joint Statistical Meetings, Boston, 1992.

Moulton, L.H.: The Weibull/GEE Model for Multivariate Survival Analysis. The Biometric Society ENAR Spring Meeting, Philadelphia, 1993.

Moulton, L.H.: The Analysis of Recurrent Childhood Diseases via Staggered and Bootstrapped Cox Regression Models. The Biometric Society ENAR Spring Meeting, Richmond, 1996.

Moulton, L.H., Benini, A.A., Conley, C.E., Messick, S.: Analyzing Landmine Incidents via Zero-Inflated Poisson Models. The APHA Annual Meeting, Atlanta, 2001.

Moulton, L.H.: Sensitivity, Specificity, and Their Relationship to Prevalence. Poster presentation. International Society for Clinical Biostatistics Annual Conference, Dijon, 2002.

Moulton, L.H., Chaudhary, M.A.: Constrain the randomization of your community randomized trial: Don't let bad luck ruin your multi-million dollar study! Poster presentation. APHA Annual Meeting, Washington, D.C., 2004.

Scientific Meetings--Invited Presentations

Moulton, L.H.: Bootstrapping Generalized Linear Models for Application to Longitudinal Data. SRCOS-ASA Cooperative Summer Research Conference in Statistics, Mobile, Alabama, 1986.

Moulton, L.H., Zeger, S.L.: Analyzing Epidemiologic Data Collected Over Time: Old Questions and New Answers. Invited speaker, the APHA Annual Meeting, Boston, 1988.

Moulton, L.H., Holt, E., Job, J.S. Halsey, N.A.: Regression Percentile Analyses of Weight-for-Age and Immunologic Response in a Haitian Measles Vaccine Study. Invited speaker, the APHA Annual Meeting, Washington, D.C., 1992.

Moulton, L.H., Holt, E.A., Job, J.S., Halsey, N.A.: Analyzing Antibody Response to Vaccine Via Percentile Regression. Invited speaker, the ASA Joint Statistical Meetings, San Francisco, 1993.

Moulton, L.H., Wolff, M.S., Brennenman, G.: Evaluation of Hib Vaccine Effectiveness Using a Case-Coverage Design. Invited speaker, the APHA Annual Meeting, San Francisco, 1993.

Moulton, L.H.: Correlated and Censored Weibull Responses in Infectious Disease Intervention Trials. Invited speaker, SRCOS-ASA Cooperative Summer Research Conference in Statistics, Williamsburg, Virginia, 1994.

Moulton, L.H.: Study Designs for the Evaluation of a Multivalent *Streptococcal pneumoniae* Vaccine in Infants with Sickle Cell Disease. Invited speaker, NIH Workshop on Immune Function in Sickle Cell Disease, Bethesda, 1995.

Moulton, L.H.: Beyond the Geometric Mean: Some Regressions Models for Antibody Responses to Vaccine. Invited speaker, Special Contributed Papers Session, The XVIIIth International Biometric Conference, Amsterdam, 1996.

Moulton, L.H.: Time-to-Event Models for Vaccine Studies: Old Answers to New Questions. Invited speaker, the ASA Joint Statistical Meetings, Dallas, 1998.

Moulton, L.H.: Community Randomized Vaccine Trials and Indirect Effects. Invited speaker, Drug Information Association 36th Annual Meeting, San Diego, 2000.

Moulton, L.H., Curriero, F.C., Barroso, P.F.: Mixture Models for Quantitative HIV RNA Data. Invited speaker, the ASA Joint Statistical Meetings, Indianapolis, 2000.

Moulton, L.H.: Covariate-Based Constrained Randomization of Group-Randomized Trials. Invited speaker, the Biometric Society ENAR Spring Meeting, Arlington, 2002.

Moulton, L.H., O'Brien, K.L, Weatherholtz, R., Reid, R., Katz, S., Donaldson, C., Parkinson, A., Hu, D., Kohberger, R., Chang, I., Hackell, J.G., Siber, G.R., Santosham, M. Efficacy of Conjugate Vaccine and Herd Immunity: Navajo/Apache Trial. 3rd International Symposium on Pneumococci and Pneumococcal Diseases, Anchorage, 2002.

Moulton, L.H.: Highly Constrained Randomization of a Clinc-Randomized Study with a Stepped Wedge Design. Invited speaker, APHA Annual Meetings, Philadelphia, 2005.

Moulton, L.H.: Design and Analysis of Cluster Randomized Phased Implementation Studies. Invited speaker, the Biometric Society ENAR Spring Meeting, Tampa, 2006.

Other Invited Seminars

Moulton, L.H.: L'Analyse des Données Longitudinales par la Méthode du Bootstrap. Séminaire de Statistiques Médicales, Paris V--INSERM, Paris, France, 1985.

- Moulton, L.H.:** Un Estimateur Robuste de la Variance: Application à l'Analyse des Etudes Cas-Témoins avec Appariement. Réunion Ouverte, l'Institut Gustave-Roussy, Villejuif, France, 1985.
- Moulton, L.H.:** Birnbaum et la Valeur de P. L'Institut Gustave-Roussy, Villejuif, France, 1987.
- Moulton, L.H.:** False Confessions: Protecting the Right of Data to Remain Silent (The multiple comparisons dilemma). Western Michigan University; Kalamazoo College; Adrian College; 1988.
- Moulton, L.H.:** Standardization of Rates: Principles and Examples. The Urban Institute, Washington, D.C., 1989.
- Moulton, L.H.:** The Lighter Side of Longitudinal Data. Henry Ford Hospital, Biometry Users Group Seminar, Detroit; The Population Studies Center, The University of Michigan, Ann Arbor; The International Center for Diarrheal Disease Research, Bangladesh; 1989.
- Moulton, L.H.:** Ecological Analysis. The 24th International Graduate Summer Session in Epidemiology, Ann Arbor, Michigan, 1989.
- Moulton, L.H.:** A Sandwich for All Seasons: Recent Uses of a Robust Variance Estimator. The University of Dhaka, Bangladesh, 1989.
- Moulton, L.H.:** Rating Maps and Mapping Rates of Treated End-Stage Renal Disease. Epidemiology Seminar, The Johns Hopkins University, 1992.
- Moulton, L.H.:** Statistical Strategies for Messy Longitudinal Data. Gadjah Mada University, Yogyakarta, Indonesia, 1992.
- Moulton, L.H.:** An Introduction to Percentile Regression With Application to High Titer Measles Vaccine. University of Maryland Medical School, Baltimore, 1993.
- Moulton, L.H.:** Asymmetric Least Squares Analysis of Correlated Antibody Response Data. Washington Statistical Society, NIH Bethesda, 1994.
- Moulton, L.H.:** Making the Data Fit the Analysis: A Case-Cohort Analysis of a Case-Coverage Vaccine Study. Center for Clinical Trials Monthly Seminar, The Johns Hopkins School of Hygiene and Public Health, Baltimore, 1994.
- Moulton, L.H.** and Santosham, M.: Observational and Community Randomized Studies of the Indirect Effects of Vaccines. Biostatistics Grand Rounds, The Johns Hopkins School of Hygiene and Public Health, Baltimore, 1998.
- Moulton, L.H.:** Interpreting Ecologic Data. Workshop on Childhood Immunizations and Insulin Dependent Diabetes Mellitus, Baltimore, 1998.
- Moulton, L.H.:** Methodologic Approaches: Ecologic Analyses. NIH Workshop on the Evaluation of the Possible Role of Vaccines and Infectious Diseases in Insulin Dependent (Type 1) Diabetes Mellitus, Bethesda, 1998.
- Moulton, L.H.:** Stratification and Restricted Randomization. Lecture in the Center for Clinical Trials course: Clinical Trials: Design, Analysis, and Dissemination of Results, Baltimore, 1998.
- Moulton, L.H.:** Not Your Average Models for Antibody Responses to Vaccine. Department of Mathematics, University of Maryland, College Park, 1998.
- Moulton, L.H.:** A Potpourri of Statistical Methods for Phase II-IV Vaccine Studies. Division of AIDS, NIAID, NIH, Rockville, 1998.
- Moulton, L.H.** and Halsey, N.A.: Type 1 Diabetes and Immunizations: No Evidence of a Deleterious Causal Link. 33rd National Immunization Conference, Dallas, 1999.

Moulton, L.H.: Indirect Effects of Vaccine: Some Approaches to Study Design and Analysis. Pasteur-Mérieux-Connaught, Serums et Vaccins, Marnes-la-Coquette, France, 1999.

Moulton, L.H.: Iran: A Leisurely Leishmanial Travelogue. The Johns Hopkins University, Baltimore, 1999.

Moulton, L.H.: A Couple Mixture Models for Data With “Excess” Zeros. Department of Community Medicine, Hôpital cantonal, HUG, Geneva, 2001.

Moulton, L.H.: Mixture Models for Antibody Response, HIV Viral Load, and Landmines. Haukeland University Hospital, Bergen, 2003; London School of Hygiene and Tropical Medicine, London, 2004.

Moulton, L.H.: Power and Constraint: A Phased Implementation Cluster Randomized Study. NIH/NIAID/OCR/Biostatistics Research Branch, Bethesda, 2007.

ADDITIONAL INFORMATION

Research

My research efforts may be placed in four categories:

1. The development of new statistical and epidemiologic methodology for the evaluation of vaccines and cluster randomized trials.
2. Novel application of existing methodology to vaccine studies and other investigations of infectious diseases. This also may be referred to as translational research.
3. Collaborative work which requires careful and sometimes innovative application of modern statistical methodologies.
4. Consultative work of a more routine and short-term nature.

The first three are about equal in their intellectual demands as well as in their impact on scientific knowledge and the advancement of public health. The bulk of my time is spent on the third category, which largely defines my role in the Department of International Health.

Keywords: Biostatistics; Statistical Epidemiology; Longitudinal Data; Vaccine Evaluation; Vitamin A; Tuberculosis; HIV/AIDS.